NHS Scotland Assure
Quality in the healthcare environment

NHS
National Services Scotland

NHS Tayside Endoscopic Decontamination Unit Key Stage Assurance Review

CONFIDENTIAL

Initial Agreement KSAR Report

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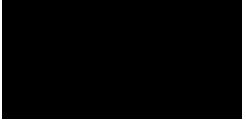
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1. Executive Summary

1.1   Executive Summary

Throughout the Key Stage Assurance Review (KSAR) it was evident that NHS Tayside have a thorough understanding of the current challenges faced by their Endoscopic Decontamination Service and the need for change to mitigate current and future risks to the service as outlined within their Initial Agreement documents.

Overall the KSAR has not identified any specific or significant findings that require to be addressed prior to the conclusion of the Initial Agreement (IA) phase of the project. There are a number of points that we recommend NHS Tayside review as part of their action plan to mitigate potential risks as the project develops and moves towards the Outline Business Case (OBC) Stage.

One of the key items we recommend NHS Tayside prioritise is the creation of a master programme, as this document does not yet exist. The master programme should be developed to allow time for appropriate levels of internal governance when assessing the finalisation of design options during the OBC design. NHS Tayside should also consider creating a detailed resource plan to ensure appropriate and adequate levels of support are provided for the OBC processes, including any required input from senior leadership personnel.

Overall the documentation provided by NHS Tayside is well developed and aligned to the level of detail expected at the IA stage of the project. Stakeholder input into the proposed solutions is evident in places, however in our opinion, there is a lack of documented sign-off evidence from stakeholder leads with respect to the approval of the options taken forward through the IA process. We recommend that NHS Tayside review how stakeholder sign-offs are formally recorded during subsequent stages to provide full transparency in the decision making processes.

With respect to the stakeholder list provided by NHS Tayside, the majority of key roles and individuals are clearly defined, however there is a lack of detail presented around the technical stakeholders at this stage (for example NHS Tayside Estates, Authorising Engineers and design team). NHS Tayside have undertaken a gap analysis to identify roles that require to be filled at subsequent design stages, however from the evidence provided by NHS Tayside, it is unclear what the formal process will be to fill the roles. Of particular note is the provision and resource of Infection Prevention and Control (IPC) staff, as the NHS Tayside gap analysis identifies that there is currently no microbiologist in place to support new capital projects. Whilst NHS Tayside have implemented contingency plans in this respect to ensure IPC representation at all stages of the project, NHS SA note a concern with respect to the resiliency of the current measures and the demands multiple concurrent capital projects will place on the individual stakeholders named on the project. We recommend that NHS Tayside develop a full resource plan for IPC input during subsequent design stages that takes cognisance of any other resource demands placed on individuals, including working on several concurrent projects.

In terms of the IPC input to the IA process, this has been evidenced at various points, however as yet there is no HAI-SCRIBE in place. The KSAR has also identified that the

potential use of flexible hoses to accommodate adjustable workbenches has not been risk assessed from an IPC perspective. NHS National Services Scotland issued a Safety Action Notice (SAN(SC)09/03) in November 2009, outlining the risks associated with flexible hoses which may have an enhanced risk of harbouring Legionella bacteria and other potentially harmful micro-organisms. NHS Tayside should ensure that the recommendations of this Safety Action Notice are considered during the development of this design.

NHS Tayside have indicated the technical standards to which the design will be developed to at subsequent stages of the project, with no derogations currently identified by NHS Tayside. NHS Tayside provided evidence of their proposed governance approach to any derogations which they plan to fully integrate into subsequent design stages. Whilst the technical standards are outlined at a high level, there are no Board Construction Requirements (BCRs) developed and the strategy for fully defining the technical brief at subsequent design stages is not clear from the evidence provided.

The KSAR has also identified a discrepancy in proposed options with respect to meeting the recommendations of SHPN 13, specifically the requirement for ante-rooms. NHS Tayside have acknowledged this through the KSAR workshops and are reviewing and will action ahead of the next design stage (OBC).

