

Audit and Risk Assurance Committee (ARAC) Risk Update



**Audit and Risk Assurance Committee (ARAC)**

**Date:** 8 June 2023 **Paper reference:** AUD 24/23 **Agenda item:** 11

**Author:** Richard Sydee, Director of Resources

**Protective marking:** OFFICIAL/CONFIDENTIAL

**Risk Update**

# Purpose of paper

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

# Decision-making to date

1. This paper was approved by the Director of Resources on 26 May 2023.

# Action required

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



# Background

1. 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.
2. Both the Business Development Team and Executive Team fully reviewed the strategic risk register in April 2023. This has resulted in some material changes to the Register including addition risks. The Executive Team undertook their most recent review of the revised strategic risk register on 23 May 2023; the assessment is summarised below:

# Risk assessment

1. **Risk 1 – Failure to regulate appropriately (9 – Medium, below tolerance).** The executive noted the recent Internal Audit report in Living Organ donation approvals and the ongoing work to review our approach to inspection, increase the number of inspections and the further use of data to risk assess establishments. SMT agreed that this risk remains below tolerance.
2. **Risk 2 – Failure to manage the impact of an incident (6 – Medium, at tolerance).** The HTA believes that our incident management response plans have been effective and robust throughout the last business year.
3. We have rewritten our Critical Incident Response Plan and tested it during 22/23 with a specialist consultant and will complete a similar exercise for our Business Continuity Plan in Q1 23/24. Moving forward we will review both procedures annually and undertake a test with all staff each January to ensure that we are sufficiently prepared to manage incidents as they arise. SMT agreed to reduce this risk to at tolerance.
4. **Risk 3 – Failure to manage expectations of regulation (9 – Medium, at tolerance).** SMT noted the number of matters currently impacting on the organisation, and that these matters are all being actively managed. The HTA has recently started a piece of work that seeks to assess the impact of the HTA as a regulator and its activities. This will culminate in a publication with the aim of sharing insight and feedback on the regulated activities and sectors and promote public confidence in the safe use of tissues and cells.
5. SMT agreed that this risk remains at tolerance.



1. **Risk 4 - Failure to deliver a diverse, capable workforce (9 - Medium, at tolerance).** SMT noted that we start the 2023/34 business year with far fewer vacancies to fill that the same period last year.
2. Colleague retention will continue to be an issue for the HTA, the specialist nature of some of our work – coupled with the number of functions maintained by just one post holder means that we could quickly see significant impact in some areas if attrition increases. SMT noted to the planned transition to an outsourced shared service over this business year will strengthen the HTA’s internal HR resilience.
3. Since the last ARAC meeting this risk has been downgraded to at tolerance, SMT agreed this remains the current position.
4. **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 and will seek Board approval to change the tolerance level to 4.
5. Although initial allocations for GIA have been received from DHSC submissions have been made to Ministers regarding options to generate reductions in GIA delegations for 2023/24 and 2024/25 and we await the conclusion of that exercise. If accepted and imposed this should not impact on HTA’s overall funding position but will increase our reliance on licence fee income.
6. SMT acknowledged a number of resource pressures in year will need to be managed, but agreed the risk should remain as currently scored.
7. **Risk 6 – Failure to take advantage of opportunities that allow the HTA to be an efficient regulator (9 - Medium, at tolerance).** This risk has been updated and redefined for 2023/24 to reflect a central priority supporting efficiency and reform.
8. SMT felt that the position was at tolerance, noting the opportunities that will be open to the HTA will likely require a prioritisation of resources it was felt this would be manageable.
9. **Risk 7 – Failure to optimise the safe use of digital, data & technology (12 – High, above tolerance).** The HTA’s IT function has been an area of consistent pressure and over commitment of internal resource for a number of years.



