Scottish Hospitals Inquiry
Witness Statement of
Thomas Rodger

Qualifications and Professional Background

1. I am Thomas Rodger. I currently hold the post of Head of Engineering at NHS Scotland Assure at National Services Scotland (NSS), which I have held since September 2022.

2. I joined NHS Scotland Assure in April 2021. I initially joined as Principal Engineering Manager. I was subsequently promoted to Head of Engineering in September 2022. I joined NHS Scotland Assure ahead of the formal launch of the NHS Scotland Assure service, which went live on 1 June 2021. Since then, I have been effectively leading the day-to-day delivery of the Key Stage Assurance Review (KSAR) process, the development of the KSAR workbooks, and helping with the wider rollout of the NHS Scotland Assure service.

3. I graduated from Heriot-Watt University in 2006 with a Master's degree with distinction in Electrical and Electronic Engineering. Following graduation, I joined the private sector and began working for a company called Faber Maunsell (later bought by an American company and rebranded as AECOM). I started as a Graduate Engineer, ultimately progressing to the position of Associate Director. I led the mechanical and electrical engineering team within their Glasgow office and was the healthcare technical lead for Scotland, feeding into the wider AECOM UK Healthcare Centre of Technical Excellence.

4. I am a Chartered Engineer and a member of the Chartered Institute of Building Services Engineers (CIBSE). I am a member of the Institute of Engineering and Technology (IET), and a Fellow of the Institute of Healthcare Engineers and Estate Management (IHEEM).

Through my role with the IET, I also sit on the National Technical Committee for the production of BS7671, commonly known as “The Wiring Regulations”, which is referred to as JPEL/64. I have over seventeen years’ experience in the health sector.

5. Over the course of my career, I have experienced a wide range of healthcare projects, both in the UK and internationally, as a senior person with responsibility for delivery of designs, provision of technical advisory services and providing subject matter advice. Whilst I qualified as an electrical engineer, I have also managed multidisciplinary engineering projects. I have a working knowledge of other technical disciplines including mechanical engineering and public health. I have been the lead designer on multiple technical design projects. Those roles involved overseeing team resources to deliver projects, coordinating technical teams, and overseeing quality assurance processes.

6. Within Scotland, I have designed various projects. During the COVID pandemic, I was the lead designer on the temporary field hospital “NHS Louisa Jordan” at the Scottish Exhibition & Conference Centre in Glasgow. That role was undertaken whilst working for AECOM on behalf of NSS. During the project, I was lead engineer on site, coordinating all the engineering design activities including design of the electrical systems, and reporting back to NSS on the progress and the processes involved. I also supported NSS as a technical advisor, overseeing the delivery of the COVID laboratory facilities in NHS Grampian, NHS Lothian, and NHS Greater Glasgow and Clyde (NHS GGC).

7. I have acted as an accredited NEC (New Engineering Contract) Supervisor and Technical Advisor to various Health Boards on projects of all different sizes. Those projects include the Golden Jubilee Hospital National Treatment Centre Phase 1, during which I was responsible for monitoring the engineering components of the construction projects on behalf of the Health Board, reviewing the works to ensure they were progressing in accordance with the relevant standards, highlighting any technical problems & defects and providing technical advice to the Boards.

8. I have also worked on other projects within the UK and overseas. I designed the electrical systems for large hospitals in Bermuda and Abu Dhabi.

Current Role

9. My current role is Head of Engineering within NHS Scotland Assure. I oversee a team of fourteen people (correct as of December 2023), ranging from Senior Engineers to Principal Engineering Managers. I have direct line management responsibility for the Principal Engineering Managers, who, in turn, manage the Senior Engineers. The Engineering & Assurance Team is responsible for the delivery of the Key Stage Assurance Reviews (KSAR) as well as the work on the production of guidance and technical standards and the provision of other subject matter technical advice to Health Boards. In my capacity as Head of Engineering, I am ultimately responsible for assigning a "supported" or "unsupported" status to any KSAR undertaken. I maintain an overview of all ongoing KSAR projects so that I am informed should any significant findings be identified during the review phase of a KSAR. Typically each KSAR project is led by one of the Principal Engineering Managers or Senior Engineers.

10. I report to the Assistant Director for Engineering and Assurance, who is currently Ian Storrar. He reports to Julie Critchley, who is the Director for NHS Scotland Assure. Julie Critchley reports to Mary Morgan who is the Chief Executive of NHS Scotland Assure. If Ian Storrar is absent, I report directly to Julie Critchley.

Role and Remit of NHS Scotland Assure

11. NHS Scotland Assure was commissioned as a result of various developing issues within the healthcare-built environment in Scotland **(A43494369 - Letter dated 27 May 2021 from Richard McCallum, Director of Health Finance and Governance to NHS Board Chief Executives and others – Bundle 9 – Page 70)**.

The service was developed in conjunction with Health Boards across Scotland and other key stakeholders, including the Scottish Government. The vision of the service was set up following an initial consultation phase with the Health Boards. I was not involved during the consultation phase.

