



**NHS Tayside  
Cancer Centre  
Key Stage  
Assurance Review**



**Initial Agreement  
KSAR Report**

V2.0 May 2022

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## Document Overview

### NHS Tayside Cancer Centre | Key Stage Assurance Review Report | Initial Agreement Stage

#### Prepared for:

NHS Tayside for the Proposed Cancer Centre

#### Prepared by:

NHS Scotland Assure – Assurance Service

## Document Control Sheet

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### Approvals

This document requires the following signed approvals:

Version	Date	Name & Organisation	Role	Signature
V1.0	18.03.22	Thomas Rodger	Principal Engineering Manager – NHS Scotland Assure	TR
V1.0	18.03.22	Ian Storrar	Assistant Director Engineering and Assurance – NHS Scotland Assure	IGS
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## Distribution

This document has been distributed to:

Version	Date of Issue	Name	Role / Area
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V2.0	17.05.22	[REDACTED]	Decontamination Lead – NHS Tayside
V2.0	17.05.22	[REDACTED]	Consultant Oncology – NHS Tayside

## 1. Executive Summary

As a result of the Initial Agreement (IA) Key Stage Assurance Review (KSAR) and based on the information presented to NHS Scotland Assure, we are able to support the project at this stage, subject to NHS Tayside's confirmation of their action plan and commitment to address the issues identified.

It is evident from the KSAR that NHS Tayside have an understanding of the current challenges faced by their Cancer Services and the need for change to mitigate current and future risks to the service as outlined within their Initial Agreement (IA) documents. Generally, documentation provided as part of the Initial Agreement was well developed and commensurate with the level of detail expected at this stage. The information provided by NHS Tayside to inform this KSAR was submitted in a format that matched the KSAR review structure and was extremely helpful to the review team in that regard.

Overall, this KSAR has not identified any major or significant findings that would prevent the project from progressing to the next phase. 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.

It is evident that stakeholder engagement has taken place during the development of the IA, however based on the information provided for review, we have found in some areas that there is a lack of documented evidence of this consultation, review and sign-off process. We recommend this process is strengthened through the next stages ensuring all relevant stakeholders are engaged and this is fully documented.

NHS Tayside have identified resource challenges specifically in respect of infection prevention and control (IPC) and microbiology support. It is noted there has been support during the development of the IA, including attendance at the HAI SCRIBE stage 1 review. Given the risks, NHS Assure recommend that IPC and microbiology resource resilience should be strengthened, a formal resilience plan should be documented and that NHS Tayside should implement appropriate risk mitigation.

It is noted the proposal includes for the provision of an aseptic dispensing unit (ADU). Given the specialist nature of this type of facility, NHS Tayside should ensure they have engaged the necessary expertise in this regard and ensure that their stakeholder engagement plan includes for all necessary consultations in relation to the ADU.

NHS Assure recommend a detailed master programme is prepared for the next phase. A high-level timetable is provided within the IA. A detailed master programme for the OBC stage should capture all the key activities and timescales including in relation to stakeholder engagement and internal governance / approvals.

Due to the number of potential concurrent construction projects on the Ninewells site, NHS Scotland Assure recommend that NHS Tayside develop an overarching site-wide masterplan / programme to monitor any ongoing dependencies and risks, including

availability of key stakeholders that are involved in concurrent projects.

Considerable work has been undertaken during the IA stage to develop the capacity planning report. It is noted that this is to be revisited and assumptions and data tested during the OBC stage, including for the impact of COVID-19. A clinical brief has also been developed during the IA stage.

NHS Tayside have indicated the technical standards that design options should be developed to at subsequent stages although some gaps have been identified e.g. in relation to SHTM fire codes (SHTM 81,83). No derogations have been identified at this stage. 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. We recommend that NHS Tayside consider how these will be defined at OBC, for example through the preparation of a detailed Project Brief to fully capture the wider project requirements. NHS Tayside should consider how these may impact on the appointment of a principal supply chain partner (PSCP) and design team. NHS Tayside should also ensure that adequate time is allowed with respect to project governance when developing the various options through the OBC phase of the project.

Net-zero and sustainability requirements are acknowledged within the IA documentation, noting strategies are to be developed at subsequent design stages. The project cost plan includes an uplift for sustainability 'in line with SFT funding for schools'. NHS Tayside should ensure these costs are reviewed against NHS Scotland sustainability targets.

