TriTech Institute Governance Review
Final Internal Audit

March 2022

Hywel Dda University Health Board

NWSSP Audit and Assurance

GIG CYMRU NHS WALES
Partneriaeth Cydwasanaethau
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Contents

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Executive Summary

Purpose

The overall objective of the review was to evaluate and determine the adequacy of the systems and controls in place within the Health Board for governance arrangements for the TriTech Institute.

Overview

Overall, the governance arrangements for the setup and establishment of the TriTech Institute has concluded limited assurance. This was based on the lack of a Board-approved business case and a lack of a clear financial structure.

Whilst the lack of a Board-approved business case impacts on many of the objectives within this review, we have provided assurance on the arrangements and actions that have been undertaken.

We also identified a number of matters arising that require refinement and further development.

Report Classification

		Trend
Limited 	More significant matters require management attention. **Moderate impact** on residual risk exposure until resolved	n/a

Assurance summary[1]

Assurance objectives		Assurance
1	TriTech Setup Arrangements	Limited
2	Strategic Objective Alignment	Reasonable
3	Financial Management and Governance	Limited
4	Quality & Safety Arrangements	Reasonable
5	Risk Management	Reasonable
6	Information Governance Arrangements	Reasonable
7	Workforce Arrangements	Limited
8	Partner and Third Party Management	Reasonable

Matters Arising

		Assurance Objective	Control Design or Operation	Recommendation Priority
1	Submission & Approval of a Business Plan	1,2,3,4,7	Design	High
2	Financial Governance	3	Operation	High
3	Risk Register	5	Operation	Medium
4	Head of TriTech Job Description	7	Operation	Medium
5	Segregation of Working Arrangements	7	Design	Medium
6	Bidding Process Operating Procedure	8	Operation	Medium

[1] The objectives and associated assurance ratings are not necessarily given equal weighting when formulating the overall audit opinion.

1. Introduction

1.1 The review of Governance arrangements for the TriTech Institute was completed in line with the 2021/22 Internal Audit Plan. The relevant lead Executive Director for the assignment was the Medical Director.

1.2 TriTech Institute is a commercial venture by Hywel Dda University Health Board offering specific services in innovative healthcare solutions. TriTech supports the development and evaluation of new technologies and devices to ensure they are making the maximum contribution to improving patient outcomes, when considered alongside their costs. The TriTech Institute supports the development of healthcare solutions on a local, national, and global level offering designers and manufacturers a single point of access to the NHS through a collaborative and agile approach**.**

1.3 The potential risks considered in the review were as follows:

- inappropriate governance and management arrangements;
- innovation activities undertaken and expenditure committed outside of scheme of delegation and standing orders;
- joint working with partners and third parties not managed and controlled; and
- risks not identified and managed.

1.4 The scope of this review was limited to the setup and governance of the TriTech Institute only and has not considered the concept of the initiative.

2. Detailed Audit Findings

Objective 1: The TriTech Institute has been appropriately established with robust governance and management arrangements in line with Standing Orders, Standing Financial Instructions and regulations

2.1 During the early part of the Covid-19 pandemic in 2020, the Research & Innovation (R&I) and Clinical Engineering Departments worked together in response to the public health emergency to support supply chain resilience due to concerns of access to ventilators and other technologies. Concluding the 'first wave' of the Covid-19 pandemic, the two departments were asked to consider how this way of working could become routine.

2.2 To sustain this collaborative way of working required a creation of a new team of in-house engineers, scientists, and researchers spanning Clinical Engineering and R&I to provide a multi-disciplinary, cross-sector team combining capabilities in engineering, technology and innovation with strong links to Higher Education Institutions. This collaboration would become known as the TriTech Institute.

2.3 In September 2020, a paper was produced setting out the benefits of developing TriTech included a detailed breakdown of the viability and sustainability of the initiative both financially and non-financially. However, this paper had only been submitted to a limited number of individuals. We identified that no formal business case had been submitted for review and approval to the Health Board (or any other group or committee).

2.4 A business plan is currently being developed and estimated to be completed by the end of April 2022. Whilst the initial paper had not been formally submitted to the Health Board, management should include the TriTech Institute agreed aims and objectives, concept, risks and benefits within the business plan for information. **[Matter Arising 1]**

2.5 A key function in the setup of TriTech will be the generation of income through consultancy work with external organisations. A review of the Health Board's Standing Financial Instructions and *NHS (Wales) Act 2006* allows TriTech (and the Health Board) to generate income under the remit of research.

