

		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%)

1 Regulation risk

Updated by	Nicolette Harrison					Updated date	17/06/2024		
Risk name	Risk 1: Notable regulation failure leading to public harm and/or loss of public/professional confidence in the HTA								
Risk levels	Inherent risk levels			Residual risk levels			Optimal risk level	Tolerable risk level	Risk tolerance
	Likelihood	Impact	Risk level	Likelihood	Impact	Risk level			
	3	5	15	2	4	8	5	8	At tolerance
Risk owner	Nicolette Harrison			Link to strategy	Approach to regulation		Trend since last update		↔
Management commentary - Cause	<ul style="list-style-type: none"> - Failure to identify notable 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. This includes insufficient expertise, reductions in staffing from attrition, inadequate contingency planning, recruitment difficulties (including Independent Assessors [IAs]), inadequate adherence to agreed policies and procedures (especially in relation to decision-making) - Poor quality or out of date policies and procedures - Failure to fully follow-up on identified risks and issues. - Inability to access relevant technical expertise; for example, to support the assessment of regulated activities or premises. 								
Management commentary - Effect	<ul style="list-style-type: none"> - Loss of public confidence - Loss of professional confidence - Compromise of patient safety - Loss of trust and respect from people in regulated sectors, potentially leading to greater non-compliance and challenging of decisions B14 - Reputational damage - Technical regulatory decisions re process or risk management that turn out to be incorrect 								
Management commentary - Existing controls	<ul style="list-style-type: none"> - Regulatory model that provides a range of proactive and targeted regulatory assessments - Well established processes supporting our core business; Regulatory decision-making framework including police referral policy and process - Training and development: Structured induction for new staff; Directorate Training Days; budget conference attendance; starting a Directorate Training Needs Analysis - Specialist expertise identified and recruited to ensure a broad range of knowledge across sectors and developing areas - Business Planning to map out anticipated Regulation work and Portfolio Management to track / support / report delivery of such - Good governance cycles recording the proposals / decisions / actions related to specific Regulation work - Critical Incident Response Plan (and Business Continuity Plan) arrangements / training / testing - In exceptional circumstances, scope for limited reallocation of resource to priority areas - Access to specialist legal advice for novel or complex matters 								
Management commentary - actions to improve mitigation	<ul style="list-style-type: none"> - Investing resource in cross-organisational work to develop considered operational policy positions on new or complex areas [Ongoing - mostly concept in initiation phase between Regulation Directorate and newly-expanded Policy Team in DTD Directorate] - Developing and implementing a programme of continuing professional development for Regulation Staff [ONGOING - Training Needs Analysis to be developed with support of CQC's HR shared service 'Learning Academy' over Quarter 2] - Access to expert advisory group(s) [ONGOING - HTA has some existing engagement in sub-sector specialist advisory panels for HA; exploring options to identify and access to other specialists on an <i>ad hoc</i> basis for specific novel or highly specialist topics] 								
Owners	Nicolette Harrison								