Currently there is no project execution plan (PEP) in place for the project. NHS Tayside have advised it is their intention to produce this document before the start of the OBC stage. NHS Scotland Assure fully support this approach as it will address a number of the observations provided in this KSAR. A robust PEP should provide sufficient detail around a range of issues including; the project governance / structure, individuals involved, roles and responsibilities including covering all specialisms required to support the design, medical equipment and ADU requirement, the stakeholder engagement process, communications including meetings and reporting, resource planning, design development/deliverable, procurement, etc.

Generally, the IA sets out the conceptual approach to the procurement journey, including how the Board will provide assurance. However, NHS Tayside have not clearly 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.

## 1.1 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 SA Recommended Action Plan issued to NHS Tayside under separate cover:

Review	No. of Issues per category				
	1	2	3	4	5
<b>Project Governance and General Arrangements</b>	0	0	2	13	15

The following categories were used in relation to the findings:

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

## 1.2 Project Overview

The project is currently at Initial Agreement (IA) stage of the NHS procurement cycle.

The aim of NHS Tayside is to design, plan and deliver a new build modern cancer centre for the population of Tayside and North East Fife based at Ninewells Hospital in Dundee. The facility will accommodate all non-surgical oncology (radiotherapy and systemic anti-cancer therapy (SACT)), acute clinical and support services and an aseptic dispensing unit.

The investment objectives as set out in the IA are:

1. Deliver a modern and compliant cancer centre for the population of Tayside and North East Fife which will accommodate all non-surgical oncology (radiotherapy and systemic anti-cancer therapy), acute clinical and support services and an aseptic dispensing unit as part of an improved pathway centred around people and their communities.
2. Provide a sustainable cancer service for Tayside through enabling planned linear accelerator (LINAC) replacements in 2023 and 2025.
3. Ensure capacity is available to meet growing demand, enabling provision of a highly responsive, patient-centred clinical model with timely provision of treatment delivered safely, effectively, and efficiently.
4. Provide fit for purpose accommodation which improves the patient experience and delivers improved patient outcomes.
5. Enhance workforce well-being, development and promote recruitment and retention of staff.



## 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 1<sup>st</sup> 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 1<sup>st</sup> 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 Cancer Centre took place between January 2022 and March 2022.

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 prevention 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.	<p>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.</p> <p>Demonstrable expertise of service lead(s) / clinician(s) in providing this advice.</p>
<p><b>NHS Scotland Assure Observations:</b></p> <p>NHS Tayside have demonstrated a good understanding of the patient cohort as part of the KSAR response, including being able to demonstrate clinical input into the development of the Initial Agreement documentation. Technical stakeholder input to this phase of the project has been limited.</p> <p>NHS Tayside have commenced development of the services design through consideration of service provision, capacity planning, establishing objectives, a design statement, Achieving Excellence in Design Evaluation Toolkit (AEDET) review and development of an indicative schedule of accommodation. At this IA stage, development of the technical solution has not yet commenced.</p> <p>In the document '<i>NHS Assure Submission Cancer Centre December 2021</i>' NHS Tayside report that Service leads and clinicians have been involved in the IA development process including in relation to the relevant patient cohort characteristics and their typical needs in terms of the accommodation's environmental requirements. This has included them being involved the development of the clinical brief.</p> <p>Service/clinical leads are recorded as having been involved in the development of the design statement at Appendix K of the Initial Agreement (IA).</p> <p>NHS Tayside have reported in the document '<i>NHS Assure Cancer Centre December 2021</i>' a project team met weekly every month throughout the completion of the IA where the IA document was thoroughly reviewed and updated. The KSAR review</p>		

team were not provided with the minutes of meetings, to confirm attendees at these meetings or issues discussed.

Details of the individuals involved in the project are set out in the documents referenced below. NHS Tayside have reported the project team and project governance arrangements have been designed to incorporate critical clinical and service stakeholders from inception through to execution.

Section 3.3 of the IA sets out the stakeholder engagement process involving the project team (which includes clinicians and service leads) and other stakeholder groups such as staff and general public representatives. NHS Tayside have reported that this included attendance at cancer centre workshops 1 & 2, AEDET workshop, design statement workshop and risk review workshop. Appendix Q of the IA is the 'stakeholder engagement and communication plan' which sets out stakeholders and their 'purpose'. Infection control is listed here. It is noted in other documents, including the HAI-Scribe report referenced below, that the Lead Infection Prevention & Control Nurse was involved in the HAI-Scribe review.

Appendix F to the IA is called 'Service Change Proposal'. This document is titled in its header as 'Work Shop 2 - 26<sup>th</sup> June 2020 Potential Options Scoring Results'. This document captures the advantages and disadvantages for the various options considered in the IA. There has been no documented evidence provided of who attended this workshop as it is not stated in the appendix. On p57 of the IA item 3.4.1.1, it notes a list of attendees is included at Appendix F. This is missing and should be documented for completeness.