2.6 Due to the nature of collaborative initiatives between two departments, managerial and professional reporting arrangements needed to be addressed. The Medical Director was managerially responsible for R&I Department staff, whilst the Director of Operations (managerially) and Director of Therapies & Health Sciences (professionally) were responsible for Clinical Engineering Department employees. The 'TriTech Institute Report' submitted to the R&I Sub Committee on 10th January 2022 stated that in December 2021, it was agreed by the Executive Directors of Operations, Medicine, and Therapies that the Medical Directorate would assume managerial accountability for the TriTech Institute. **[Matter Arising 1]**

2.7 In April 2021, the TriTech Management Group was established that would report into the R&I Sub Committee and the Medical Devices Group. We can confirm that agendas, minutes and papers were retained for TriTech Management Group meetings. A terms of reference has been agreed and the frequency of meetings have been taking place in line with the requirements.

Conclusion:

2.8 This has resulted in a Limited assurance rating due to the lack of a Board-approved business case that included changes to the managerial and professional reporting structures.

Objective 2: The TriTech strategy/plans align with those of the Health Board, including Research & Innovation Strategy, the Annual Plan and Planning Objectives

2.9 The R&I Department have produced and issued an '*Our Research and Innovation Strategy 2021-2024*' document that sets out to improve the profile, quality and quantity of research and innovation activity within Hywel Dda through the strong relationship between R&I and Clinical Engineering Departments.

2.10 This strategic document forms part of the Health Board's long-term health and care strategy '*A Healthier Mid and West Wales: Our Future Generations Living Well*' that sets out a number of portfolio programmes to enable the transformation of services, including Education, Training, Research and Development.

2.11 The R&I Strategy 2021-2024 document appears in line with the portfolio programme narrative of the '*A Healthier Mid and West Wales: Our Future Generations Living Well*' document including explicit narrative on the emerging relationship and working goals between the R&I and Clinical Engineering Departments within its strategic objectives.

2.12 A review of the Health Board's '*Annual Recovery Plan 2021-22*' identified a planning objective (3.G) that sets out the development and implementation of a three-year strategic plan, working in partnerships with universities, life sciences companies to increase research, development and innovation to be delivered against Welsh Government and Health and Care Research Wales expectations and targets. We can confirm a key deliverable and milestone is the development of a new engineering, innovation and research facility designed to support the development of new technologies (i.e. TriTech).

2.13 We can confirm that regular planning objective updates were submitted to the Health Board, including progress on the development of the TriTech Institute, within the Quarter 1 paper submitted in September 2021.

2.14 The initial TriTech paper setting out the proposal of this project in 2020 was produced prior to the rollout of current strategic and planning objectives. TriTech's objectives and business goals should be reviewed to ensure they align with that of the Health Board, and this should be reflected in the business plan currently being developed. **[Matter Arising 1]**

Conclusion:

2.15 This has resulted in a Reasonable assurance rating due to the need for management to link TriTech business goals to the Health Board's strategic and planning objectives.

Objective 3: Financial management and governance arrangement appropriately established

2.16 The paper setting out the benefits of TriTech that was produced in September 2020 included a financial breakdown over a five-year period. The breakdown included pay and non-pay costs including assumptions on received grant funding, premises cost, and expected growth of applications. TriTech was projected to breakeven at Year 5.

2.17 A key part of the financial breakdown was the income generation through consultancy work. Whilst we acknowledged that income costs were based on assumptions, we were unable to establish the evidence to support the reported figures. During the first year, it was estimated that approximately £78k of income would be raised through consultancy work.

However, the financial tracker maintained by Finance had only recorded £2k of consultancy work for 2021/22 (that has yet to be received).