12. The aforementioned letter notes

"*NHS Scotland Assure has been co-designed with users 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 our 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. NHS Scotland Assure, via NSS, is accountable to the Scottish Government, and will provide assurance that the Healthcare Built Environment is safe, fit for purpose, cost effective and capable of delivering sustainable services over the long term. Its relationship with the Scottish Government will be with both the Health Finance, Corporate Governance and Value Directorate and the Chief Nursing Officer's Directorate."*

Note that the reference to sustainability is not necessarily linked to net-zero, although that is important. Rather it refers to the need for the healthcare built environment to not only function at day one but to continue to function over the lifecycle of a building.

13. It is the intention that NHS Scotland Assure, through its functions, be there for all Health Boards where healthcare is delivered. Its role does not extend to private healthcare providers.

14. I have been asked what other services NHS Scotland Assure provides out with my team. There are eight core services outlined in the initial NHS Scotland Assure Target Operating Model (TOM) **(A32341688 - Target Operating Model for the Centre of Excellence – Bundle 9 – Page 4)**.

15. They are knowledge management and communication, guidance, provision and coordination of subject matter expertise, research development and innovation, intelligence, the response service, compliance (which we would recognise as the “Assurance,” service) and workforce planning and development. My team predominantly supports the provision of the Assurance service and subject matter expertise, but also supports other areas of NHS Scotland Assure.

16. An example of how my team support other NHS Scotland Assure services includes provision of Subject Matter Expert (SME) support to the research service. NHS Scotland Assure has a managed research fund in conjunction with Napier University. My team support the wider NHS Scotland Assure research team in the assessment of research applications by providing technical SME advice. We work very closely with the research team to identify potential areas for forthcoming research. Similarly, on matters such as workforce planning, we liaise with Health Board colleagues through forums such as the Scottish Engineering & Technology Advisory Group (SETAG) and the National Advisory Groups (NAGs’) (these include, but are not limited to, the National Electrical Advisory Group (NEAG) and the National Water Safety Advisory Group (NWSAG)). Collaboration with other stakeholders and service lines very much depends on what the operational priorities are, which are reviewed regularly.

Assurance Team Structure & KSAR

17. The NHS Scotland Assure Assurance Team (which is part of the Engineering & Assurance division of NHS Scotland Assure) comprises built environment professionals from various backgrounds including infection prevention & control, fire safety, design, construction and operational healthcare estates. The members of the Assurance Team noted above are responsible for undertaking the KSAR “reviews” – I have referred to them as the “KSAR team” within my statement. We want to ensure that the team that assesses a project has the relevant competence and experience to assess what is being provided. That is a critical function of what we do.

As Head of Engineering, I am responsible for the day-to-day delivery of the Assurance service within NHS Scotland Assure. The team undertaking the KSAR will consist of multiple professional people within the organisation.

18. The Assurance Team includes colleagues from the Antimicrobial Resistance & Healthcare Associated Infection (ARHAI) team, which is also part of NHS Scotland Assure. They are specialists in infection prevention control within the healthcare built environment and include healthcare microbiologists. We further have fire safety colleagues who are part of the team. It is all these people that deliver the service together. The Assurance service team is truly multidisciplinary in that sense.

19. I have been asked by the Inquiry who is responsible for the overall management of the multi-disciplinary team across all the different disciplines. In terms of the overall NHS Scotland Assure structure they report to Julie Critchley and Mary Morgan. Below them there would be the service leads within the respective departments. The engineers, for example, would report to me, whereas ARHAI and fire safety colleagues have their own line management structure. Each discipline has their own management structure. We work on a matrix management approach, which is essentially task management in terms of delivery on the KSAR process. When it comes to the delivery of a KSAR, one of my team manages the KSAR processes. For the purposes of the review phase, and writing a KSAR report, the team would feed into either myself or to one of my team, because the primary authors on those reports would be coming from my team.

Role of Authorised Persons

20. There are people within my team who had previously fulfilled the role of an “Authorised Person” for Health Boards prior to joining NHS Scotland Assure. However, we do not offer an “Authorised Person” service within the operating model of NHS Scotland Assure. NHS Scotland Assure does provide Authorising Engineer services, for which there is a prerequisite requirement for individuals undertaking that role to have completed Authorised Person training.

21. Note that a health board is not mandated to utilise NHS Scotland Assure for Authorising Engineer services – they are free to utilise the services of other independent third parties should they wish to do so.

22. Scottish Health Technical Memorandum (SHTM) 00 **(A33662233 - Scottish Health Technical Memorandum 00, Best Practice Guidance for Healthcare Engineering, Policies and Principles dated February 2013 – Bundle 13, Volume 3, Page 325)** provides an overview of the role of both an Authorised Person and an Authorising Engineer. SHTM 00 notes that the authorised person has the key operational responsibility for the specialist service and that specialist service would be covered under the respective SHTM (for example SHTM 03-01 is for ventilation, SHTM 04-01 is for water and SHTM 06-01 is for electrical services). The Authorised Person should be qualified and sufficiently experienced and skilled to fully operate the specialist service. The Authorised Person is typically nominated by the Authorising Engineer. That person will have attended appropriate levels of professional training courses in order to do that. They will have a certain level of experience relative to the systems that they maintain and will be able to evidence their knowledge and skills.

