Audit and Risk Assurance Committee (ARAC)

**Date:** 19 October 2023

**Paper reference:** AUD 34/23

**Agenda item:** 10.

Author: Tom Skrinar, Director of Resources

Risk Update

# Purpose of paper

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

# Decision-making to date

1. This paper was approved by the Director of Resources on 11 October 2023.

# Action required

1. ARAC Members are asked to:
	* Comment on the strategic risks and assurances within the HTA Strategic Risk Summary 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 Portfolio meetings, and the register is updated and stored.
2. The Executive Team undertook their most recent review of the revised strategic risk register on 22 August 2023; it was presented at the September Board meeting; the assessment is summarised below:

**Risk assessment**

1. **Risk 1 – Failure to regulate appropriately (9 – Medium, below tolerance).** Since its last review, there have been no significant changes to this risk. 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. Our Critical Incident Response Plan and Business Continuity Plan has been re-written. A test is planned for Q4 of the 2023/24 business year. At the end of September we created a training video for Business Continuity that is mandated for staff to review via our training platform Astute. This also is the final piece of evidence for the Business Continuity audit conducted in 2019/20. A copy of the video will be shared with our Internal auditors (GIAA) in due course. SMT agreed to reduce this risk to at tolerance.
4. **Risk 3 – Failure to manage expectations of regulation (9 – Medium, at tolerance).** Since its last review, there have been no significant changes to this risk. SMT agreed that this risk remains below tolerance.
5. **Risk 4 - Failure to deliver a diverse, capable workforce (16 – High, above tolerance).** SMT have reviewed this risk in light of changes within the HR sphere and the challenges currently being faced around delivery of the Business Plan.
6. Staff 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 that the transition to an outsourced shared service over this business year should strengthen the HTA’s internal HR resilience.
7. There is a paper on the agenda that takes a more detailed look at the issues around the HTA workforce and delivery, which the committee are requested to comment on. SMT agreed this remains the current position.
8. **Risk 5 – Insufficient, or ineffective, management of financial resources (9 – Medium above tolerance).** Although this risk remains above tolerance SMT are content to accept this risk at the assessed residual risk level. Board approval to change the tolerance level to 4 was sought at the September meeting.
9. Our forecast financial position is broadly break-even, but this could change if unexpected costs arise or if staff turnover increases or we experience unexpected fluctuations in income.
10. The Reform and Efficiencies programme has resulted in reductions to our GIA for the next two financial years which will require an increase to our fee levels. We will need to factor those key projects that were agreed to be deferred in 2023/24 whilst funds were limited into the 2024/25 budget. Furthermore, policy currently being developed within the Department may create additional duties for HTA that would require additional resource and that may not be appropriate to fund through fees. The HTA will continue to engage with the Department on this issue, as well as on fee increases.
11. **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.
12. SMT felt that the position was at tolerance, noting the need for currently limited management time and financial resource in order to make appropriate investments and improvements.
13. **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, with over committed internal resource for a number of years.
14. 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.
15. Since the last update, we have recruited to the Head of IT position with the candidate due to commence in November. Whilst the recruitment of a new member of staff does not necessarily reduce the risk, it is expected that over the coming months, the work that will be undertaken will have an impact on residual risk. SMT agreed this risk remains above tolerance.
16. **Risk 8 – Failure to deliver the agreed Business Plan (12 – Medium, above tolerance).** This was a new risk for 2023/24 and considers the HTA’s overall ability to successfully meet its agreed business plan.
17. SMT assess this risk to be 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.