Based on the information provided for this review, there is a lack of documentary evidence on who contributed to and approved the clinical brief which is Appendix C of the IA. It is reported in the document '*NHS Assure submission Cancer Centre December 2021*', that the cancer service multidisciplinary team all contributed to its completion however this is not evidenced in the IA document. NHS Tayside have also reported that the clinical Lead provided inputs at weekly meetings as part of the project team. There is a lack of documented evidence provided for the review, to demonstrate these inputs including in relation to input into the clinical brief.

Based on the information provided for this review, it is clear there is a structured process in place to obtain clinical input to the patient cohort characteristics and typical needs. There is however a lack of documented evidence in relation to key document approvals. The IA notes in Table 4.7 (p87) that the IA was approved by NHS Tayside on 26/8/21, by service directors at Project Board on 15/6/21. This table also states that the Scottish Health Council have confirmed via attendance at the cancer care workshops in 2020 that they are content with the kind and level of engagement carried out to date and that it is in line with guidance. In the document '*NHS Assure submission Cancer Centre December 2021*' at item 3.4.1 Table 5, a different timetable of approval is set out, for example it notes NHS Tayside Board approval March 2022.

Given the passage of time since both documents were drafted it would be helpful to produce an update for the final version of the IA.

On p56 of IA, Table 3.2, it is noted that some stakeholders (patient/service users/staff/resources) commented on final version of IA by email and that comments were incorporated. No documented evidence of these comments have been provided for this review.

In the document ‘*NHS Assure Cancer Centre December 2021*’ NHS Tayside have provided evidence of the relevant service/clinical leads. Generally, we have no concerns in this respect, however there is a lack of evidence to demonstrate if NHS Tayside have the necessary internal expertise to develop a user requirements specification (URS) to form part of their BCRs for the ADU and to fulfil the role of managing the ADU validation process and the development of the associated documentation.

***Documents referenced are:***

*NHS Tayside – Cancer Centre – Initial Agreement 16.06.21 V2.0 – including appendices*

*NHS Assure submission Cancer Centre December 2021*

*Design Statement (Appendix K to the IA)*

*Clinical Brief (Appendix C to the IA)*

*Cancer Centre SHFN 30 Part B hai-scribe Form Word format of electronic version 1 19 January 2022*

<b>Workbook Ref No.</b>	<b>Areas to probe</b>	<b>Evidence expected</b>
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.	<p>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.</p> <p>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).</p> <p>Details available of proposed service model, understanding of what the patient journey will be through the service, and records of expected patient throughput levels.</p>

		<p>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.</p>
<p><b>NHS Scotland Assure Observations:</b></p> <p>NHS Tayside have demonstrated a good understanding of the needs of main users and the patient cohort and proposed accommodation. Evidence has been provided of engagement with relevant stakeholders including in respect of how user and patient needs will influence design. Technical stakeholder input has been limited at this stage of the project.</p> <p>NHS Tayside have provided, within the IA and the document '<i>NHS Assure submission Cancer Centre December 2021</i>', evidence of stakeholders and their roles and responsibilities. They have also set out the members of the Project Board and the Project Team, detailing their roles and responsibilities.</p> <p>An Equality Impact Assessment (EQIA) is provided at Appendix P to the IA and this identifies stakeholders and service users including the impact on the nine protected characteristics of diversity. There is no documented evidence provided for this review on who prepared the EQIA, when it was prepared, or if it was 'approved', other than as part of the IA approval process.</p> <p>NHS Tayside also advised in the document '<i>NHS Assure submission Cancer Centre December 2021</i>' section 3.2.1, that the NHS Tayside Patient Public Partners and Healthcare Improvement Scotland Community Engagement Team were involved in both the design and AEDET workshops and contributed to the development of the clinical model.</p> <p>There is no documented evidence provided for this review to validate NHS Tayside Patient Public Partners and Healthcare Improvement Scotland Community Engagement team attended the AEDET workshop on 20/11/20 as noted at sections 3.3 and 3.9 of the IA or contributed to the clinical brief.</p> <p>There has been no involvement yet of a design team, however during the IA stage of the project, NHS Tayside have advised two key workshops were facilitated to capture the current condition of the cancer centre units and the future requirements. These included:</p> <ol style="list-style-type: none"> <li>1. AEDET workshop, facilitated by Health Facilities Scotland, 29 October 2020</li> </ol> <p>NHS Tayside reported within the '<i>NHS Assure submission Cancer Centre December 2021</i>' documents that '<i>the purpose of this workshop was to support the stakeholders</i></p>		