Purpose of the Key Stage Assurance Review (KSAR) Process

23. The KSAR process falls under the Assurance service part of NHS Scotland Assure. The Assurance service looks to assess compliance with guidance. It supports Health Boards in demonstrating compliance at key stages within the full life cycle of a healthcare-build. That is from the initial procurement and design stage right through to construction, commissioning, and the ultimate handover of the facility. Currently, NHS Scotland Assure does not undertake a KSAR in the operational stages of a building. There is currently no scope agreed with the Scottish Government for that. That may be something that comes in the future. If it happens, that would be something that would need to be developed in conjunction with Health Board stakeholders (in a similar way to how the initial NHS Scotland Assure service was set up).

A building must be compliant, and functional, not just on day one but on day ten, day one hundred and day one thousand. It is a challenge in the healthcare-built environment to achieve that.

24. The purpose of the Assurance service, provided through the KSARs, is to support Health Boards to increase patient safety and public confidence and to reduce the costs associated with incidents and retrofits. It is about being proactive rather than reactive. We are promoting a culture of getting things right first-time round, to reduce avoidable delays in build timescales and to tackle emerging issues early on. It can be the nature of construction that problems are not clear until the end, for example during the commissioning and validation, if for example, defective components were identified. The KSAR workbooks have been designed to cover key milestone stages of a project and by seeking assurance from health boards from an early stage in their project journey, it reduces the potential for problems to go undetected.

25. The ultimate legal responsibility and project liability, in terms of the accuracy of the design information and calculations, is retained solely by the Health Board and its Project Team. The KSAR process does not change this.

26. During a KSAR, the NHS Scotland Assure KSAR team will assess the information provided by the Health Board and make an assessment on whether it provides assurance or not – for example whether the design is developed to an appropriate level reflective of the current stage of the project. If no assurance is provided the project would be noted as 'unsupported.' If it does provide assurance, then the project would be noted as 'supported.' However, NHS Scotland Assure's ultimate decision on whether a project is 'supported' or 'unsupported' does not happen until the end of the KSAR review period. After making our decision, the status is notified to the Senior Responsible Officer (SRO), the Health Board Project Director and the Health Board Project Manager in writing and noted within the KSAR report. We would also notify the Scottish Capital Investment Group (SCIG) in writing. SCIG are also provided with a copy of the final KSAR report.

27. During the design stages of a project (typically covered by the Initial Agreement (IA), Outline Business Case (OBC) & Full Business Case (FBC) KSAR workbooks), the SCIG has intimated that if a project is unsupported, the project will not be approved by it to progress to the next stage until it is supported (e.g. it would not be allowed to move from OBC to FBC or from FBC into Construction). In such instances the Health Board will be expected to prepare an action plan to address the findings of the KSAR and subsequently demonstrate resolution of the significant findings. Once such assurance has been provided to NHS Scotland Assure, we will then notify SCIG and the Health Board that the project is supported.

28. We are still working through that mechanism for projects that are in the construction cycle. We recognise that you cannot suddenly just say “stop” in a build, as in certain instances that could introduce more risk. If a project is unsupported at Construction stage, we will work collaboratively with the Health Board and SCIG to identify an appropriate course of action. Central to this will be the Health Board action plan and the onus will remain with it to evidence resolution of the significant findings that led to an unsupported status being allocated.

29. A directorate letter (DL (2023) 03) was published in February 2023 **(A43494372 – Letter Dated 6 February 2023 from Alan Morrison, Deputy Director of Health Infrastructure, Investment and PPE to NHS Board Chief Executives and others – Bundle 9 – Page 75)** which notes that if a project is not supported at the Handover stage, the Scottish Government’s recommendation is that the building does not open. Any such decision, were it to be taken, would be enforced by the Scottish Government rather than by NHS Scotland Assure. We have not yet encountered this scenario in a KSAR project.

30. NHS Scotland Assure’s scope was originally intended to be for new builds and major refurbishments within the acute estate. The service was designed for the bigger builds because they typically would be the most complex builds.

31. It became clear following discussions with SCIG, that they were concerned that there would be other projects that may have be of a significant value out with the acute estate that may benefit from the KSAR process.

32. SCIG was looking to achieve an appropriate level of assurance within those projects, prior to them being allowed to progress. Because of that, the scope of the service provided by NHS Scotland Assure has changed. There are quite a lot of projects that now go through SCIG which require a KSAR. One example would be the Northeast Health Hub (often known as the Parkhead Health Centre). It is currently the largest primary care centre in Scotland and has a construction value of approximately £60 million value. The Scottish Government took the view that it was a significant investment within the healthcare estate and asked if there was the relevant level of assurance. That resulted in a KSAR being undertaken for the project. Generally, in order to establish whether a project requires use of the KSAR process, NHS Scotland Assure would discuss and agree this with SCIG.