There was no evidence within the KSAR response as to how NHS Tayside will monitor subsequent compliance with the technical requirements of the project. We would recommend that this element forms part of the NHS Tayside action plan.

NHS Tayside have indicated that Framework Scotland 3 is the preferred procurement route for contractor, supporting professional services and design services moving forward through the OBC. NHS Tayside have not identified how they plan to utilise IPC and technical specialists in the procurement process to define and assess the competencies of potential supply chain partners.

1.2 Summary of Findings

The findings of this report have been collated based on information provided by NHS Tayside. The following table outlines the status of key findings as derived from the KSAR and identified within the NHS Scotland Assure 'Recommended Action Plan' issued to NHS Tayside under separate cover:

Review	No. of Issues per category				
	1	2	3	4	5
Project Governance and General Arrangements	0	0	1	15	9

The following categories were used in relation to the findings:

Category	Definition
1	Significant – Concerns requiring immediate attention, no adherence with guidance
2	Major – Absence of key controls, major deviations from guidance
3	Moderate – Not all control procedures working effectively, elements of noncompliance with guidance
4	Minor – Minor control procedures lacking, or improvement identified based on emerging practice
5	Observation and improvement activity

1.3 Project Overview

NHS Tayside advised that, the current endoscopic decontamination unit and equipment, at Ninewells hospital, is not compliant with current guidance, Scottish Health Planning Note 13: Part 3 Decontamination Facilities, and the existing installed equipment is past its operational lifespan, which has introduced risks associated with difficulty to support and maintain a reliable safe service.

Due to constraints with the existing Ninewells facility, NHS Tayside have noted within the IA documentation that it is not possible to extend the existing facility. Having such constraints supports the consideration towards the need for a new facility.

The aim of the Endoscopic Decontamination replacement Project is to ensure that the Endoscopic Decontamination Units, at NHS Tayside, are equipped to provide a sustainable decontamination service to fit the clinical model and which has facilities that are compliant with best practice standards as set by Health Facilities Scotland.

The NHS Tayside Initial Agreement documentation sets out the case for change and assesses the project financial, commercial and management implications for a new 263m² Endoscopic Decontamination Unit.

2. Review Methodology

2.1   Overview of NHS Scotland Assure & The KSAR Process

Good management and effective control of projects is an essential element to the successful delivery and maintenance of healthcare facilities across NHS Scotland estates.

The NHS Scotland Assure - Assurance Service was launched on the 1st June 2021 following a letter issued by Scottish Government to Health Board Chief Executives, Directors of Finance, Nursing Directors and Directors of Estates. This letter outlined the purpose of NHS Scotland Assure, with an overarching aim to deliver a co-ordinated approach to the improvement of risk management in new builds and refurbishment projects across NHS Scotland. The new service will underpin a transformation in the approach to minimising risk in our healthcare   buildings and environments, protecting patients from the risk of infection and supporting better outcomes for patients in Scotland.

From the 1st June 2021, all NHS Board projects that require review and approval from the NHS Capital Investment Group (CIG), will need to engage with NHS Scotland Assure to undertake key stage assurance reviews (KSARs). Approval from the CIG will only follow once the KSAR has been satisfactorily completed. The KSARs have been designed to provide   assurance to the Scottish Government that guidance has been followed. The Scottish Government may also commission NHS Scotland Assure to undertake reviews on other healthcare built environment projects. This does not change accountability for the projects; NHS Boards remain accountable for their delivery. NHS Scotland Assure will be accountable for the services it provides that support delivery of the projects.

NHS Scotland Assure will also work closely with Health Boards to identify where a KSAR may be required for projects under their Delegated Authority, utilising a triage system to assess risk and complexity of projects.

The KSARs will assess if Health Boards Project Management teams (inclusive of clinicians, appointed construction consultants, and contractors) are briefed and following best practice procedures in the provision of facilities. We will review if projects are compliant in all aspects of safety, if specific engineering systems are designed, installed and commissioned, and for ongoing safety maintenance including Infection Prevention and Control (IPC).