*to work together to ensure they understood the facility/design proposals, understand the AEDET statements and facilitate a discussion to reach a wide consensus on the scores. All comments, notes and actions were recorded within a report and distributed to all attendees who had an opportunity to contribute to the final version.'*

The report produced detailing stakeholders involved has not been included as part of the evidence for this review, so it has not been possible to review. Final scores of the AEDET are included in the IA at Appendix J. NHS Tayside should document this information in the final IA for completeness

2. Design Statement, facilitated by Architectural and Design Scotland, 19 November 2020

NHS Tayside reported within the '*NHS Assure Submission Cancer Centre December 2021*' documents that '*the purpose of this workshop was to support NHS Tayside to describe a clear path between the business objectives for the cancer centre project and the necessary qualities of the building development to deliver on these. In addition, to check that the cancer centre project is on target to meet the national standards for healthcare design and sustainability. The stakeholders reviewed what the preferred clinical model was and then described the non-negotiable design attributes for patients, staff and visitors within the facility.*

*The attendance at the NDAP Design Statement is listed in the IA and includes all stakeholders including infection prevention and control.'*

The IA contains The Design Statement at Appendix K, however whilst a wide range of stakeholders attended this, it appears that none of the attendees are noted as being infection prevention and control specialists. Going forward, NHS Tayside should ensure this specialism is involved and that involvement is clearly documented.

A HAI-SCRIBE document has been provided by NHS Tayside dated 19/01/22. The stakeholders involved in the review have been documented and we consider that these are appropriate for this stage.

The HAI-SCRIBE review identifies a risk related to potential for insufficient microbiologist support. Mitigations are noted and NHS Tayside should action these going forward as noted.

The project team members for the development of this proposal are identified in Table 4.5 of the Initial Agreement document. The individual roles specific to the aseptic dispensing unit (ADU) are the Specialist Clinical Pharmacist and Lead Pharmacist for ADU.

However, it is noted in various locations within the Initial Agreement document that the ADU is part of the NHS Scotland Shared Services programme. Appendix Q – Stakeholder Engagement and Communication Plan, does not identify anyone within NHS Scotland Shared Services as part of the external engagement. NHS Tayside

should clarify if any external stakeholder engagement with NHS Shared Services is required.

The IA document, including Item 34 of the project risk register (Appendix I within the IA), identifies the risk of the electrical infrastructure needing to be in place to support this project. Item 2.6.3 also notes there are physical infrastructure constraints and a need for co-ordination with this project.

NHS Tayside should ensure that dialogue with the estates team, Authorising Engineers, specialist designers and the relevant project teams associated with any ongoing utilities infrastructure works is undertaken at the earliest opportunity to clearly identify known limitations, restrictions or abnormalities & their associated capacities e.g. water, HV/LV, medical gases etc. that may impact on the proposed development.

Item 33 of the project risk register, (Appendix I within the IA), identifies the risk associated with concurrent projects on the Ninewells site and the associated interdependencies, however there is no reference to any overall master programme for the site.

Whilst there is some evidence indicating an overall strategic assessment of patient requirements at Board level, there is no indication of specific resilience measures required at project level, e.g. plant redundancy, operations etc. for a cancer care unit environment.

In the document '*NHS Assure Submission Cancer Centre December 2021*', NHS Tayside have advised:

*'Demand forecasting over the next 10 years was completed by a healthcare planner and is included within the IA (Appendix D – capacity planning report). This data has been used to determine capacity for inpatients beds, radiotherapy, SACT and aseptic dispensary unit. This information was then used to complete the schedule of accommodation (Appendix E in the IA), for a co-located unit.'*

A clinical brief is provided at Appendix C of the IA however this is a high-level document with limited technical details. A fully detailed project brief should be developed during the next stage of the project.

There is no documented evidence provided for this review that demonstrates the capacity planning report has been formally approved other than as part of the IA. The report contains various assumptions in relation to the capacity planning model for future requirements, in addition to projected growth activity and notes on p14 that '*at the time of writing this report no feedback or request for amendment/ratification of assumptions has been received.*'

It is recognised that the project is at IA and the report highlights the need to further review and test the data and assumptions at OBC stage, not least to consider any

impacts from COVID-19. This will be a key activity for NHS Tayside during the next stage.