2.18 A review of the latest financial position confirmed that the financial breakdown originally proposed in the paper produced in 2020 had significantly changed with addition pay costs evident. We were unable to corroborate the full financial requirements of TriTech as no financial plan has been agreed by the Health Board. **[Matter Arising 1]**

2.19 No exit strategy had been documented in the event of TriTech being unsuccessful. However, we were verbally informed that Research Assistants/ Associates and Healthcare Scientists would be absorbed into the R&I and Clinical Engineering Departments respectively, with the financial risk agreed with the Health Board. An exit strategy should be documented and included in the TriTech business plan and/or risk register. **[Matter Arising 1]**

2.20 We can confirm that finance updates were received at every TriTech Management Group meeting for the period June to December 2021. Concluding a review of the latest finance tracker (Month 9), we identified variations with the financial breakdown in the initial setup paper in 2020 in regard of the setup costs, project accounting arrangements had not been implemented during fieldwork in order to track the financial performance of individual projects and trials, and the increase in establishment numbers and positions including the lack of a Head of TriTech budget. **[Matter Arising 2]**

Conclusion:

2.21 This has resulted in a Limited assurance rating due to the lack of an agreed financial plan.

Objective 4: Appropriate arrangements have been established for quality and safety governance covering all activities of the TriTech Institute

2.22 TriTech have a suite of quality related documents that they have adopted from R&I and Clinical Engineering. This includes a quality management system manual currently in use within the Clinical Engineering Department that was set out to meet the needs of ISO 13485:2016 (Medical Devices). We can also confirm that a suite of R&I Department standard operating procedures (SOPs) were in place in regards of grant bidding processes and trials, whilst general guidance documents for government health agencies were also available.

2.23 We can confirm that TriTech have developed project template forms for project submissions for external companies and organisations that included information regarding device specification and regulatory marks, use of treatment type set by NICE[2], remits and training required on devices or treatments.

2.24 A review of two projects confirmed that quality and safety requirements had been established and agreed within the project template forms and/or the signed contracts.

2.25 We noted the steps taken to implement quality and safety governance within TriTech processes and procedures. To further enhance the quality and safety governance arrangements, we would recommend outlining the relationship structure in place between TriTech and the Health Board. **[Matter Arising 1]**

[2] National Institute for Health and Care Excellence

Conclusion:

2.26 This has resulted in a Reasonable assurance rating due to the need to define with relationship structure between TriTech and the Health Board on issues such as quality and safety.

Objective 5: Risk management processes have been established, including development of a risk register

2.27 We can confirm that risks relating to the TriTech Institute have been identified and recorded onto the R&I Department risk register. However, we noted that the detail of the recorded risks do not address the title requirements set out in the risk register such as risk statements and identified existing controls. **[Matter Arising 3]**

2.28 A review of the TriTech Management Group confirmed that the risk register had been a standing agenda item at meetings since June 2021 and evidence of discussion was captured in the minutes.

2.29 During our fieldwork, we identified a small number of entries in the TriTech risk register that required updating. These were highlighted to the Head of Clinical Engineering/ Interim Head of TriTech during fieldwork and were promptly amended.

Conclusion:

2.30 This has resulted in a Reasonable assurance rating due to current risk information not addressing the requirements of the risk register.

Objective 6: Appropriate arrangements established to meet information governance requirements

2.31 All TriTech Institute staff are governed by the Health Board and as such are required to comply with the organisational policies and procedures. The information governance policies and procedures are available to all individuals on the organisation's internet site.

2.32 The *Information Governance Framework* document requires that each service area and major system, which contains personal information, is owned by a named Information Asset owner (IAO). A review of the Health Board's Information Asset Register (IAR) confirmed that no information regarding TriTech had been received. The lack of an IAR and identified IAOs for TriTech was highlighted to the Head of Clinical Engineering/ Interim Head of TriTech during fieldwork and were promptly amended.

2.33 A review of three recently signed contracts between external organisations and Hywel Dda was undertaken to ensure the information governance requirements met the standards of the Health Board. We can confirm that information governance requirements were explicitly noted in the contracts that had also been scrutinised by Legal & Risk Department (NHS Wales Shared Services Partnership) prior to approval.