**Annex A**

##### 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** | òóóó |
| R2: Failure to manage an incident | Delivery, Development and Deployment objectives | **6 – Medium** | Director of Regulation | Attolerance | **6** | óóóó |
| R3: Failure to manage expectations of regulation | Delivery e) and Development c) | **9 – Medium** | Director of Data, Technology & Development | At tolerance | **9** | óóóó |
| R4: Failure to utilise our staff capabilities effectively  | Delivery, Development and Deployment (a, c, and d) | **16 - High**  | Director of Resources | At tolerance | **9** | ñóòó |
| R5: Insufficient or ineffective management of financial resources | Deployment (b) objective | **9 – Medium** | Director of Resources | Above tolerance | **3** | óóóñ |
| 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** | óóóò |
| R7 Failure to optimise the safe use of existing and emerging 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** | óñóó |
| R8: Failure to deliver the agreed Business Plan | Delivery, Development and Deployment objectives | **12 - High** | Deputy Director of Performance and Corporate Governance | Above tolerance | **6** | óñ |

\* Strategic objectives 2021-2024:

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

## 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. Recent internal audits gave moderate assurance on Living Organ Donation approvals (March 2023) and the Effectiveness of the Inspection Process (April 2022).The HTA has further refined its approach to living organ donation assessment in recognition of emerging risk and continues to play a significant role in multi-agency efforts to address risks related to some overseas travel for organ transplantation following the introduction of new offences under the Human Tissue Act in July 2022. An update was provided to the Board in June 2023, who approved our updated Living Organ Donation approvals policy.The HTA is continuing to evolve our approach to inspection, one of our core regulatory tools, introducing Evaluated Self-Assessments (ESAs) this year. We are on track with the further increased target for inspection coverage of 222 inspections for 2023/24 on existing licences, in addition to full assessment of all new licence applications. Inspection is only part of our regulatory toolkit, and we continue to manage and respond to incident reports, whistleblowing / informant information and provide advice and guidance to our sectors and the public. We also have an active programme of engagement with our regulated sectors and other relevant stakeholders. We have also recently undertaken a risk-focused data collection exercise across all licensed establishments.We continue to be transparent about our regulatory activities and outcomes through various means, including publication of inspection reports, performance data and other data, such as the quarterly summaries of closed incidents reported to us. These provide public assurance on our delivery of core regulatory functions. We also provide suitable public comment on matters within our remit where relevant, including on our website and through engagement with media. We continue to support Sir Jonathan Michael’s Independent Investigation into offending at a hospital mortuary and are pursuing 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. SMT believes this risk is just below tolerance.  |

## 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 incidents, irrespective of their nature or cause whilst maintaining delivery of core business objectives. It is not confined to incidents relating to our regulatory remit. We have rewritten our Critical Incident Response Plan and tested it during 2022/23 with specialist consultancy and completed a similar exercise for our Business Continuity Plan in Q1 2023/24. These have provided assurance on the effectiveness of our plans and our ability to use them. 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. In addition, those plans have also been deployed and found effective in a number of differential circumstances over the past few years, including managing the impact of the pandemic and related restrictions, managing the potential impacts of EU Exit following the end of the Transition Period and in our mobilisation planning in preparation for the trial of Fuller. 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 still continues and is expected to report on Phase 1 during 2023 and on Phase 2 in 2024. Given there are currently 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 SMT considers the residual risk remains at the tolerance level. |

## 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** |
| **At tolerance.** The HTA has successfully completed year 1 of the delivery of its revised Communications & Engagement Strategy. Progress on embedding the strategy and new channels and tools that have been adopted was reported to the Board at the end of June.The strategy is underpinned by a commitment for being more proactive and open in our communication and engagement with professionals and the public. In the last quarter we have continued to embed sector-based forums and roundtables, strengthen social media presence, and proactively respond to media enquiries. The work of the Comms & Engagement Team has contributed to the generation of positive headlines in relation to stories such as the first uterine transplant, press statements on successful prosecutions and strengthened partnerships with DHSC, ALBs and license holders. In addition to the strategy there has been a significant focus in Q1 & 2 to ensure any published material including the experience of using the HTA website meets accessibility standards. The HTA’s website has been independently audited and identified some further opportunities to improve accessibility. A revised accessibility statement has been approved and published.The HTA remains committed to improving the accessibility of all published information.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 is progressing 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 be 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 | **4** | **4** | **16 - Medium** |
| **Tolerance threshold:**  | **9 – Medium** |