1. Resource continues to constrain progress in this area with key appointments under active recruitment. Two projects in particular (Outsourced IT service and development of the Regulatory Insight Model and Index) remain at risk given the current resource constraint and active vacancies. Remco has recently approved an enhanced package for the Head of IT, and we are confident that this will deliver suitably qualified candidates as we again advertise the role.
2. At the start of 2023/24SMT agreed this risk is remains above tolerance.
3. **Risk 8 – Failure to deliver the agreed Business Plan (9 – Medium, above tolerance).** A new risk for 2023/24 this considers the HTA’s overall ability to successfully meet its agreed business plan.
4. SMT assess this risk to be above considered above tolerance on the basis of an ambitious Business Plan coupled with possible resource pressures and changing Departmental demands that could impact our ambitions in-year. It is hoped that this risk will return to tolerance as we progress through the business year and more certainty as resourcing and departmental priorities crystalise.
5. **Risk 9 – Failure to adhere to our corporate responsibilities (9 – Medium, above tolerance).** This is a draft risk, and SMT will be considering whether this should become a full risk in future meetings.
6. SMT are conscious of increasing demands from Government, DHSC and other professional bodies and organisations on governance requirements across a number of areas. SMT will continue to take a pragmatic approach to prioritising resources to operational delivery and has and will continue to make decision to not pursue some required or best practice approaches to governance where we believe the risk is low and the return on investment will be limited.
7. There is a clear risk that external perception of HTA's compliance with external requirements fails to reflect the proportionate approach agreed by the organisation presenting a reputational risk.



Latest review date – 23/05/2023

Strategic risk register 2023/24 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 | **6 -****Medium** | Director of Regulation | At tolerance | **6** |  |
| R3: Failure to manage expectations of regulation | Delivery e) and Development c) | **9 -****Medium** | Director of Data, Technology & Development | At tolerance | **9** |  |
| R4: Failure to utilise our staff capabilities effectively | Delivery, Development and Deployment (a, c, and d) | **9 -****Medium** | Director of Resources | At tolerance | **9** |  |
| R5: Insufficient or ineffective management of financial resources | Deployment(b) objective | **4 - Low** | Director of Resources | Above tolerance | **3** |  |
| R6: Failure to take advantage of opportunities that allow the HTA to be an efficient regulator responsive to change and aware of the impact that it has on the sectors and activities that it regulates to ensure public trust and confidence is maintained | Development (a-d) objectives | **9 -****Medium** | Director of Data, Technology and Development | At tolerance | **9** |  |
| R7 Failure to optimise the safe use of existing and emerging digital data and technology | Delivery (a- e), Development (a-d) | **12 - High** | Director of Data, Technology and Development | Above tolerance | **~~9~~** |  |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Risk area** | **Strategy link\*** | **Residual risk** | **Risk owner** | **Status** | **Tolerance** | **Trend\*\*** |
|  | Deployment (a, c and d) |  |  |  |  |  |
| R8: Failure to deliver the agreed Business Plan | Delivery, Development and Deployment objectives | **9 -****Medium** | Deputy Director of Performance and Corporate Governance | Above tolerance | **6** |  |
| R9: Failure to adhere to our corporate responsibilities | Delivery, Development and Deployment objectives | **9 -****Medium** | Director of Resources | Above tolerance | **6** |  |

\* 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 Below tolerance.**

We believe we have a sound regulatory framework, which we continue to evolve in response to emerging risks and our own desire to continue to be risk-based, proportionate and data-driven.

We have not identified any underlying or systemic failures or weaknesses in our approach to regulation that would contribute to a loss of public safety and confidence. We received an assessment of substantial assurance on the previous internal audit on key regulatory processes (final report issued 16 April 2019).We received an assessment of moderate assurance on the internal audit on the Effectiveness of the Inspection Process (final report issued 11 April 2022). Three out of the five recommendations have been accomplished on time, with two having an agreed deferred due date during the 2023/24 business year.

Recent activity with the potential to raise public concern about the changing nature of risk in the Living Organ Donation sector has included information in the public domain concerning people trafficking for organ donation and changes to the offences in the Human Tissue Act to introduce an extra-territorial offence for organ tourism. The HTA continues to play a significant role in multi-agency efforts to address these issues as well as undertaking actions ourselves to address the changing nature of risk and to ensure clear, robust and proportionate messaging.