Conclusion:

2.34 This has resulted in a Reasonable assurance rating.

Objective 7: Appropriate arrangements established for workforce management

2.35 The paper produced in 2020 setting out the case for collaborative working between R&I and Clinical Engineering Departments to generate new innovations and opportunities outlined a breakdown of pay costs. However, since 2020 the resources budgeted for TriTech do not align with the current establishment pay costs listed in their financial tracker due to the ongoing development of the TriTech team. **[Matter Arising 1]**

2.36 A review was undertaken to ensure that all positions currently in place within TriTech have an approved computer aided job evaluation (CAJE) reference number. We can confirm job descriptions for Research Assistants/ Associates, Healthcare Scientists, Administrative Assistant and Deputy Head of TriTech had a CAJE reference number and managerial/ professional responsibilities appear accurate. A job description for the Head of TriTech has yet to be approved or issued. **[Matter Arising 4]**

2.37 TriTech is a collaborative project between the R&I and Clinical Engineering Departments. Due to the nature of this approach, arrangements within the Clinical Engineering Department should be reviewed to ensure a clear segregation of duties is evident and any work undertaken on behalf of TriTech is accurately capture to ensure it does not impact of the daily duties of the Clinical Engineering Department. **[Matter Arising 5]**

Conclusion:

2.38 This has resulted in a Limited assurance rating due to resources budgeted for TriTech not aligning with the current establishment, the job description for Head of TriTech had not yet been approved or issued, and the need to ensure clear segregation of duties within the Clinical Engineering Department.

Objective 8: Arrangements established for the management and control of activities with partners and third parties

2.39 We can confirm that TriTech have in place signed memorandums of understanding with the University of Wales Trinity Saint David, Aberystwyth University, Respiratory Innovation Wales and Welsh Wound Innovation Initiative Limited with a number of others in draft format at the time of fieldwork.

2.40 A sample of five projects was tested to ensure a completed contract was retained on file. Of the five projects tested, we can confirm all contracts were fully signed by all parties.

2.41 The 'Project Plan Agreement Form' requires the legal and intellectual property arrangements (Section D) to be completed. A review of the sampled five projects confirmed that this section had been completed the projects tested. In addition, as noted above all contracts were scrutinised by Legal & Risk Department (NHS Wales Shared Services Partnership) prior to their approval.

2.42 Liability arrangements were also included in issued contracts between the Health Board and external parties. Again, the Legal & Risk Department would review all contracts prior to their approval. We can also confirm that all TriTech staff have completed a declaration of interest form that was retained on file, whilst conflicts of interest were also declared at the TriTech Management Group meetings.

2.43 The bidding of funds is currently the responsibility of the Deputy Head of TriTech. The current arrangement is funding bids will come through TriTech but will be reviewed and processed by the R&I Department. All grant applications are reported through to the TriTech

Senior Management Team. Whilst the bidding process was evident, a SOP has yet to be developed to document these arrangements. **[Matter Arising 6]**

Conclusion:

2.44 This has resulted in a Reasonable assurance rating due to the lack of a grant bidding SOP.

Appendix A: Management Action Plan

Matter Arising 1: Submission & Approval of a Business Plan (Design)	**Impact**
Whilst a paper was developed setting out the benefits and opportunities of collaborative working between the R&I and Clinical Engineering Departments, this paper was submitted to a limited number of individuals. No formal business case had been submitted to the Health Board for review and approval.	Potential risks of: • inappropriate governance and management arrangements; • innovation activities undertaken and expenditure committed outside of scheme of delegation and standing orders; and • risks not identified and managed.
Recommendations	**Priority**
1.1 A formal business plan is currently being developed for TriTech. Management should ensure the business plan is submitted to the Health Board for scrutiny and include, but not limited to, the following in order to provide the Health Board the information on this collaborative initiative: • the scope, objectives and mission statement of TriTech; • detailed financial breakdown including the establishment of budgets and resources; • an exit strategy setting out the risk appetite and tolerances; • required quality and safety standards are explicitly outlined; and • key performance indicators.	**High**
1.2 Management should establish and document the relationship structure in place between TriTech and other collaborative departments and groups to ensure responsibilities for items such as risk management, quality and safety, and managerial and professional arrangements have been identified and agreed by all parties.	**High**