|  |
| --- |
| **Commentary** |
| **Above tolerance.** We started off 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 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 several of our functions rely on a single individual 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 current DHSC controls on the use of contingent labour. There is a risk that the transition to outsourced shared services creates pressures on key HR operations in the short term as we transition, we will need to resource both ongoing operations and transition activities concurrently. There will also 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. In the medium term we feel the new service will provide a greater breadth of options and services available to our colleagues, as well as greater service resilience as it will be based within a large, structured HR team within CQC. We recognise the risk of losing staff confidence in the service and will tailor communications to ensure that the process is clear to staff, including how the transition will proceed. We also recognise that we have single points of failure where individuals that hold significant amounts of organisational knowledge and understanding of HTA HR systems and processes and are engaging closely with CQC to manage any short-term risks to service continuity.Long term absences amongst key staff and a delay in new employees starting is reflected in our residual risk scoring as we believe it impacts on our ability to deliver a capable and diverse workforce. This also is reflected in risk 8 (delivery of our business plan). There are plans in place to build in resilience across the organisation utilising staff within the Private Office function. |

## 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 | **3** | **3** |  **9 – Medium** |
| **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 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 were made to Ministers regarding options to generate reductions in GIA delegations for 2023/24 and 2024/25 and this has been confirmed wef 1st April 2024 but with no reductions in the 2023/24 GIA.The budget for 2023/24 has absorbed several pressures, including additional costs related to the support of the Independent Inquiry. A number of work programmes at the start of the year were part funded with the expectation that underspends will emerge through staff churn, and that licence fee income will again significantly overshoot our estimate. We are currently forecasting an overspend as the underspend through staff churn or the expected increase in our income has not materialised. This will need to be carefully monitored and managed through the rest of the financial year and we could require decisions to pause some programmed work to ensure that the HTA does not exceed its spending controls, though we are not actively holding back planned spend at this stage. Requests to the Department have been made for additional GIA to fund the support to the Fuller Inquiry where we had previously thought we could absorb this cost, though this additional funding cannot be relied on, or could potentially be approved later in the year when we would have less opportunity to plan for and realise the benefits from it.The departure of the incumbent Director of Finance & Resources has led to additional workload pressures on the team during the two-month period prior to the new Director’s arrival. This has been managed very well but will continue whilst the new Director embeds and focuses on prioritised issues. |

## 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 – Medium** |
| **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 several 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 follow 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 take advantage of economies of scale and consolidation of improvement opportunities and skills.Since the start of 2023/24 there have been a range of different activities including independent reviews such as the McLean Review and the Review of Pregnancy Loss that have led us to consider and work with partners on opportunities for change and improvement in regulation. |

## 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 for several 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 given the competitive IT recruitment market, successful recruitment and retention is an ongoing risk.A revised recruitment plan and approach has been identified and was 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  | **4** | **3** |  12 – High |
| **Tolerance threshold:**  | **6 – Medium** |

|  |
| --- |
| **Commentary** |
| **Above tolerance.**The 2023/24 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 2023/24 Business Plan has been noted as acceptable, albeit that several indicative Project start dates have been adjusted through change control to later in the year. This risk is currently considered above tolerance. We have an ambitious Business Plan and the Q1 financial outturn is such that it is unlikely that we will be able to progress all the items that we have identified for delivery (see Risk 5). We are also experiencing staffing issues within key technical positions, and this is impacting our capacity to deliver key work (see Risk 4). The combined effect means that we may have to scale back some of our ambitions in-year.  |

##  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.

**(23/05/23) SMT review April/May 2023**

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.

Risk 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.

 **(22/08/23) SMT review August 2023**

SMT reviewed each of their risks. Ratings were amended for the following risks:

* Risk 4 – residual risk increased to a rating of ‘high’. Whilst we are experiencing almost full complement of staff, the SMT recognise that there are additional pressures created from absences, staff leave. A key function is currently understaffed which in the short term may impact on other areas of the business.
* Risk 5 – has been uprated due to the challenges currently being faced around funding for key projects and pressures that have arisen from changes to the Living Organ Donation (s32). There are mitigations which involve reaching out to the Department, however until feedback is received, the rag status will remain.
* Risk 8 – impacted by risks 4 and 5 as detailed in the commentaries above.

**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** | 5Medium | 10Medium | 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.