KSAR Stages

33. The 'Project Procurement Journey and KSAR Process Interface document' or 'tube map,' as it is more informally known, can be found at **(A43406829 - Project Procurement Journey and KSAR Process Interface Diagram – Bundle 9 – Page 90)**. The tube map shows that the KSAR process is a continual journey. This document shows some of the key interfaces that we would have with a Health Board. The "tube map" indicates that a KSAR is undertaken during the following stages of a healthcare build project: Initial Agreement, Outline Business Case, Final Business Case, Construction Stage, Commissioning Stage and at the Handover Stage. The full life cycle of a build is important because a decision made on day one could have an impact on how that building is run in ten, fifteen or twenty years' time.

34. I would note that an Initial Agreement KSAR is no longer undertaken. This was a decision taken in conjunction with Scottish Government as a result of similar findings being identified on each of the IA KSARs undertaken to that point.

35. It has been superseded by a ‘lessons learned phase’ where we have a workshop with Health Board stakeholders. The presentation affords a Health Board an opportunity to learn and helps it to establish a solid foundation for the future stages of the project to build upon. The change was all about making sure that time was spent in an optimal manner to get to a successful outcome for the project.

36. Where projects are not mandated to undertake a KSAR, Health Boards are advised they can still use the KSAR workbooks as a tool to support the development of their project. In such instances these would generally not be assessed by NHS Scotland Assure. All KSAR workbooks are available on the NHS Scotland Assure website. This may be applicable for example to a smaller project, under a Health Board’s delegated authority, which may not require to be approved by SCIG.

37. It is important to note that a KSAR also looks to identify any positive lessons learned from a project. We have also found that there is a lot of good work that Health Boards do through the course of a project that they do not formally record. That has been a key theme that we have been trying to get Health Boards to address through the KSAR process. Maintaining a documented “golden thread” through a project is important. The Building Regulations Advisory Committee (BRAC) define the golden thread as:-

    “*The golden thread is both the information that allows you to understand a building and the steps needed to keep both the building and people safe, now and in the future”.*

38. The initial scope of the KSAR process was developed in conjunction with the Scottish Government and key stakeholder groups. Some of that stage predates my time with NHS Scotland Assure. I am aware that there was a consensus group that was set up to look at the formation of the KSAR workbooks. The initial core topics were water and drainage, ventilation, electrical, medical gas, and fire safety.

39. Obviously, in a healthcare environment infection prevention and control (IPC) must be considered at all levels. When I present on KSARs, I highlight that IPC, and patient safety, is at the heart of everything we do. We have a dedicated section for IPC in each KSAR. IPC is also considered currently within the governance section of the KSAR workbooks. Governance, as it relates to these topics, is not about procurement or contractual governance. That is not within the scope of the KSAR and does not sit within the Assurance Service area of expertise.

40. I have been asked by the Inquiry why, when KSARs were being developed, there was a focus on the topics of water and drainage, ventilation, electrical, medical gas, and fire safety, and whether the issues at Glasgow and Edinburgh had any influence on that focus. I was not party to the actual development of the workbooks, so I cannot comment as to what went on at that time. I cannot talk through the specific detail of how and whether those focuses were drawn from Glasgow and Edinburgh, but I imagine that learning fed into the development of the KSARs. I do know that these topics tend to represent some of the more complex areas within any build. The mechanical and electrical (M&E) services can sometimes constitute fifty per cent, if not more, of the cost of a project.

41. We want to make sure that Health Boards have an avenue to access the relevant part of the wider NHS Scotland Assure service. Where we discover issues that are out with the current scope of the KSAR, we would look firstly to identify the issue to the Health Board so it could take appropriate steps to resolve and secondly, if required, provide support to it through the wider NHS Scotland Assure service. For example, if any issues relating to architectural and structural engineering elements were identified we would liaise with the relevant subject matter experts within other parts of NHS Scotland Assure. We would discuss the issue(s) internally then support the Health Board to identify the relevant people or processes required to address the issue(s).

Content and Structure of the KSAR Workbooks

42. NHS Scotland Assure continually tries to improve the content in the KSAR workbooks and the way that we frame our questions to Health Boards. Areas evolve over time and, as and when we get feedback from Health Boards on the KSAR process, NHS Scotland Assure takes that on board, to ensure the service works as effectively and efficiently as possible. NHS Scotland Assure is currently working on version 2.0 of the KSAR workbooks to formally capture feedback which we aim to launch in 2024. The consensus group previously referred to will be involved in the final sign-off of the revised V2.0 workbooks before they go into service.

43. The structure of the workbooks provides a framework that allows NHS Scotland Assure to undertake the KSAR. The questions provide a framework for the review that allows us to adapt the workbook to suit any particular nuances of a project. They can also be applied to any project, irrespective of the procurement route being utilised. It would be impracticable to produce a list of every single question that you may want to ask on a healthcare build. We want to ensure that we have an overarching topic or a question that covers those items. We use our skills, built on our knowledge, qualifications, and experience, to delve into the required level of detail on a project. There are times where the initial information provided by a Health Board provides the necessary assurance and therefore, we don't need to ask for further information. However, if we do not get that initial assurance, we will probe further and seek to identify if further assurance can be provided – if not the project will be "unsupported" and the Health Board will be expected to implement an action plan to address the findings of the KSAR.