The KSAR focuses on key topics, specifically – IPC, water, ventilation, electrical, plumbing, medical gases installations and fire. This ensures they are designed, installed and functioning from initial commissioning of a new facility and throughout its lifetime. Health Boards are required to have appropriate governance in place at all stages of the construction procurement journey.

Each NHS Health Board will be fully responsible for the delivery of all projects, and its own internal process and resources for carrying out internal reviews and audits of its activities. The KSAR is seen as a complementary independent review, and not as a replacement for the responsibilities of NHS Tayside.

Whilst the KSAR focusses on actions to improve the end product, it is not intended to detract from the merits of a development that will add significant benefit for the healthcare of the population served, and which has many exemplary elements. Rather, it is a reflection of the complexity of healthcare construction projects and the stage of development at which it was

reviewed. Some conflicts and changes are to be expected as complex projects develop and project teams have in place mechanisms to identify and address these. This report adds a layer of scrutiny and assurance to that process to address the above requirement from government.

2.2   KSAR Process

2.2.1   The IA KSAR for NHS Tayside EDU took place between 06th October 2021 and 5th November 2021.

2.2.2   To inform the findings of the KSAR, NHS Tayside were issued with key documents outlining the assurance question set and expected level of evidence and supporting documents in accordance with relevant legislation and guidance. This included the IA KSAR Workbook.

The KSAR report includes an overview of the main findings of the review, with a further itemised list of detailed observations provided under separate cover to NHS Tayside. The detailed observations are recorded in an action plan that should be adopted by NHS Tayside following the review and subsequently monitored by them to ensure appropriate actions are completed in a timeous manner.

2.2.3   As part of the KSAR process, NHS Tayside issued a document transmittal log which details the evidence provided in response to the KSAR Workbook and NHS SA recommended deliverables list. As part of an initial gap analysis, NHS SA reviewed the transmittal log to ensure all documents had been successfully received. The transmittal log provides a version history and audit trail of information reviewed.

2.3   Application of Standards & Legislation

2.3.1   Health Facilities Scotland (HFS) currently provides a range of advisory and delivery services across a wide variety of topics from a portfolio which covers the built estate, engineering and environment and facilities management. With some exceptions these services are largely advisory in nature, identifying best practice and developing national guidance and standards.

2.3.2   Antimicrobial Resistance and Healthcare Associated Infection (ARHAI) Scotland currently provides advice and guidance on all aspects of infection protection and control nationally in Scotland, inclusive of expert advice and guidance on the topic of Healthcare Associated Infections (HAI) and antimicrobial resistance. It maintains and continues to develop a practice guide (National Infection Prevention and Control Manual – NIPCM) as well as a HAI Compendium of all extant guidance and policy appropriate for use in NHS Scotland. Like HFS, these services are largely advisory in nature, identifying best practice and developing national guidance and standards. The NHS Scotland NIPCM was first published on 13 January 2012 as mandatory guidance, by the Chief Nursing Officer (CNO (2012)1), and updated by a second edition on 17 May 2012 (CNO(2012)01-update). The NIPCM provides guidance for all those involved in care provision and should be adopted for infection, prevention and control practices and procedures. The NIPCM is mandatory policy for NHS Scotland.

The authority of guidance produced by National Services Scotland (NSS) and other national organisations e.g., Healthcare Improvement Scotland is best described by the definitions outlined below (SHTM 00 – Best practice guidelines for healthcare engineering):

> **Regulations** are law, approved by Parliament. These are usually made under the Health and Safety at Work etc Act following proposals from the Health & Safety Commission. Regulations identify certain risks and set out specific actions which must be taken.
>
> **Approved Codes of Practice** give advice on how to comply with the law by offering practical examples of best practice. If employers follow the advice, they will be doing enough to comply with the law.
>
> Approved Codes of Practice have a special legal status. If employers are prosecuted for a breach of health and safety law, and it is proved that they did not follow the relevant provisions of an Approved Code of Practice, they will need to show that they have complied with the law in some other way, or a court will find them at fault.
>
> **Standards** (British or European), institutional guides and industry best practice play a large part in how things should be done. They have no direct legal status (unless specified by Regulations). However, should there be an accident; the applied safety practices at the place of work would be examined against existing British or European Standards. It would be difficult to argue in favour of an organisation where safety was not to the described level.
>
> **Guidance** is issued in some cases to indicate the best way to comply with Regulations, but the guidance has no legal enforcement status.