The recent internal audit on the LOD approval process (final report issued 28 March 2023), including our internal review, gave moderate assurance overall, recognising that whilst our review and processes were robust, the risk profile of this activity was changing. We are in the process of making changes to our processes, including training for Independent Assessors and HTA staff and Board members involved in LOD approvals, to implement the recommendations of this audit. This will be covered in a paper to the Board in June 2023.

The HTA is continuing to evolve our approach to inspection, one of our core regulatory tools, introducing Evaluated Self-Assessments (EVAs) this year. We are further increasing our inspection coverage to 222 inspections on existing licences, plus full assessment of all new licence applications. The significant increase in inspection coverage over the last two years, plus the continuing publication of inspection reports and updates to the website to make these more visible, help provide public reassurance, as do the regular publication of data on incidents and our ongoing communications and engagement strategy.

The new suite of KPIs, reported quarterly to the Board and published in those Board Papers, provides public assurance on our delivery of core regulatory functions.

We prepare suitable public and media comment, at an appropriate time, on those cases we refer to the police for further investigation and which are taken forward for prosecution, ensuring alignment of messaging where appropriate with other relevant stakeholders.

We continue to support Sir Jonathan Michael’s Independent Investigation into offending at a hospital mortuary and continue to pursue a programme of related activity, including with wider sector stakeholders, as set out in our published advice to the Secretary of State in December 2021.

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, adopting a wide range of approaches for dealing with issues of concern, including investigations and unannounced inspection where relevant.

SMT believes this risk is now reduced to just below tolerance.

**4**

**R2: There is a risk that we will be unable to manage the lifecycle of a significant 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 | **2** | **3** | **6 – Medium** |
| **Tolerance threshold:** | **6 – Medium** |

**Commentary**

**At tolerance.**

This risk concerns our ability to respond to and manage the whole lifecycle of incidents, irrespective of their nature or cause i.e. these are not necessarily incidents relating to our regulatory remit.

Given this risk concerns our ability to respond to an incident whilst maintaining delivery of core business objectives, we believe it is within the HTA’s control through the use of the Critical Incident and Business Continuity Plans (or based on those approaches). Hence we have set a low tolerance level.

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 few 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.

We have rewritten our Critical Incident Response Plan and tested it during 22/23 with a specialist consultant and will complete a similar exercise for our Business Continuity Plan in Q1 23/24. Moving forward we will review both procedures annually and undertake a test with all staff each January to ensure that we are sufficiently prepared to manage incidents as they arise.

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. Sir Jonathan Michael’s Independent Inquiry into the circumstances of Fuller’s offending and any related wider concerns about settings in which the deceased are managed is still continuing and is expected to report on Phase 1 during 2023 and on Phase 2 in 2024. Given there are also other criminal proceedings concerning unrelated matters within our broader remit, we believe there is still the potential for significant impact of an incident, on our corporate objectives, either from those causes or others of which we may still be unaware.

Hence the residual risk is now at the tolerance level, a reduction unchanged from the last review.

**R3: There is a risk that we will fail to manage public and professional expectations of human tissue regulation stemming from limitations in current legislation, misperception of HTA regulatory reach and innovations in the use of human tissues and cells.**

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

**Commentary– to be updated based on agreement of the risk**

**At tolerance.**

The HTA is approaching the end of the first year of delivering and embedding its Communications & Engagement Strategy. The strategy is underpinned by a commitment for more proactive and open in our communication and engagement with professionals and the public. In the last year this has been tested through day to day operational activity with improvements informed and impact evidenced through website analytics, feedback and a better understanding of how HTA communication and engagement channels are used. A similar approach has been adopted in our engagement with professionals with the establishment of sector based forums and roundtable events. These forums and events have been used to explore specific and emerging issues identified through horizon scanning and specific issues relating to the regulatory approach, sector based practice or the legislative framework. The combined impact of this work reflects an opportunity to clarify and confirm the vision and mission of the HTA and how we work to deliver the safe use of tissues and cells.