44. There is a workbook for each stage in the life cycle of the project. There are specific question sets within each of the workbooks associated with each of the core topics explained earlier in my statement (specifically governance, water and drainage, ventilation, electrical, medical gas, and fire safety). Importantly, NHS Scotland Assure is not an inspectorate service or regulatory body. We stress this to Health Boards when we work with them.

45. There are other organisations that fulfil those roles, such as the Health and Safety Executive (HSE) and Healthcare Improvement Scotland (HIS). Our role is very much an advisory one. When you look at what our strategic aims and objectives are, it is important that we make that differentiation.

46. Whether we are producing a piece of guidance or evolving a workbook, collaboration with Health Boards is important. A Health Board must trust us and feel supported. Whenever I present the KSAR process to Health Boards I want to make sure that they are aware that it is not a 'them and us' type scenario. I explain our function and what we have come in to do. We do not want Health Boards to feel hesitant in any way when accessing NHS Scotland Assure's services. We are also very aware that there are other services within NHS Scotland Assure and it is important that we do not prejudice or restrict access to those services through the KSAR process.

Experience of the KSAR Process

47. I think that, overall, the KSAR process has been successful. It continues to evolve to reflect on our own learning and Health Board feedback. There have been challenges which would be expected, given that it is a new process – for example, a number of healthcare build projects were part way through a particular Royal Institute of British Architects (RIBA) Stage of Design and, following issue of the Scottish Government Directorate Letter (DL(2021) 14 27 May 2021) **(A43494369 - Letter dated 27 May 2021 from Richard McCallum, Director of Health Finance and Governance to NHS Board Chief Executives and others – Bundle 9 – Page 70)** which noted

"*From the 1 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)*"

Health Boards found that their projects required to be reviewed using the KSAR process. In such instances, as there was no time allowed within their existing

programme for the KSAR process to be undertaken, they had to adapt their existing project programmes and processes to provide a response to the KSAR workbooks. To assist Health Board colleagues adapt to the new process, NHS Scotland Assure provided support in the form of presentations and workshops.

48. Overall, the feedback NHS Scotland Assure has received from Health Boards has been positive. Health Boards have intimated to us that they have changed some of their processes as a result of learning through the KSAR process. We regard that as positive as it relates back to both the TOM and the supportive functions of NHS Scotland Assure.

49. There have been several examples of behavioural changes evidenced by Health Boards, particularly where they have undertaken KSARs across different complexities of projects and business case stages. One such example is where a Health Board received an unsupported status on a project, primarily as a result of lack of evidenced supporting documentation in relation to their governance processes. This was subsequently addressed through its own action plan. In subsequent projects, the Health Board in question was able to demonstrate that it had learned from this experience and was able to provide evidence and assurance for its project in response to the KSAR team's request. We have subsequently reflected on this with the Health Board and noted it as a positive step in it adapting its internal processes.

50. On wider reflection, NHS Scotland Assure has found through the experience of a number of KSARs, that the KSAR process and workbooks have helped health boards to enhance their governance processes, including how they are documenting key decisions. The KSAR workbooks promote a theme of good governance throughout all stages of a project.

The NHS Scotland Design Assessment Process (NDAP) and KSAR

51. NDAP and KSAR are distinct processes that were developed separately. The NDAP process predates the KSAR and is overseen by the NHS Scotland Assure Property and Capital Planning team, supported by Architecture and

Design Scotland. Further information on the NDAP process can be found in CEL (2010)19 **(A37215536 – Chief Executive Letter (2010) "A Policy on Design Assurance for NHS Scotland 2010 Revision" – 2 June 2010 – Bundle 13, Volume 5, Page 57)**. The KSAR is overseen by the Engineering & Assurance team within NHS Scotland Assure, as described previously. Both processes benefit from SME input across NHS Scotland Assure, as the teams work very closely internally.

52. What we have tried to do at NHS Scotland Assure is to minimise any duplication between the two processes for the Health Boards – for example the engineering topics that are reviewed as part of KSAR will not be duplicated in the NDAP report. For some of the early KSARs we did find that, at times, there were still elements of duplication taking place – for example in the way information was being transmitted to review teams – however, as the KSAR process has matured, this is now working more efficiently. NHS Scotland Assure is also reflecting on whether further improvements can be made to enhance these efficiencies so that time can be best spent reviewing the evidence provided by the Health Board in response to the KSAR.

53. Within NHS Scotland Assure there are regular internal meetings between the NDAP and KSAR teams to discuss progress and any concerns surrounding projects, to ensure we are aligned as an organisation. With respect to external meetings, whilst there may be separate and distinct KSAR and NDAP meetings, we will also look at when it make sense to have a single meeting, where the agenda will span both processes – for example to discuss hospital theatre layouts.