In the document '*NHS Assure Submission Cancer Centre December 2021*' NHS Tayside advise:

*'All stakeholders influenced the Design Statement brief. Cancer Treatment Facilities Health Briefing Note 02-01, October 2014, sets out the current standards for cancer centre facilities and was used to determine the schedule of accommodation. The project team commented on the Capacity planning report and schedule of accommodation.'*

There is no documented evidence provided for this review as to how the capacity planning report was translated into the schedule of accommodation. A schedule of accommodation is provided in summary form at Appendix E of the IA. It is unclear who carried out this exercise or how it was approved, other than as part of the IA. The IA does state it was prepared with reference to all current technical guidance including SHTMs and HBNs (item 3.5, p68 of IA). Within the schedule of accommodation, the areas noted for communication and plant space appear to be based on a standard assumption of 15% of the gross internal floor areas noted. There is no evidence to demonstrate if NHS Tayside have considered any requirements for greater communication and plant space to meet the functional requirements of the facility – for example dedicated ventilation systems for certain clinical spaces, etc.

Appendix N (Construction Cost Estimate) within the IA notes in relation to Sustainability Uplift - Net Zero Carbon: *'details not available therefore cost uplift percentage included at 12% which is in line with SFT funding for schools programme'*. It is unclear whether this uplift has been benchmarked against current NHS Scotland sustainability and net zero carbon targets.

***Documents referenced are:***

*NHS Tayside – Cancer Centre – Initial Agreement 16.06.21 V2.0 – including appendices*

*NHS Assure Submission Cancer Centre December 2021*

*Design Statement (Appendix K to the IA)*

*EQIA (Appendix P to the IA)*

*Clinical Brief June 2020 (Appendix C to the IA)*

*Capacity Planning Report Vs 5.0 (Appendix D to the IA)*

*Schedule of Accommodation (Appendix E to the IA)*

*Construction Cost Estimate (Appendix N to the IA)*

*Cancer Centre SHFN 30 Part B hai-scribe Form Word format of electronic version 1  
19 January 2022*

Workbook Ref No.	Areas to probe	Evidence expected
1.3	What is the Heath Board's formal process for derogations'?	<p>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).</p> <p>List of any proposed derogations from NHS or other guidance and / or list of known gaps in guidance that will need to be resolved in order to meet the needs of the patient / user cohort.</p> <p>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.</p>

#### NHS Scotland Assure Observations:

NHS Tayside have largely identified the technical standards to be achieved on the new cancer centre, as well as their approach and process for managing derogations. Further detail will be required to fully develop these requirements through the OBC stage including in relation to sustainability. NHS Tayside have identified and set out a process including relevant individuals for input to the infection and prevention control and microbiology aspects of the brief/design. They have also identified resource challenges in this regard and confirmed their intention to mitigate associated risks.

Within the document 'NHS Assure Submission Cancer Centre December 2021', Section 3.3.1 Table 4 there is a list of NHS and non NHS guidance that is applicable to the project.

In some instances, the date of the noted guidance referenced is not the most current revision. There are also some other documents that are not listed that NHS Assure believe would be relevant to this project such as the SHTM fire codes (SHTM 81, 83) and other guidance relevant to this project (e.g. HBN 02-01 cancer treatment facilities, HBN 06 Vol 2 diagnostic imaging, HBN 14-01 medicines management: pharmacy and radio pharmacy facilities)

No evidence has been provided for this review that a BCR document is available at this stage.

Within the document '*NHS Assure Submission Cancer Centre December 2021*', Section 3.3.1 notes 'Net Zero Carbon 2045 requirements will be considered by the

Project Team through the business case process'. The project risk register (Item 29 of Appendix I within the IA also highlights the risk of failing to meet 'carbon/green targets'. However, the documentation provides no further detail on the net zero requirements and any other project sustainability goals/aspirations. It is noted the project cost plan includes an uplift for sustainability 'in line with SFT funding for schools'. NHS Scotland Assure recommend this is reviewed against NHS Scotland Sustainability targets.

Within the design statement at Appendix K of the IA, section 4.3 addresses sustainability, recognises obligations/requirements and objectives but does not quantify NZC targets at this stage.

Item 28 of the project risk register (Appendix I within the IA) identifies the risk of emerging guidance associated with the Covid-19 pandemic and the potential impact on the project and the need to capture emerging guidance within project requirements

Within the document '*NHS Assure Submission Cancer Centre December 2021*', NHS Tayside have advised:

*'NHS Tayside endeavour to have no derogations from relevant standards/guidance however all derogations will be recorded on a Derogation Schedule. In addition, it is proposed a separate 2-sided sign off sheet will be required to document any derogations, with an assessment of the level of risk for sign off by the Project Board.'*

*Once a site has been chosen and a design team appointed, a robust review of all SHTM will be undertaken to understand if there are any gaps in guidance that require clarification. Designers will be asked to provide a list of any derogations from standards for review. This will be discussed at regular technical / design team meetings.'*

NHS Tayside have also provided three documents they intend to use to record/process the creation of any derogations. These documents are listed below.