2 Sector risk

Updated by		Nicolette Harrison					Updated date		17/06/2024	
Risk name		Risk 2: Misperception of the HTA's role and reach or poor external relationships leading to gaps in sectoral risk management								
Risk levels	Inherent risk levels			Residual risk levels			Optimal risk level	Tolerable risk level	Risk tolerance	
	Likelihood	Impact	Risk level	Likelihood	Impact	Risk level				
	3	5	15	2	4	8				4
Risk owner	Nicolette Harrison			Link to strategy	Trust & confidence			Trend since last update		↔
Management commentary - Cause	<ul style="list-style-type: none"> - Complex regulatory landscape creates potential for confusion (for the public and sectors) about regulatory remits of different regulators; real or perceived regulatory gaps - Issues managing intersections in remits between different regulators - HTA's formal regulatory framework, including legislation, may not keep pace with sector developments and so may not be able to effectively manage emerging risks - Lack of clarity about changes in responsibilities eg following any legislative changes - Lack of HTA insight into broader pressures and issues affecting our sectors that may be indicators of new or emerging risks - Lack of suitable engagement or information or intelligence-sharing mechanisms between the HTA and other regulators, relevant agencies or law enforcement impedes the HTA's ability to share and escalate concerns or to refer concerns or issues to other more appropriate agencies, where relevant 									
Management commentary - Effect	<ul style="list-style-type: none"> - Diminished professional confidence in the adequacy of the legislation and/or the regulatory framework operated by HTA - Reduced public confidence in regulation of matters relating to human tissue - Reputational damage 									
Management commentary - Existing controls	<ul style="list-style-type: none"> - Horizon scanning process; Communications and Engagement Strategy; Formal and informal engagement with, and feedback from, our sectors and stakeholders - Effective management of HTA's public profile to maintain awareness and professionalism and deal with media enquiries, including developing HTA lines and positions - Active management of professional stakeholders, in our sectors, other bodies, other Government Departments and Devolved Administrations, including providing advice - Regular engagement with DHSC sponsorship team and Substances of Human Origin (SoHO) team on matters which might impact public and professional confidence - Identifying and taking action on issues where we believe these will support public and professional confidence - HTA representation on relevant multi-agency groups and forums, including particularly those dealing with new and emerging issues or innovative practice - Maintaining and utilising existing Memoranda of Understanding (MOUs) and Information Sharing Agreements with other relevant bodies eg other regulators - Maintaining, utilising and periodically updating relevant HTA policies and processes (eg the Police Referral and Warrants Policy) 									
Management commentary - actions to improve mitigation	<ol style="list-style-type: none"> 1) - Wider awareness-raising activities following conviction of private hospital for licensing breach in 2023/24 [ONGOING - paused during pre-election period] 2) - Reviewing and updating existing Memoranda of Understanding (MOUs) and Information Sharing Agreements (ISAs), especially with CQC and other health regulators [ONGOING - initiated revival of review of HTA/CQC MOU / ISA in Quarter 1; should be complete by end of Quarter 3] 3) - Joining (as an observer) the NHSE-led 'Mortuary Oversight Group' [ONGOING - Initiated Quarter 1 - should be complete by end of Quarter 2] 4) - Joining the Health and Social Care Regulators Forum and Emerging Concerns Protocol [ONGOING - exploration during Quarter 1; should be initiated during Quarter 2] 5) - Revision of the horizon scanning process planned for 2024-25 to ensure it is fit for purpose and proportionate [ONGOING throughout 2024/25] 6) - HTA Annual Review of 2023/24 published and shared in Stakeholder event [ONGOING - deferred to late Quarter 2 because of pre-election period] 									
Owners	Nicolette Harrison									

3 Staff risk

Updated by		Tom Skrinar					Updated date		14/06/2024	
Risk name		Risk 3: Inability to progress core activities due to insufficient staff capacity and capability to deliver organisational goals								
Risk levels	Inherent risk levels			Residual risk levels			Optimal risk level	Tolerable risk level	Risk tolerance	
	Likelihood	Impact	Risk level	Likelihood	Impact	Risk level				
	4	5	20	3	4	12				9
Risk owner	Tom Skrinar			Link to strategy	Efficient & effective		Trend since last update		↔	
Management commentary - Cause	<ul style="list-style-type: none"> - General high staff turnover putting recruitment pressure on managers and capacity pressures on broader teams to cover gaps - Turnover of staff in key roles that are 'single points of failure', leading to gaps in essential capability - Poor leadership and line management practices, including unclear objectives. Also poor job design and recruitment techniques and/or poor support from HR. - Poor prioritisation or insufficiency of resources - Poor H&S and risk assessment and monitoring of staff safety 									
Management commentary - Effect	<ul style="list-style-type: none"> - Lack of key expertise leading to organisational inability to deliver key objectives or to effectively manage risk - Insufficient staff capacity to manage the extent of the HTA's core duties and corporate responsibilities. - Poor deployment of staff leading to inefficient working and increasingly pressured staff leading to further loss of staff - Reduction in staff resilience, or inability to protect staff in the workplace, leading to sickness absence and staff loss. Poor advice from HR not resolving issues. 									
Management commentary - Existing controls	<ul style="list-style-type: none"> - Recruitment to identified vacancies and skills gaps ongoing. Succession planning, talent management and future skills needs to be developed further. - Prioritisation of resources (human and financial) against organisational tasks and objectives to ensure pinch points are recognised and staff not overloaded - Business Planning to map out anticipated Human Resources work and Portfolio Management to track / support / report delivery of such - Good governance cycles recording the proposals / decisions / actions related to specific Human Resources work - Business Continuity Plan (and Critical Incident Response Plan) arrangements / training / testing 									
Management commentary - actions to improve mitigation	<ul style="list-style-type: none"> - Staff survey and review of HR MI to ensure there is a clearer senior understanding of staffs' feelings and situations [Q2 2024] - People Strategy for the period 2025 - 2028, starting with the staff survey, that focusses on valuing and supporting employees to deliver [Q3 2024] - Revision of people policies and procedures that protect staff, including Health and Safety, risk assessments and sickness management [throughout 2024/25] - Development of the HTA leadership team and managers, and improvements to how we manage performance. [Ongoing] - Stngthen L&D and induction processes to ensure staff are equipped to succeed in their roles [alongside People Strategy] - Leavers / handover process formalised via a checklist to ensure corporate knowledge is retained [throughout 2024/25] - Development of a staff forum to support networking and a focus on social / organisation culture and to have a stronger staff voice in the organisation. [Q2 2024] 									
Owners	Tom Skrinar									