2.3.3 Whilst guidance is deemed not compulsory by the Health and Safety Executive (HSE), where compliance with guidance is specified in a contract, as is the case here, it becomes a contractual requirement. Therefore, any permitted deviation from it would be expected to follow a formal process with input from all relevant parties, with clarity around how the outcome was reached, including risk assessments where appropriate and sign off by all those authorised to approve it.

3 KSAR Review Summary

The following narrative relates directly to the IA KSAR workbook and the evidence indicated therein. The comments associated with the points are because of the evidence presented by the Board and their advisors during the review process.

3.1   Project Governance and General Arrangements

3.1.1   Project Governance and General Arrangements KSAR Observations

Workbook Ref No.	Areas to probe	Evidence expected
1.1	Service / clinical input into early design decisions based on knowledge of patient cohort.	o Recorded input taken from service lead(s) / clinician(s) about relevant patient cohort characteristics and their typical needs in terms of the accommodation's environment, safety and infection control standards. o Demonstrable expertise of service lead(s) / clinician(s) in providing this advice.

NHS Scotland Assure Observations:

As the project relates to an Endoscopic Decontamination Unit (EDU), the focus of the evidence in response to the KSAR relates to the clinical support function being provided by the EDU and associated process flows.

NHS Tayside have demonstrated a formal, structured approach to the management and development of the project, focusing particularly on clinical input and requirements. The structure and role and input of Stakeholders is identified as:

- Service & Clinical Stakeholders who are embedded within the Project Team and directly accountable to the Project Board
- Wider Service & Clinical Stakeholders who are reported & consulted with by the Project Team

The initial agreement documentation clearly identifies the issues currently faced by the NHS Tayside endoscopic decontamination service, this is also demonstrated within the AEDET and design statement. With respect to documented input from stakeholders, there is limited evidence out with the AEDET and design statement to document the decision making process.

The strategic context of the IA documents identifies a potential cross infection risk with the current EDU sink configuration used for manual testing and cleaning. The IA also identifies that the existing facility is non-compliant with current SHTM guidance and suffers from a lack of space which is leading to an inability to provide Endoscope Washer Disinfector (EWD) for flexible endoscopes for ENT and Cardiology scopes. Documented stakeholder input to the development of the proposals was provided via recorded attendance at meetings and workshops, however contributions from individual service leads is not clearly identified.

The overall process for decision making is set out in the high level governance structure, detailing that the Project Team are required to agree the development of the specifications in conjunction with stakeholders and ensure these are met. The Project Team is required to log decisions as risk and /or escalate to the Project Board as required.

Key clinical service leads are actively engaged within the Project Team and their roles, terms of reference and biographies are documented, generally there were no significant

concerns identified as part of the KSAR, however there is no evidence of details provided for the following:

- o Microbiologist, authorising engineers, safety group members (water, electricity, medical gas, ventilation, fire safety, etc).

References:
- 2021-10-07 v4.2 NHST EDU Initial Agreement
- 3.1.2 table 2 - NHS Assure KSAR Submission 23092021 v2.0
- Appendix 9 Project Team Biography 17092021 V1.0
- Appendix 15 Project Team ToR 07102021 v4.1
- Strategic Risk Management Group 01/09/17
- Revised Risk Assessment 21/01/21 (Appendix 4)
- Design Statement Workshop facilitated by Health Facilities Scotland, 03/09/2020 (Appendix 18)
- AEDET workshop, facilitated by Health Facilities Scotland, 25/09/2021. (Appendix 7)
- Design Statement, facilitated by Architectural Scotland, 24/09/21(Appendix 8)