Agreed Management Action	Target Date	Responsible Officer
1.1 The original case, presented as an SBAR, contained detailed activity and financial assumptions and has been instrumental to the set up phase and first year of TriTech's activities. A detailed five-year business plan, informed by the set up phase, is now being developed, with a first draft to be completed by the end of April 2022 and a final draft in place by May 2022. The business plan will contain: • The scope, objectives and mission statement of TriTech; • Governance • Service assessment; • Market research, analysis, and strategy; • Competitor analysis; • Staffing plan; • Costs and pricing strategy; • Activity plan, with targets; • Financial forecast; • An exit strategy setting out the risk appetite and tolerances; and • Quality and safety standards with key performance indicators.	31st May 2022	Head of Clinical Engineering & TriTech Institute
1.2 The business plan will contain a governance section, so that the robust arrangements that have been put in place are clearly documented for future review. For assurance, it should be noted that several of the suggestions were already in place at the time of the audit: • There is a risk register which is incorporated in Hywel Dda University Health Board's risk management system and associated arrangements. Individual risk registers also exist for specific projects; • Quality and safety is of paramount importance to the initiative, with a clear governance route into the Research and Innovation Sub-Committee, which can then escalate the quality and safety arrangements as appropriate. Projects are only supported by TriTech when a sponsoring department has signed off that it is content with a project and this will often be done through their operational quality and safety arrangements.	31st May 2022	Head of Clinical Engineering & TriTech Institute

• Managerial and professional accountability arrangements have been agreed by the Medical Director, Chief Operating Officer, and Director of Therapies & Health Science. Evidence of this has been provided to the internal audit team.		

Matter Arising 2: Financial Governance (Operation)		**Impact**
Concluding a review of the latest finance tracker (Month 9), we identified variations with the financial breakdown in the initial setup paper in 2020 in regard of the setup costs, project accounting arrangements had not been implemented during fieldwork in order to track the financial performance of individual projects and trials, and the increase in establishment numbers and positions including the lack of a Head of TriTech budget.		Potential risk of: • innovation activities undertaken and expenditure committed outside of scheme of delegation and standing orders.
Recommendations		**Priority**
2.1 Management should review the financial requirements for the TriTech Institute to ensure expenditure and income generation targets are appropriate and align with the business plan currently being developed.		**High**
2.2 Management should ensure that the financial performance of individual projects are recorded and reported to the TriTech Management Group in order to ensure expenditure is in line with allocated grants.		**High**
Agreed Management Action	**Target Date**	**Responsible Officer**
2.1 Management agree that the financial assumptions originally proposed in the business case SBAR produced in 2020 have changed. Whereas the original business case projected the majority of income would be secured through grant and advisory work, the reality has seen a much greater demand for real world evaluations commissioned directly by commercial organisations. These income lines are reflected in the finance	31st May 2022	Senior Finance Business Partner

tracker, which has been established with finance business partners and provides a more accurate and real time overview of the position. Additional pay costs were evident from the appointment of a temporary 'Deputy Head of TriTech' post but these costs have been built into the finance tracker in order to provide a balanced and accurate position on pay and non-pay costs. It should be noted that, due to being fixed term, they do not reflect a change in the agreed establishment. The finance tracker is updated and presented to the Tritech management group in the monthly meetings by the finance business partner and the tracker is also included within the TriTech updates to R&I sub-committee for assurance. As detailed in Matter 4 below, the Head of Tritech job description has been developed and has been through the A4C matching panel. Funding has been secured and this will be reflected within the finance tracker pay costs going forwards. The Finance business partners are actively involved with the preparation of the business plan to ensure all assumptions are robust and sensitivity checked.		
2.2 The finance team already track the financial performance of individual projects on the finance tracker. The Tritech Finance Business partners will look to introduce a more detailed individual project breakdown as part of the Financial performance reporting presented to the Tritech Management Group.	31st May 2022	Senior Finance Business Partner

Matter Arising 3: Risk Register (Operation)		**Impact**
We noted that the detail of the recorded risks do not address the title requirements set out in the risk register such as risk statements and identified existing controls.		Potential risk of: • risks not identified and managed.
Recommendations		**Priority**
3.1 Management should review risks recorded on the current register to ensure the detail provided addressed the title requirements set out in the register.		**Medium**
Agreed Management Action	**Target Date**	**Responsible Officer**
3.1 This management action applies to Risk 1144 '*There is a risk the TriTech Service is unable to gain Corporate and Health Board support to deliver on its research & innovation objectives*'. This risk has now been archived / closed as we have gained corporate support, finances have been agreed and the internal audit report has concluded and thus provides assurance in this regard.	24th March 2022 (Complete)	Head of Clinical Engineering & TriTech Institute