54. I have been involved in NDAP reviews from an engineering perspective (where projects were not subject to a KSAR). However, that has been very much feeding into the collation of the NDAP report rather than anything else.

55. I have been asked by the Inquiry what would happen if the NDAP had raised certain concerns and recommendations, but the KSAR was supported and also if the KSAR would proceed where such NDAP recommendations were still

outstanding? There can be, and have been, scenarios where the NDAP has been ‘unsupported’ but the KSAR has been ‘supported’, and vice versa. In such instances, NHS Scotland Assure will advise SCIG of the respective findings and where further assurance may be required. We will also support SCIG in its understanding of potential interdependencies between the processes, any risks identified in the respective reviews and how they may impact on the project moving forward, if not addressed. Ultimately, any decision as to project funding and/or approvals to proceed to a subsequent stage will remain the responsibility of SCIG.

56. An example of a project where this occurred was where assurance was provided by the Health Board in relation to the KSAR workbook topics, however the NDAP identified concerns around the architectural form of the building. In this instance the KSAR noted a supported status but also noted that, as the assurance provided was related to a particular architectural scheme, if the scheme had to change because of the NDAP findings, the KSAR might require to be revisited. Through open dialogue with the Health Board, SCIG and NHS Scotland Assure colleagues from the Property & Capital Planning team, we were able to monitor the steps taken to address the NDAP recommendations without the need to revisit the KSAR. Ultimately, the Health Board received a supported status from NDAP and KSAR.

57. I have been told by the Inquiry that it has been informed that when NDAP is carried out at an early stage there can be limited engineering information available and, as a consequence, it is not designed to spot highly technical issues.

58. I have been asked whether this is also my understanding. NDAP as a process will undertake a detailed technical analysis of a project, however at an “early stage” of a project (for example the Strategic Assessment or Initial Agreement Stage as outlined in SCIM guidance), the health board will not yet have commenced its detailed technical design. At these stages it will be developing the project briefing requirements and initial strategies – the NDAP will focus on these. As a design matures through subsequent stages, a health board would

be expected to provide much more in the way of technical detail and NDAP (or KSAR) will review this. Even at OBC, the level of technical information would not necessarily be considered “detailed” as this would typically be provided at FBC, aligned to a RIBA Plan of Work Stage 4 level of detail – the RIBA Stage 4 being classed as “Technical Design”. NDAP is an iterative process that spans the IA stage all the way through to the end of the FBC stage.

KSARs & Sustainability

59. The assessment of a Health Board’s sustainability strategy is not directly in the scope of KSAR. The KSAR would consider the consequential impacts of a Health Board’s sustainability strategy on the KSAR workbook topics. By way of example, Scottish Government policy outlines a requirement for zero direct emissions by 2038 for heating infrastructure. It would be our role to look at the technologies employed as part of the engineering assessment within a KSAR. However, how that related back to the overall sustainability strategy in terms of a net-zero carbon strategy would fall out with the scope of the KSAR. The assessment of the sustainability strategy would fall within the NDAP and Sustainable Design and Construction Guide – SHTN 02-01 (SDaC) processes.

60. Within NHS Scotland Assure, the KSAR team works closely with colleagues who are assessing the NDAP and SDAC components to ensure a co-ordinated approach. This is an important element of the NHS Scotland Assure approach, as it is essential that we do not assess the project in silos. In the same vein, it is important that the project design team does not develop the design in silos.

    Put simply, architecture has an impact on engineering and engineering has an impact on architecture. It is imperative that the Health Board provides assurance that there is a coherent and a coordinated approach to the design.

61. The KSAR will consider implications on patient safety with respect to sustainability strategies. NHS Scotland Assure would never accept a situation where safety was compromised, even if it was part of a Health Board’s sustainability approach or policy. Health Boards, as part of their governance

processes, should be able to demonstrate an awareness of risks on their projects. This could include processes such as the HAI-SCRIBE (Healthcare Associated Infection Systems for Controlling Risk in the Built Environment) which is underpinned by Scottish Health Facilities Note (SHFN) 30. A HAI-SCRIBE is an assessment tool health boards use to help them identify, manage and record built environment infection control risks.

62. We would also consider Health & Safety Executive (HSE) guidance in terms of assessing how the Health Boards have considered risks, asking - can a risk be eliminated altogether and, if not, has the Health Board provided mitigations to ensure the risk has been reduced to as low a level as reasonably practicable? For example, such mitigations might not be able to be addressed through engineering design, it may be that a management policy would be required.

KSAR Workbooks

Construction of the Workbooks

63. The stages of the KSAR are linked to the Scottish Capital Investment Manual (SCIM) stages **(A32375006 – Scottish Capital Investment Manual (SCIM) – Introduction – Bundle 13, Volume 5, Page 2279)**. I don't know why the decision to link them was made because I was not party to that. The SCIM stages are aligned to the RIBA plan of work **(A46192243 – RIBA Plan of Work 2020 – Bundle 13, Volume 5, Page 2289)**. The RIBA plan of work is a well-defined process within the built environment, not just in healthcare. The KSAR workbook questions are typically aligned and reflective of the level of detail expected at each of the milestone stages of a construction project.