Workbook Ref No.	Areas to probe	Evidence expected
1.2	Health Board Project team understanding of needs of main users and patient cohorts of the proposed accommodation and how this will influence the design of critical building, engineering, and infection prevention and control quality and safety standards.	o List available of all stakeholders, service users and patient cohorts impacted by this project, plus the identification of any high risk groups and their specialist needs. o Recorded engagement on these designs issues having taken place between the project team and service lead(s) / clinician(s), infection prevention and control team, and other key stakeholders (e.g. the AEDET, NDAP or other design briefing workshops). o Details available of proposed service model, understanding of what the patient journey will be through the service, and records of expected patient throughput levels. o Details available of how service users / patient cohort needs and their expected use of the accommodation has influenced the initial design brief; including critical building, engineering and infection prevention and control quality and safety standards.

NHS Scotland Assure Observations:

A number of key strategic stakeholders have been identified and engaged as part of the development of the project, with evidence of documented meetings provided as part of the KSAR response.

A list of stakeholders was provided within the KSAR response appendices including evidence of engagement during the development of the design statements, AEDET with engineering, and clinical specialists. (Reference Appendix 10 Stakeholder Map, Table 9, 2021-10-01 v4.0 NHST EDU IA.)

The stakeholder list contains a good overview of clinical and operational stakeholders, however it lacks detail on technical stakeholders at this stage. NHS Tayside have identified through the KSAR meetings that this will be developed throughout the project programme as the initial focus has been on developing the operational/clinical strategies.

As the project relates to an Endoscopic Decontamination Unit, there are no '*high risk groups*' in the context of patient cohort, however in terms of a wider NHS Tayside strategic service, the IA documentation provides a clear narrative as to the wider service risk in relation to EDU service across the NHS Tayside Board. The IA identifies that there are currently three Endoscopic Decontamination Units (EDUs), located within Ninewells Hospital, Perth Royal Infirmary (PRI) and Stracathro Hospital. The units currently support 9 clinical specialities across NHS Tayside: Gastroenterology, respiratory service, Intensive Care Units, Theatres, Paediatrics, Urology, Anaesthetics, Cardiology and Ear Nose and Throat services.

An AEDET assessment for the existing and new EDU facilities, has been included within the project information, including a list of stakeholders that were present at the workshop and their input into the AEDET development and scoring.

The project team and Health Board stakeholders have identified that the existing facilities are performing poorly across all categories with the following key themes being identified:

- EDU cannot sustain a service due to ageing equipment and non-compliant facilities
- No sustainable contingency plan in the event of catastrophic failure of EWDs
- EDU facilities do not meet current standards
- Poor ventilation (odours) and limited heat control
- Poor accessibility

The proposed case for change is to create new EDU facilities in compliance with SHPN 13 Part 3. The AEDET assessment undertaken for the target decontamination facilities scored strongly across all applicable categories, through the rectification of the operational and organisational risks currently being experienced.

As noted previously, whilst there is evidence of stakeholder engagement at various points in the design, there is generally a lack of evidence of documented review/sign-off from the stakeholders out with the AEDET process.

The new endoscopic decontamination unit is a clinical support facility, therefore there is no '*patient journey*' as such. The KSAR evidence provided by NHS Tayside indicates they do have a good understanding of the clinical support services required (at Board level) and identifies clearly the required capacity for decontaminating and cleaning flexible endoscopes, including an overview of the wider NHS Tayside Board challenges being faced on the Stracathro and Perth Royal Infirmary Sites.

The KSAR response evidences how the organisation cannot meet the current requirements to provide an automated service for all flexible endoscopes, due to a lack of space and capacity. The five machines on the Ninewells site are particularly heavily used and operating at or near maximum capacity. In the event of failure at one of the three sites, service continuity could be affected.