Matter Arising 4: Head of TriTech Job Description (Operation)	**Impact**
The formalisation of the Head of TriTech post and subsequent job description had yet to be approved or issued.	Potential risk of: • inappropriate governance and management arrangements.
Recommendations	**Priority**
4.1 Management should ensure the position of the Head of TriTech is formalised and a job description is developed, approved and promptly issued.	**Medium**

Agreed Management Action	Target Date	Responsible Officer
4.1 The job description has been developed and has been through the A4C matching panel. Funding has been secured and recruitment will begin in April 22. Pending successful recruitment, we envisage the new Head of Tritech to be appointed and in post by the end of August 22. The Medical Director, Chief Operating Officer, and Director of Therapies & Health Science have agreed a clear plan to ensure appropriate governance and managerial arrangements are in place for the intervening period.	31st August 2022	Director of Research, Innovation & University Partnerships

Matter Arising 5: Segregation of Working Arrangements (Design)	**Impact**
TriTech is a collaborative project between the R&I and Clinical Engineering Departments. Due to the nature of this approach, arrangements within the Clinical Engineering Department should be reviewed to ensure a clear segregation of duties is evident and any work undertaken on behalf of TriTech is accurately capture to ensure it does not impact of the daily duties of the Clinical Engineering Department.	Potential risk of: • inappropriate governance and management arrangements.
Recommendations	**Priority**
5.1 Management should review arrangements within the Clinical Engineering Departments to ensure: • clear segregation of duties for individuals undertaking work on behalf of TriTech; and • any work undertaken on behalf of TriTech is accurately captured.	**Medium**

Agreed Management Action	Target Date	Responsible Officer
5.1 The original business case SBAR was reviewed and agreed by the Deputy Director of Operations and the Director of Research and Innovation to ensure the segregation of duties during the set up period. Learning from the set up period, a further plan was put in place within Clinical Engineering to ensure the Head of Clinical Engineering has dedicated time to spend on TriTech until the new 'Head of TriTech' is appointed. The	24th March 2022 (Complete)	Deputy Director of Operations & Head of Clinical Engineering & TriTech Institute

Deputy Director of Operations keeps this plan under review to ensure the Clinical Engineering Department continues to support TriTech, while not compromising the daily duties of the department. Capturing this is a routine management task. Following the appointment of the new 'Head of TriTech', any contribution from the Clinical Engineering department will be considered on a project-by-project basis.		

Matter Arising 6: Bidding Process Operating Procedure (Operation)		**Impact**
Whilst the bidding process was evident, a standard operating procedure has yet to be developed to document these arrangements.		Potential risk of: • joint working with partners and third parties not managed and controlled.
Recommendations		**Priority**
6.1 Management should develop a standard operating procedure to document the grants bidding process for TriTech.		**Medium**
Agreed Management Action	**Target Date**	**Responsible Officer**
6.1 A new standard operating procedure to document the grants bidding process for TriTech is in development and will be complete by end of May 22.	31st May 2022	Deputy Head of TriTech Institute

Appendix B: Assurance opinion and action plan risk rating

Audit Assurance Ratings

We define the following levels of assurance that governance, risk management and internal control within the area under review are suitable designed and applied effectively:

	**Substantial assurance**	Few matters require attention and are compliance or advisory in nature. **Low impact** on residual risk exposure.
	**Reasonable assurance**	Some matters require management attention in control design or compliance. **Low to moderate impact** on residual risk exposure until resolved.
	**Limited assurance**	More significant matters require management attention. **Moderate impact** on residual risk exposure until resolved.
	**No assurance**	Action is required to address the whole control framework in this area. **High impact** on residual risk exposure until resolved.
	**Assurance not applicable**	Given to reviews and support provided to management which form part of the internal audit plan, to which the assurance definitions are not appropriate. These reviews are still relevant to the evidence base upon which the overall opinion is formed.

Prioritisation of Recommendations

We categorise our recommendations according to their level of priority as follows:

Priority level	Explanation	Management action
High	Poor system design OR widespread non-compliance. Significant risk to achievement of a system objective OR evidence present of material loss, error or misstatement.	Immediate*
Medium	Minor weakness in system design OR limited non-compliance. Some risk to achievement of a system objective.	Within one month*
Low	Potential to enhance system design to improve efficiency or effectiveness of controls. Generally issues of good practice for management consideration.	Within three months*

* Unless a more appropriate timescale is identified/agreed at the assignment.

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