64. In my opinion, the alignment to the milestone SCIM and RIBA Plan of Work stages is logical. The RIBA Plan of Work is generally considered as the "norm" within industry in terms of benchmarking at the respective stages of design. With respect to alignment between SCIM and the RIBA Plan of Work stages, OBC would align with a RIBA Stage 2 level of detail and FBC would align to a RIBA Stage 4 level of detail. As a project moves through the relevant stages of

a design, the level of technical detail increases, and that is considered within the KSAR workbooks in terms of the types of questions asked and the level of detail the KSAR team will be expecting to see presented in the Health Boards KSAR response.

65. At OBC the presented designs will not represent the finalised detailed technical solution. The Health Board should provide assurance that they have in place suitably developed project briefs (relevant to RIBA Stage 2 “Concept Design”) and that concept design proposals have been developed. The Health Board should also be able to demonstrate assurance as to how it plans to develop these into detailed technical design solutions in subsequent stages of the project. We would typically be provided with outline specifications and drawings related to the KSAR topics. We would also consider the Health Board’s project governance associated with the development of these concepts, including for example evidence of stakeholder input to and approval of the briefing requirements.

66. RIBA Stage 3 is considered as the “Developed Design” stage and is where the Project Team will start to build upon that detail. It represents a pivot point before the Health Board would finalise their detailed design during RIBA stage 4 (Technical Design). There is no requirement for a Health Board to undertake a KSAR at the end of RIBA Stage 3. We do however recommend to Health Boards that they continue to implement a robust internal governance process and potentially “pause and reflect” that the development of the designs is in accordance with their briefing requirements at this stage.

67. Some Health Boards have expressed a desire to undertake a RIBA stage 3 review, however, as noted above, that is not something that is currently mandated within the scope of the KSAR, as agreed with stakeholders when the KSAR workbooks were created. This may change in the future if there is a collective drive for this amongst stakeholders, including SCIG, however at this time it is not something that has been explored.

68. With respect to my personal involvement in constructing the content of the KSAR workbooks, when I joined NHS Scotland Assure, KSAR workbooks were already in place for the IA stage through to Construction Stage. The Handover and Commissioning workbooks had not yet been finalised (they existed in draft form only) and it was my team that developed those to a conclusion.

69. The content of all the KSAR workbooks was formed through a consensus group of various stakeholders from NHS Scotland Assure (previously HFS), Health Board colleagues and Scottish Government. NHS Scotland Assure retains editorial responsibility for the content of the workbooks, however all workbooks are issued to the consensus group for review prior to publication. NHS Scotland Assure provides specific subject matter expertise relevant to each KSAR workbook section – for example the fire safety sections are developed with support from the NHS Scotland Assure fire safety team, the IPC sections developed with support from ARHAI colleagues and so on.

70. Health Board representatives within the consensus group consist of estates professionals, estates directors and IPC professionals. Having those professionals within the group allows for a balanced perspective. We have a collective approach across the whole of NHS Scotland. It is only when we have consensus that the workbooks are released into circulation. This process will continue to be utilised for any future updates of the workbooks.

71. In undertaking a KSAR, the NHS Scotland Assure SMEs' will use their experience in the field of healthcare construction projects to probe the Health Boards further, as required, and additional questions may be asked of Health Boards over and above those noted in the workbooks.

72. When undertaking a KSAR, a KSAR lead is allocated on each project. Their role is to coordinate project specific KSAR activities on a day-to-day basis. Each of the technical sections will have a technical lead who is a relevant SME. The leads come together as a project team and it is through that that we exemplify what we are looking for the Health Boards to do in terms of a co-ordinated multi-disciplinary approach to managing projects.

73. In the course of a KSAR, there will also be a number of technical workshops related to each of the KSAR topics held with the Health Board to discuss any emerging findings of the KSAR. These would typically be led by the relevant discipline SME outlined above. We would look to have attendance from both IPC and technical colleagues, given the significant independencies between these engineering systems and infection control measures.

The KSAR Process and Guidance

74. KSAR workbooks at all stages provide explanatory text around the types of guidance that a project may be expected to comply with and provides some examples. The KSAR workbook is not "guidance" in its own right. Throughout any KSAR, NHS Scotland Assure seeks assurance from the Health Board that it can demonstrate compliance with the relevant statutory and guidance requirements. That can include British Standards, Building Regulations, Health Technical Memoranda and so on. The starting point for that process would be looking at what guidance and technical standards the Health Board and their Project Team (e.g. including external advisors, design teams, etc) and any other third-party experts have defined as being applicable to their project.

75. The ultimate responsibility for defining standards applicable to a particular project remains with the Health Board and their Project Team. We expect the Health Board to be able to clearly evidence the standards to which their building is being designed and constructed. We would look to establish through the KSAR that they were appropriate standards for that type of facility.