The initial design brief has been developed following a review of risks and constraints by the Stakeholder group. The business case proposes to adopt standard configurations identified within SHPN13 PART3:2010 to address these challenges. The key representative stages detailing and documenting service user consultation and input into the project is as follows:

- Design Statement, facilitated by Architectural Design Scotland, 3rd September 2020, sets out the objectives for the project in conjunction with stakeholders and service Users (Appendix 8 Design Statement 24092021 V1.0).
- An AEDET workshop was facilitated by Health Facilities Scotland on 25th August 2021. This was attended by a broad stakeholder group and their review and input assessed the current facilities to determine a benchmark score and a target score against which the future designs will be measured. (Appendix 6 AEDET Scoring & Appendix 7 AEDET Workshop Attendees).

The business case proposes to adopt standard configurations identified within SHPN 13 Part 3:2010, however, there is a conflict in the standards being referred to within the business case, which includes:

- Two Room EDU Model (App 2), is identified within the IA document.
- Two Room EDU model with Ante Rooms (App 3), is identified within the schedule of accommodation that has been developed.

The precedent images included within the design statement identify the use of height adjustable benches. It is unclear from the evidence provided whether any consideration has been given to the potential for bacterial growth within any flexible connections to the adjustable benches, nor whether IPC or other stakeholders have been consulted as to their use.

References:

- 2021-10-07 v4.2 NHST EDU Initial Agreement
- Appendix 6, AEDT scoring & notes 25082021
- Appendix 7 AEDET Workshop Attendees 25082021 V1.0

Workbook Ref No.	Areas to probe	Evidence expected
1.3	What is the Heath Board's formal process for derogations?	o List of the relevant NHS and non-NHS guidance to be used and adopted (see previous section of workbook for examples of appropriate guidance) and how this is to be highlighted in the Board's Construction Requirements (BCR). o List of any proposed derogations from NHS or other guidance and / or list of known gaps in guidance that will need to be resolved to meet the needs of the patient / user cohort. o Knowledge of the role of infection prevention and control and microbiologist advisors to be used throughout the design stages, and details of the resource plan in place to ensure this advice will be available.

NHS Scotland Assure Observations:

As part of their IA documentation, NHS Tayside have created a list of SHTMs and NHS/Non-NHS Regulatory requirements (included within their KSAR response as Appendix 23).

Whilst the list provides an overview of some of the key guidance documentation, this is not yet captured in a BCR type document.

The business case is proposing to adopt standard configurations identified within SHPN 13 Part 3:2010. There is a conflict in the standards being referred to within the business case, which includes:

- Two Room EDU Model (App 2), is identified within the IA document (Section 1.1.1, 1.1.2, 2.14, 2.2.1, 2.2.2, 3.5.3)
- Two Room EDU model with Ante Rooms (App 3), appears to have been identified within the schedule of accommodation (Appendix 19)

There is no derogations schedule in place at this stage of the project. NHS Tayside advised during the KSAR workshops that as the options detailed within the IA are developed, as to will the derogations.

NHS Tayside have provided a draft copy of a proposed Board wide derogations process they plan to adopt on the project moving forward. This outlines their proposed governance approach, including review of any potential risks, mitigation measures and stakeholder review/sign-off.

NHS Tayside Infection Prevention and Control (IP&C) Team are identified within the project stakeholder list. The stakeholder list provided notes that no microbiologist advisor is currently identified for the project.

Evidence of the IP&C Team input is demonstrated through the identification of the potential ARHAI risks with the current EDU service, and through the identification of the preferred EDU model to provide a safe and resilient service. NHS Tayside advised during the KSAR meetings that a HAI-SCRIBE had not yet been undertaken. NHS Tayside provided no evidence of an IPC resource plan.

References:
- Doc: 2021-10-01 v4.0 NHST EDU IA.docx - Ref Appendix 23 - SHTMs & NHS/non-NHS Regulatory requirements
- Technical Lead has prepared a list of SHTMs and NHS/Non-NHS Regulatory requirements to be considered at the design phase of the project; this will be explored at OBC Stage.
- 3.3.2 (NHS T KSAR Submission 23092021)
- NHS Endoscopic Decontamination Project - Initial Agreement (ref Doc:2021-10-01 v4.0 NHST EDU IA.docx)
- Noted that wider stakeholders (Appendix 15) have met and support the recommendations.