The above response demonstrates a recognition that derogations need to be addressed early in the design process and provides some evidence of the process for approvals including relevant stakeholders.

Within the document '*NHS Assure Submission Cancer Centre December 2021*' (section 3.3.3), NHS Tayside have advised that IPC input is provided by the Decontamination Clinical Lead and Building Lead for Infection Prevention and Control (IPC). This role is defined as including medical device decontamination; infection prevention and control in the built environment; water management and testing; and ventilation in healthcare facilities.

NHS Tayside also identify the Lead Infection Prevention & Control Nurse as the IPC nominated deputy.

It is noted that whilst IPC input will be provided by these individuals, they are not represented on the Project Team or Project Board

It is noted in the 'NHS Assure Submission Cancer Centre December 2021' document that the IPC team will provide appropriate IPC nursing support and the support of the Decontamination Clinical Lead and Building Lead for Infection Prevention and Control throughout the project where applicable and where the available resource permits. It is highlighted (in item 3.3.3), that this may be challenging at times due to competing projects and other work priorities, as well as the current skills and competencies within the IPC team, i.e. only one person in the team currently has the relevant skills and competencies and represents a potential single point of failure.

It is also noted that currently NHS Tayside do not have a resource for dedicated support from microbiology colleagues and a post to mitigate this risk is currently being advertised.

**Documents referenced are:**

*NHS Tayside – Cancer Centre – Initial Agreement 16.06.21v2.0 – including appendices*  
*NHS Assure Submission Cancer Centre December 2021*  
*Design Statement (Appendix K to the IA)*  
*Appendix 1 – NHST Derogation Process V1.6dr*  
*Appendix 3 – NHST Derogation Form 1.10 DRAFT*  
*Appendix 4 – Derogation Schedule Draft – v1.3*

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.	<p>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.</p> <p>Gap analysis on expertise required specifically for the project and details of how gaps in expertise are to be filled.</p> <p>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.</p>

		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.
<p><b>NHS Scotland Assure Observations:</b></p> <p>NHS Tayside have set out within the IA the approach for managing the design process to ensure compliance with agreed and approved standards. However, this is lacking in detail which should be captured within a comprehensive project execution plan for the OBC stage.</p> <p>The Initial Agreement sets out the proposed governance arrangements in section 4.3 The management case. This is supplemented by additional information provided by NHS Tayside titled '<i>NHS Assure Submission Cancer Centre December 2021</i>'</p> <p>The governance structure reflects current arrangements. Whilst much of this is likely to remain in place, NHS Tayside should consider updating this to reflect the structure, organisations, individuals and specific responsibilities involved, moving forward into the next stage. We would recommend that this is captured in a detailed project execution plan. NHS Tayside have advised their intention to prepare a PEP prior to commencing the OBC.</p> <p>At section 4.1.2 of the IA an implementation timetable is set out for the project. It is also stated in this section that an outline programme is enclosed at Appendix O, however this has not been provided with the documents submitted for review. The timescales stated have informed the costs set out within the IA. NHS Tayside note within the IA that the programme will be subject to detailed development once the PSCP is appointed.</p> <p>No evidence has been provided, for this review, of a resource plan being in place for the next stage, however NHS Tayside have advised within the '<i>NHS Assure Submission Cancer Centre December 2021</i>' document that this will be developed for the OBC stage and will be shared with the Project Sponsor and approved by the Project Board to ensure resources are aligned to the project accordingly.</p> <p>NHS Tayside have identified resource challenges specifically in respect of infection prevention and control (IPC) and microbiology support.</p> <p>In the '<i>NHS Assure Submission Cancer Centre December 2021</i>' document (section 3.4.2), HNS Tayside have highlighted various roles that will have to be appointed for the OBC stage. They have also advised that an independent verifier will be employed to provide an independent review of mechanical, electrical and plumbing services as the project progresses. Whilst some of the key consultant input is noted, a project of this size and complexity will typically require other specialist consultant input such as:</p>		

access consultant, fire engineer, landscape architect, medical planner, acoustician, etc. It is not clear from the evidence provided as to whether NHS Tayside have considered these roles.

With regard to the aseptic dispensing unit (ADU), the documentation provided by NHS Tayside, does not set out any roles specifically in relation to the ADU whose responsibilities would include the development of a user requirements specification (URS) for the facility, or in managing the ADU validation process through the various design, installation, operational and performance qualification stages (design qualification, installation qualification, operational qualification, performance qualification).