The HTA acknowledges that to continue to regulate effectively it is important that it understand the impact of its activities whilst at the same time continuing to be responsive to innovation and growth across Life Sciences. The HTA has recently started a piece of work that seeks to assess the impact of the HTA as a regulator and its activities. This will culminate in a publication the aim of which will be to share insight and feedback on the regulated activities and sectors and promote public confidence in the safe use of tissues and cells.

Looking ahead at 2023/24 the HTA will be reviewing its Strategy. This will set the direction of travel for the next 3 years and potentially beyond as well as showcasing the ongoing importance of regulating the use of human tissues and cells.

SMT consider this risk to at tolerance.

**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 | **3** | **3** | **9 - Medium** |
| **Tolerance threshold:** | **9 – Medium** |

**Commentary**

**At tolerance.**

We start of the 2023/34 business year with far fewer vacancies to fill that the same period last year. Churn and recruitment have returned to within expected tolerances, and with the exception of one IT post, we have been able to successfully fill most vacancies from the initial recruitment round.

Retention of colleagues will remain an issue, our overall package of salary and benefits remains competitive across the public sector sphere in which we operate – although headline gross pay does not always seem competitive with the NHS. Our revised approach to advertising, and the work to review our salary bands, will manage internal and external expectations around salary – although the continued absence of real terms pay progression to band maximum will likely mean that churn will remain an issue and the lack of progression within the organisation a barrier to retaining necessary internally developed skills. We must continue to acknowledge that a number of our functions rely on a single individuals and that unexpected departures in key roles will inevitably impact on delivery of some key outputs in the short term – this risk is further exacerbated by the difficulty current DHSC controls on the use of contingent labour.

The transition to outsourced shared services should not impact significantly on key HR operations as we transition and in the medium term we feel this will provide a greater breadth of options and services available to our colleagues. There will need to be careful management of areas such as corporate training and organisational development to ensure that this is not lost sight of as internal HR colleagues are required to focus more on transition and handover to CQC.

**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 2023/24 have been agreed and delegation letters to Directors issued. Our Grant in Aid (GIA) funding from the Department has initially been confirmed at previous levels and we have been provided with cover for asset purchases (Capital DEL - £30k) and depreciation and amortisation costs (Ring Fenced RDEL). Submissions have been made to Ministers regarding options to generate reductions in GIA delegations for 2023/24 and 2024/25 and we await the conclusion of that exercise. The position of the HTA is to make no reductions in the 2023/24 GIA.

The budget for 2023/24 has absorbed a number of pressures, including additional costs related to the support of the Independent Inquiry, these were met by the DHSC last year. We have part funded a number of work programmes at the start of the year with the expectation that underspends will emerge though staff churn, and that licence fee income will again significantly overshoot our estimate. This will need to be carefully managed through the first and second quarters of the financial year and could require decisions to pause some programmes work before completion to ensure that the HTA does not exceed its spending controls.

The departure of the incumbent Director of Finance & Resources will lead to additional workload pressures on the team for the remainder of the year – both in terms of the gap before the new Director starts and the onboarding process for the new incumbent.

**R6: Failure to take advantage of opportunities that allow the HTA to be an efficient regulator responsive to change and aware of the impact that it has on the sectors and activities that it regulates to ensure public trust and confidence is maintained.**

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

**Commentary**

**At tolerance.**

This risk has been updated and redefined for 2023/24 to reflect a central priority supporting efficiency and reform. As with risk 3 the HTA has progressed and delivered a number of projects in the post pandemic period reflecting changes in the way that it works and to ensure it remains responsive to opportunities for working differently. The 2023/24 Business Plan includes a number of projects that will this direction of travel. Activities under risk 3 and this risk 6 coalesce to support the HTA’s vision and mission.

It is anticipated that updates on the risk will reflect the progress of identified projects and align with updates and actions identified across other risks specifically risks 3, 4, 5 & 7. This alignment is critical as in previous years the availability of resources (people and financial) have been significant factors in setting the pace and appetite for change. A further consideration and alignment opportunity for the HTA will be with the myriad of central initiatives and programmes that see to take advantage of economies of scale and consolidation of improvement opportunities and skills.