Workbook Ref No.	Areas to probe	Evidence expected
1.4	Planned approach for managing the design process to ensure successful compliance with agreed and approved standards.	o The project governance arrangements and resource plan in place to ensure that the necessary decision making authority and technical expertise is available to take responsibility for and deliver the project as planned and agreed. o Gap analysis on expertise required specifically for the project and details of how gaps in expertise are to be filled. o Details of how compliance with the appropriate guidance, design brief and other standards will be agreed, signed off, monitored, reported against and if necessary escalated / adjudicated throughout the design, construction and commissioning stages. o Details of how all stakeholders' interests will be agreed, signed off, monitored, reported against and if necessary escalated / adjudicated throughout the design, construction and commissioning stages.

NHS Scotland Assure Observations:

NHS Tayside have demonstrated through the IA documentation that their governance structure is controlled through the Project Board, chaired by the Chief Officer Acute Services of NHS Tayside. The Project Board is accountable for monitoring progress and providing the necessary steer to resolve issues that cannot be resolved at Project Team level.

The Project Team are noted as being responsible for establishing the necessary project infrastructure, identifying resource requirements and undertaking monitoring and control

activities. This is currently identified for the Outline Business Case (OBC) stage, but there is no evidence of consideration of resource for subsequent stages, including the operational phase of the project.

The documents provided as part of the KSAR response note that the Project Team are required to ensure risks and issues are managed and escalated as required to the Clinical Care Group Manager (Appendix 15 Project Team Tor 07102021 V4.1) and Senior Responsible Officer. Generally, the roles are well defined, however some ambiguity does exist with respect to the definition of the Senior Responsible Officer (ref Appendix 15 Project Team TOR 07102021 V4.1) and the Senior Responsible Owner (ref 3.4.1 NHS Assure KSAR Submission 23092021 v2.0).

The resource plan for the project is outlined in the project execution plan, which identifies key project roles, however, there is no evidence of how all stakeholders' interests will be agreed, signed off, monitored, reported against and if necessary escalated / adjudicated throughout the design, construction, and commissioning stages.

With respect to a gap analysis on roles/expertise required to deliver the project at subsequent stages, NHS Tayside have identified the following Internal and external technical roles required as the project progresses to OBC:

- Cost Adviser
- NEC 4 Project Manager
- Soft Landings Champion
- Principal Designer
- Consulting Engineers (M&E, Civil & structural)
- Main Contractor Lead

NHS Tayside have also identified within their stakeholder list that there are currently no Microbiologists for NHS Tayside capital build projects. For this project, it is proposed that the Decontamination Clinical Lead & Building Lead for IPC, will be providing expertise by ensuring that IP&C is designed into all build projects.

It is unclear from the information provided as to whether this is an exhaustive list, nor how resource will be managed with respect to time allocated on the project. NHS Tayside have demonstrated that they plan on utilising HFS Framework Scotland 3 for a number of roles, however it is not clear at this stage how internal roles will be filled.

NHS Tayside have not yet identified authorising engineers, microbiologist, and safety group members (water, ventilation, etc).

There is no evidence identified for the process on how the appropriate guidance and design brief will be agreed, signed off, monitored, reported against and if necessary escalated / adjudicated throughout the design, construction, and commissioning stages.

The KSAR response provided by NHS Tayside indicates that stakeholder interests will be represented by the Project Team and fortnightly meetings will be undertaken under the Terms of Reference. The Project Team is required to engage with all Stakeholders as the project progresses. Any project issues which are not agreed or signed off at this level are required to be escalated to the Project Board.