4 Financial risk

Updated by		Tom Skrinar					Updated date		14/06/2024	
Risk name		Risk 4: There is a risk that the HTA has insufficient or ineffective management of its financial resources								
Risk levels	Inherent risk levels			Residual risk levels			Optimal risk level	Tolerable risk level	Risk tolerance	
	Likelihood	Impact	Risk level	Likelihood	Impact	Risk level				
	4	5	20	3	3	9	6	9	At tolerance	
Risk owner	Tom Skrinar			Link to strategy	Efficient & effective		Trend since last update		↔	
Management commentary - Cause	<ul style="list-style-type: none"> - Under-recovery of income / poor debt recovery (including regulated establishment inability to pay) or inability to forecast variable income accurately - Failure in setting a robust operating budget or to effectively prioritise work and / or manage costs / efficiencies - Unexpected significant cost pressures (eg legal, urgent infrastructure investment, etc) or budget change requests from DHSC or HMT arising in year - Inability to robustly control expenditure / manage operating budgets or failure to adhere to HMT and Cabinet Office Standards (finance and commercial) - System of control unable to prevent fraud / error or adapt to new risks - Insufficient finance resource to manage transactions or support sound financial management / finance system no longer fit for purpose 									
Management commentary - Effect	<ul style="list-style-type: none"> - Late or non-payment of HTA debt leading to reputational damage / pressures on suppliers / staff - Resources lost due to fraud, error or avoidable fees/charges - Inability to stay within budget leading to leading to the need to stop work or to lose the confidence of DHSC. - Inability to manage costs over the longer term leading to unreasonable increases in licence fees or requests for further public funding. - Reputational risk to the Accounting Officer, increased scrutiny (including the PAC) and difficulties in gaining business case approval 									
Management commentary - Existing controls	<ul style="list-style-type: none"> - Budget management framework to control and review spend and take early action when diverging from budget. - Close engagement with DHSC sponsors and finance, with timely openness about financial position and pressures to allow amendments to budget/access reserves. - Financial projections, cash flow forecasting and monitoring, good communications between finance and operational teams allows robust financial management. - Robust licence fee modelling and rigorous debt recovery procedure ensures income comes in as expected. - Annual external audit and internal audits of financial processes and control environment to identify weaknesses in procedure. - Horizon scanning for changes to DHSC funding and networking with DHSC and ALB FDs regarding Spending Reviews, etc to ensure we can engage effectively - Business Planning to map out anticipated Finance work and Portfolio Management to track / support / report delivery of such - Good governance cycles recording the proposals / decisions / actions related to specific Finance work - Business Continuity Plan (and Critical Incident Response Plan) arrangements / training / testing 									
Management commentary - actions to improve mitigation	<ul style="list-style-type: none"> - Improved internal financial monitoring and management and teach-ins for SMT, including a focus on resource use. [Q3 2024] - Action plan to move from rudimentary to basic level of maturity on the GovS:013 Functional Standards [throughout 2024/25] - Develop plans to improve structure, systems and processes across HTA and HFEA finance teams to improve efficiency and staff development [throughout 2024/25] - Focus on financial and commercial skills and awareness of HTA managers. [throughout 2024/25] 									
Owners	Tom Skrinar									