**R7: Failure to optimise the safe use of existing and emerging 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**

**Above tolerance.**

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.

Two projects were identified in 2022/23. These were (1) the adoption of an IT Shared Services model and (2) stage 2 development of the Regulatory Insight Model and Index. As identified under risk 6 progress has not been possible due to resource constraints. The HTA’s IT function has been an area of consistent pressure and over commitment of internal resource for a number of years. As part of the 2023/24 business plan there has been confirmation of a substantive Head of IT position. The identified resource is positive however the given the competitive IT recruitment market, successful recruitment is a risk. A revised recruitment plan and approach has been identified and will be shared with RemCo.

As with risk 6 the HTA’s ability to optimise the use of existing and emerging data, digital and technology opportunities is largely reliant on investment and resource. There is a clear vision and confidence in what could be delivered although the reliance on single roles in this area and wider ambitions means that substantive recruited resource is at capacity.

At the start of 2023/24 this risk is above tolerance.

**R8: Failure to deliver the agreed Business Plan**

|  |  |
| --- | --- |
| **Inherent risk level:** | **Residual risk level:** |
| Likelihood | Impact | Inherent risk | **Likelihood** | **Impact** | **Residual risk** |
| 3 | 4 | 12 – High | **3** | **3** | **9 – Medium** |
| **Tolerance threshold:** | **6 – Medium** |

**Commentary**

**Above tolerance.**

The 23/24 Business Plan has been created through a codesign process involving Board and staff such that we are confident that it is both challenging but achievable.

We operate a formal Portfolio Management approach to the management of our Business Plan delivery, with explicit processes and best practice outputs tracking progress and scrutiny at Business Delivery Team (middle management) fortnightly, Portfolio SMT (senior management) monthly and Board quarterly.

Portfolio Management allows us to be flexible in-year so that as we are reviewing our performance, we can also consider additional requests and pressures as they arise, refining our Business Plan through change control and redeploying resources as needed.

To date, progress to deliver the 23/24 Business Plan has been noted as acceptable, albeit that a number of indicative Project start dates have been adjusted through change control to later in the year.

This risk is currently considered slightly above tolerance on the basis that we have an ambitious Business Plan and anticipate that any repetition of staffing issues from 22/23 or the wider financial pressures and the drive for efficiencies from government may mean that we have to scale back our ambitions in-year. It is hoped that we will be able to bring this risk back to tolerance as we progress through the business year and start delivering outputs.

# Reviews and revisions

**(25/04/23) SMT review April/May 2023**

At its meeting in April, the SMT reviewed each of its Strategic risks. There was discussion around whether we have sufficient breadth of risk and whether a risk that focused on data and digital was needed in addition to the risk around delivery of the Development programme. It was agreed that each risk owner should review their risk descriptions and in addition create 2 new risks around business plan delivery and strategy – strategic direction. A risk focussing on compliance is to be discussed at the next meeting.

At its May meeting, the SMT agreed the re-wording of risk 2 and a reduction in the likelihood. Risk 4 has been amended to reflect not just recruitment and vacancies but to reflect risks around the workforce.

Risk 5 has been re-cast, however, SMT felt that the tolerance level was too low and that this will be brought to ARAC in June to discuss a recommendation to the Board to increase it to 4.

Risks 6 has been split into two (risk 6 and risk 8) to reflect risks around our strategy and our business planning.

There is a final risk (risk 9) which requires further discussion. The risk update paper presented to ARAC in June will refer to this risk and the need for discussion.



**Strategic Aims/approach**



**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 |

|  |  |
| --- | --- |
| **IMPACT** | **Risk Scoring Matrix** |
| **5. Very High** | 5 10Medium Medium | 15High | 20Very High | 25Very High |
| **4. High** | 4Low | 8Medium | 12High | 16High | 20Very High |
| **3.****Medium** | 3Low | 6Medium | 9Medium | 12High | 15High |
| **2. Low** | 2Very Low | 4Low | 6Medium | 8Medium | 10Medium |
| **1.Very Low** | 1Very Low | 2Very Low | 3Low | 4Low | 5Medium |
| **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.

**15**