The stakeholder and engagement communication plan within appendix Q of the Initial Agreement document, notes a key contact for NHS Tayside estates. However, there is no further detail around a planned approach & strategy for more specific individual/collective stakeholder engagement within the NHS Tayside estates team. For example, interfaces with NHS Tayside's local safety groups (e.g. water, electrical, medical gases etc) and identification of other key consultees & stakeholders such as the relevant Authorising Engineers (AE) and Authorised Persons (AP) across the NHS Tayside estate.

The detail of how compliance with appropriate guidance, design brief and other standards will be agreed, signed off, monitored, reported against, etc., through design, construction and commissioning stages, are addressed in various sections of the IA, for example in section 4.3.3.3, it is noted the Project Board is accountable, amongst other matters, for agreeing the scope, developing and agreeing project documentation and outputs, agreeing specifications and quality expectations, etc. Further information on governance has been provided in the document titled '*NHS Assure Submission Cancer Centre December 2021*'. The information provided has limited detail and would benefit from further development to set out in detail how standards will be agreed, signed off, monitored, reported against, through the various stages. NHS Tayside should consider how best to document this, such as within the project execution plan (PEP) that they propose to develop before the OBC stage commences.

In their submission '*NHS Assure Submission Cancer Centre December 2021*', NHS Tayside set out proposals to manage change including working with the independent verifier and design team. The proposed process, and forms are linked to the NEC contract process and appear appropriate. There is no evidence of a specific IPC step in the change request map or change forms.

In the document '*NHS Assure Submission Cancer Centre December 2021*', NHS Tayside have advised '*The interests of the wider stakeholder groups will be agreed, signed off, monitored, and reported against through the NDAP process e.g., AEDET and Design Statement at each Business Case stage and into construction and occupancy stages.*'



*All stakeholder comments at the IA AEDET meeting are fully documented within the Critical Care AEDET IA Benchmark and Target report. (Appendix 2).*

*Clinical and non-clinical stakeholders have representatives on the project team and the project board, which ensures that their interests will continue to be monitored as the project develops and decisions are taken. The clinical reference group will also continue to meet as the project progresses, and again this will ensure that the interests of staff and patients are considered throughout the design, construction, and commissioning stages.'*

It is noted the 'NHST Cancer Care AEDET IA Benchmark and Target v3 11.01.21', is included in Appendix J of the Initial Agreement. However, the document referred to above as 'Appendix 2' was not submitted as evidence for this KSAR. The document in the IA contains the scoring and has details on stakeholder comments but does not have detail of attendees at the meeting.

The IA contains some details on the stakeholder engagement process which is supplemented by the document 'NHS Assure Submission Cancer Centre December 2021' from NHS Tayside. The information provided has limited detail and would benefit from further development to set out in detail how the stakeholders interests will be agreed, signed off, monitored, reported against, through the various stages. NHS Tayside should consider how best to document this, such as within the project execution plan.

**Documents referenced are:**

*NHS Tayside – Cancer Centre – Initial Agreement 16.06.21v2.0 – including appendices  
NHS Assure Submission Cancer Centre December 2021  
Change Request Map 23092021 V6.2  
Change Request Form 16092021 V1.1  
Clinical Change Form 16092021 V1.0  
NHST Cancer Care AEDET IA Benchmark and Target v3 11.01.21*

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.	<p>Initial plans on how this requirement will be managed and how it fits with the project governance arrangements.</p> <p>Initial plans to identify any gaps in the procurement approach that may require to be addressed.</p> <p>Initial plans to indicate that the Health Boards selected procurement route will go through the Health Board's Governance channels.</p>