5 Digital risk

Updated by	Louise Dinely					Updated date	23/04/2024		
Risk name	Risk 5: Failure to make use of available data, digital and technology to ensure systems are kept up to date and support the delivery of business activities.								
Risk levels	Inherent risk levels			Residual risk levels			Optimal risk level	Tolerable risk level	Risk tolerance
	Likelihood	Impact	Risk level	Likelihood	Impact	Risk level			
	5	4	20	3	4	12	9	9	Above tolerance
Risk owner	Louise Dineley			Link to strategy	Use of Information		Trend since last update		↔
Management commentary Cause	<ul style="list-style-type: none"> - Core systems identified as either approaching or out of support in the event of an incident - Data management is inconsistent across the business limiting opportunities to optimise and make use of information and intelligence. - Ageing business technology systems that have evolved rather than be designed limit alignment to business needs and / or opportunities for digital developments. - Staff confidence and capability in data and digital services can limit developments - Cyber Security changes in compliance requirements and standards not aligned to business capabilities - Knowledge and intellectual property of HTA systems is held by third party supplier - Inconsistency in data and information management practices is a limiting factor in our ability to make better use of information held. 								
Management commentary Effect	<ul style="list-style-type: none"> - IT breach and/or loss of sensitive data - Increased risk of system and process vulnerabilities being exploited by third parties resulting in restricted access or system failure - Loss of core IT systems required by HTA staff to deliver their work - Options that make use of existing technology and digital developments need to be adopted to address inefficient ways of working and reduce manual work-arounds - Knowledge and insight that can be obtained from data holdings results in poor quality regulation or opportunities for improvement being missed - Reliance on manual processes and single points of contact to bridge digital gaps - Large volume of data and records held beyond designated retention schedules impacting on storage, records management, data quality and information governance - Digital ambition such as the use or consideration of AI in regulated activities is constrained and / or not understood to determine compliance with standards - Limited internal resourcing capacity risks maintaining a reliance on third party supplier support 								
Management commentary Existing controls	<ul style="list-style-type: none"> - Policies, processes and practices covering all aspects of system security and data management have been reviewed, revised and or updated on a 12 month schedule. - Data relating to establishments securely stored with the Customer Relationship Management System (CRM) - Appropriate procedures to manage personal data including GDPR compliance. - Staff training in key business systems and mandatory annual training on policies and required controls - Training and development of professional competence part of annual PDPs and performance reviews - IT systems protected and assurances received from 3rd party suppliers that protection is up to date - System performance analytics available and reported monthly - Business Planning to map out anticipated Information Technology and Data work and Portfolio Management to track / support / report delivery for example 2024/25 Business plans and identified projects covering updates and data development (including AI) - Good governance cycles recording the proposals / decisions / actions related to specific Information Technology and Data work - Business Continuity Plan (and Critical Incident Response Plan) arrangements / training / testing - Ongoing knowledge gathering and transfer from third party suppliers and wider health system partners - Compliance with DSPT 2024 assessment and forward look to Cyber Essentials Plus. 								
Management commentary actions to improve mitigation	<p>Agreed Digital and IT Strategy 2024-27 sets the direction of travel through a defined vision, mission and priorities. Plans in place to communicate and embed the strategy from early Q2 2024/25. These priorities will inform projects delivered through the annual business planning process to drive change, improvement and identify opportunities to strengthen and or / exploit the use of current systems and data holdings.</p> <p>Priorities identified for 2024/25 aim to establish a strong foundation through supported systems, resourcing and developments to strengthen future digital capacity and capability. These include: CRM update (phase) 2 - Q4 2024/25; Pilot of AI - Q3 2024/25; RIMI - initial build to agreed indicators Q4 2024/25; Data publications - Q2 2024/25 and Q4 2024/25.</p> <p>The increased and continued threat posed through cyber security is kept under continual review with formal assurance reported on a quarterly basis. Reports to ARAC - Q3 2024/25 and Q1 2025/25.</p> <p>Mitigation of the risk through controls and actions is dependent on an ongoing commitment and prioritisation of resources relative to the risk. It is anticipated that the risk will move to within tolerance on commencement of the CRM update scheduled for Q2 2024/25.</p>								
Owners	Louise Dineley 14/06/2024								