References:
- Appendix 2 - Service Level Risk 01092017 - 2021-10-01 v4.0 NHST EDU IA
- Appendix 9 - Project Team Biography
- Appendix 10 - Stakeholder Map - 2021-10-01 v4.0 NHST EDU IA
- Appendix 11 - Stakeholder List - 2021-10-01 v4.0 NHST EDU IA

- Appendix 15 - Project Team – ToR 07102021 v4.2
- Appendix 16 - Project Execution Plan – 2021-10-01 v4.0 NHST EDU IA
- NHS Tayside KSAR Submission 33092021
  - 3.4.2 Table 6 NHS Appointed Roles & Table 7 NHS Assure KSAR Submission 23092021 v2.0:
  - 3.5.2 NHS Assure KSAR Submission 23092021 v2.0

Workbook Ref No.	Areas to probe	Evidence expected
1.5	Conceptual approach on the procurement journey with initial plans on how the Board will provide assurance, particularly on the identified areas described earlier.	o Initial plans on how this requirement will be managed and how it fits with the project governance arrangements. o Initial plans to identify any gaps in the procurement approach that may require to be addressed. o Initial plans to indicate that the Health Boards selected procurement route will go through the Health Board's Governance channels. o Initial consideration on how the Infection Prevention and Control Procedures and management will fit with the conceptual procurement approach and initial thinking on how it will be managed.

NHS Scotland Assure Observations:

A Project Execution Plan (PEP) has been provided as a governing document that defines how the project procurement process will be executed, monitored, and controlled.

The PEP sets out at high level how the project execution phase of the procurement works, and activities project will be managed to meet the requirements of the project.

The PEP also notes that the NHS Tayside procurement team representatives are part of the Project Team and attend meetings / workshops as required. The procurement team's remit is to ensure all necessary procurement considerations are identified and adequate time is allowed in the Project Plan to deliver these.

There is limited evidence provided on the required internal and external technical competencies and resource required for progressing to the next stage of procurement. Whilst a procurement route (i.e. HFS Frameworks Scotland 3) is identified, including associated required roles (within the gap analysis), the evidence provided does not clearly demonstrate as to how the competency of those being considered for the roles will be assessed.

No project programme has been provided.

There is no evidence of consideration as to how the early technical development of preferred option will be developed in conjunction with the procurement process and overall project programme.

The Project Execution Plan sets out the high-level detail of the procurement process, and it is anticipated that the Frameworks Scotland 3 will be the preferred option. NHS Tayside have indicated within the IA documentation that this will progress through NHS Tayside's

Governance channels, however there is a lack of detail as to specific internal governance processes that will be applied, including interfaces with the Project Board and Senior Management.

Whilst the process outlines some roles and responsibilities, there are inconsistencies noted in the role of the Procurement Manager as detailed in the appendix 15 table (ref Reference Appendix 15 – 2021-10-01v4.0 NHST EDU IA) which does not align with Appendix 15 (ref Appendix 15 Project Team ToR 07102021 v4.1). It is therefore unclear how this role will then interface with senior personnel associated with the NHS Tayside governance process.

NHS Tayside Infection Prevention and Control (IP&C) Team are identified with defined roles and responsibilities within the project documentation, however it is unclear what inputs they will have with respect to the procurement approach. Their general duties are defined within the project, including what inputs they will have in relation to developed solutions.

References:
- Appendix 16 Project Execution Plan 21092021 v1.0 - 2021-10-01 v4.0 NHST EDU IA
- 4.3.1 HAI SRIBE, 2021-10-01 v4.0 NHST EDU IA
- Appendix 7 & Appendix 8, 2021-10-01 v4.0 NHST EDU IA
- NHS Endoscopic Decontamination Project - Initial Agreement (ref Appendix 14, Doc:2021-10-01 v4.0 NHST EDU IA.docx)

3.1.2 Project Governance and General Arrangements: Further Observations

In addition to the points raised via the KSAR workbook above, we also include the following observations as a result of the review, all of which relate to the evidence presented by NHS Tayside.

3.1.2.1	There is no evidence of risk management/mitigation if key project team members change or are unavailable to engage with the project.
3.1.2.2	NHS Tayside have evidenced an awareness of various risks throughout the IA documentation and note that an overarching Project Risk Register is in place, however this was not provided by NHS Tayside as part of the KSAR response and has not been reviewed by NHS Scotland Assure.

4. Appendices

Appendix 1: Glossary

Please refer to NHS Scotland Assure – Assurance Service Master Glossary document available to download from NHS National Services Scotland website