		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.
<p><b>NHS Scotland Assure Observations:</b></p> <p>NHS Tayside have provided evidence describing the conceptual approach on the procurement journey including setting out how the Board will provide assurance. However, there are some areas that would benefit from more detail as noted, including how the Board will utilise IPC and technical specialists in the procurement process.</p> <p>The details of the procurement arrangements are set out in the commercial case of the Initial Agreement and have been amplified within the ‘<i>NHS Assure Submission Cancer Centre December 2021</i>’ document produced by NHS Tayside for this KSAR.</p> <p>NHS Tayside have confirmed the procurement arrangements ‘<i>will be presented to a number of internal governance committees for approval before it is submitted to Capital Investment Group (CIG). NHS Tayside will be calling off from the HFS FS3 procurement process a Lead Adviser and Principal Supply Chain Partners (PSCP). This will be a New Engineering Contract (NEC) standard form of design and build contract. This process will be developed further in the OBC including evaluation criteria. An “Advanced Information Day” will be held with PSCP to allow them to familiarise themselves with the project. A Lead Adviser will also support and manage all contractual management obligations that are required through this process.</i></p> <p>These ‘committees’ are set out in other parts of the information provided by NHS Tayside. The procurement route has previously been employed by NHS Tayside and will be supported by HFS who provide overall management and support of the frameworks being used.</p> <p>In the ‘<i>NHS Assure Submission Cancer Centre December 2021</i>’ document, NHS Tayside have noted that any gaps in the procurement approach will be addressed as the project progresses and that the Project Team has a senior member of procurement in attendance at meetings. The detail of how and when this will be done, has not been provided other than to note elements will be post IA approval. It also sets out the approach to appoint the PSCP (who also provides the design team) and the lead advisor who provides NEC Project Manager, cost advisor and typically technical support including the NEC supervisor role.</p> <p>Table 7 of the ‘<i>NHS Assure Submission Cancer Centre December 2021</i>’ document (Section 3.4.2) identifies the need for the PSCP to appoint a design team from OBC onwards. Whilst some of the key consultant input is noted such as architect, M&amp;E engineer, structural engineer there may be other specialist consultant input required. NHS Tayside should identify any other specialist consultant input that they will require the PSCP to provide eg. access consultant, fire engineer, landscape architect, medical planner, acoustician etc.</p>		

NHS Tayside have not clearly 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. NHS Tayside do note in section 3.5.4 of the document '*NHS Assure Submission Cancer Centre December 2021*', that IPC representatives should have sight of IPC critical works for comment and have the opportunity to raise any concerns throughout the life of the project.

The IA Document confirms the requirement for a variety of medical equipment associated with the project to deliver the clinical model for the facility (e.g. LINACs, MRI scanner, negative pressure isolators). This equipment will have a significant impact on the planning and design of a new facility. Whilst NHS Tayside do advise that all current technical guidance was used to inform the schedule of accommodation (SoA), there is no evidence on how the required equipment was factored into the SoA. Item 38 of the project risk register (Appendix I within the IA) identifies the process of procuring this equipment and the associated lead time as a project risk.

It is also noted that the radiotherapy equipment is funded by the Scottish Government as part of a national rolling programme for renewal of equipment, however there is no specific methodology providing clarity on how the procurement of medical equipment will interface with PSCP works, e.g. demarcation of design responsibilities, development of basis of design, procurement impact on design assumptions.

It is noted that the Project Team does contain a 'Procurement Team Leader – Equipment' whose role is described as providing advice with equipment procurement.

The details of the procurement arrangements are set out in the commercial case of the IA. NHS Tayside have confirmed that the IA is presented to a number of internal governance committees for approval before it is submitted to Capital Investment Group (CIG). Details of the relevant committees have been set out by NHS Tayside in the document '*NHS Assure submission Cancer Centre December 2021*' in Table 5 although the table needs to be updated to reflect dates and status of approvals

NHS Tayside have also confirmed that Frameworks Scotland has been used successfully by them for several years and that there is a clear organisational understanding of the process for appointment of the principal supply chain partner. Due to the potential scale, value and complexity of the project, NHS Scotland Assure recommend that engagement with the Framework Scotland team is commenced to ensure appropriate development of briefing and procurement documents.

NHS Tayside have carried out a development stage 1 HAI Scribe review as part of the IA process.

Within the KSAR response, NHS Tayside have noted that their IPC representative will have knowledge of the built environment and be consulted fully on matters relating to the project, including water and ventilation strategies. Whilst this strategy indicates

NHS Tayside have considered required competencies of individuals to be involved, it is not clear how this will be formally interfaced into the project governance controls.

**Documents referenced are:**

*NHS Tayside – Cancer Centre – Initial Agreement 16.06.21 v2.0 – including appendices  
NHS Assure Submission Cancer Centre December 2021*

*Cancer Centre SHFN 30 Part B HAI-SCRIBE Form Word format of electronic version  
19 January 2022*

### 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 during the appraisal.

<p><b>3.1.2.1</b></p>	<p><b><u>Aseptic Dispensing Unit - Licensing</u></b></p> <p>The documentation provided does not confirm if the aseptic dispensing unit is a licensed facility or if there will be a Section 10 exemption from the Medicines Act 1968.</p>
<p><b>3.1.2.2</b></p>	<p><b><u>Aseptic Dispensing Services Risk Item</u></b></p> <p>Item 11 of the project risk register (Appendix I within 'NHS Tayside - Cancer Centre - Initial Agreement 16.06.21') notes 'Aseptic Dispensing Services - Text Required'. There is no further commentary to define the risk description and mitigation associated with this identified risk.</p>

## 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](#)