    If we felt there were gaps, or if there were particular standards that they should be compliant with, we would seek further assurance from the Health Board as to, for example, why it had decided not to comply with a particular document, or to whether it was possibly an oversight.

76. I have been asked by the Inquiry if it is the case that a hospital would not be deemed safe if the ventilation did not comply with published guidance. That is a

question that is subject to many variables and not one I could categorically answer without further context relating to what the “non-compliance” related to. Compliance and safety are different concepts, sometimes safety is demonstrated by compliance with a particular document, other times they are not related. There are many complex variables to consider when assessing safety. In the context of a healthcare project, ventilation would be considered as one of a series of infection prevention measures to, for example, reduce the risk of airborne contamination. However, it is not just a case of considering the “ventilation” in the singular sense – you would also need to consider adjacencies to other rooms, patient cohorts, patient pathways and the clinical triage systems that were in place. You cannot make an assessment based on air changes alone. They are important, but safety must be assessed on a wider basis than through just one component part.

77. There may be scenarios that arise in the process of a KSAR where it is identified that a project does not comply fully with guidance, but the Health Board can provide assurance that it is safe. In such instances, NHS Scotland Assure would seek supporting evidence from the Health Board as to how it had assessed the safety of the facility in relation to the non-compliance with guidance. For example, where there was an air change rate lower than that contained in published guidance, we would probe how the Health Board had assessed this (including what the actual air change rate achieved was); we would also establish how the Health Board proposed to monitor air change rates over time to ensure that they did not degrade; we would also question whether there was to be any enhanced air monitoring regimes or maintenance regimes.

78. We would also consider whether the Health Board could evidence an appropriate pressure cascade, what their patient cohort was and whether there was likely to be any greater risk present because of that. We would further probe the Health Board as to whether the variation in air changes was restricted to one room or to a larger space. These are just some of the examples of the complexities that we assess. One line in a SHTM is important, but so is the sum of all the parts of all the guidance documents and all the

requirements that go into designing a healthcare project, when it comes to assessing safety.

79. It is just not possible for guidance to cover every scenario. When people refer to ‘ambiguity in guidance’ one needs to question whether it is truly an ambiguity or whether it is something that is just not covered in extant guidance. In the context of applying that to a project, NHS Scotland Assure would expect a Health Board to have outlined what its approach was to implementing the guidance and be able to demonstrate the rationale for arriving at a decision.

80. During a KSAR, NHS Scotland Assure will assess the Health Board’s inputs (e.g. project briefing requirements) before assessing their outputs (e.g. the design), because there might be a very particular reason as to why they have made a decision, or where they have taken an alternative approach to what is outlined in guidance. A Health Board should be clear on what its requirements are and demonstrate why it has arrived at that decision. This then gives the KSAR team a clear indication as to what investigations we need to undertake next. The direction of the review will be dependent on the types of evidence the Health Board provides. Often a detailed solution is an intricate web formed of various different guidance requirements. Guidance must be considered in a wider context and be implemented in practice by competent individuals and organisations.

Typical Structure of a Key Stage Assurance Review

81. The structure of a KSAR can be thought of in distinct sections, specifically the “information exchange process” where Health Boards provide a response to NHS Scotland Assure in relation to the KSAR workbooks, moving on to a “gap analysis” to ensure successful transmission of a KSAR response from the Health Board to NHS Scotland Assure, and then ultimately the “review period” itself where we assess the evidence provided by the health board in detail. These stages are outlined for each KSAR project in a Dashboard, which I discuss later in this statement.

The Information Exchange Process

82. On a typical project, the lead up to the information exchange process can take several months and builds up to the point where we can start the KSAR. The first point of reference for any Health Board will be the KSAR workbook, as that represents the framework for undertaking the review. NHS Scotland Assure supports Health Boards to identify the type of evidence that they can provide and how they can prepare their KSAR response. Health Boards must ensure that the documentation provided is of an appropriate standard/quality and addresses the KSAR workbook questions – it is not a case of ticking a box to say something has been provided, the evidence must provide the assurance.

83. At OBC, FBC, and the Construction Stage we also provide an aide-memoire document with recommended deliverables the Health Board may wish to provide in response to the KSAR questions **(A46190585 – Exemplar FBC Key Deliverables List – Bundle 13, Volume 5, Page 2437)**. This was created following feedback received from Health Boards who underwent some of the earlier KSARs following the launch of the NHS Scotland Assure service. Health Boards intimated that they would welcome further support in identifying a "good practice" deliverables list for their projects. These aide-memoires provide an expanded list which is aligned to Building Services Research and Information Association (BSRIA) BG6 (detailed below) and other relevant industry guidance relative to each stage, including SHTMs. It is not a mandated requirement for Health Boards to provide the documents within the list and not all may be applicable. If the Health Board doesn't provide a particular document we would, through the course of the KSAR, try to understand why. We would ask, for example, whether it was because the health board deemed it not to be required or whether it might have been captured within another document. The deliverables list should be viewed as a support tool for Health Boards.

84. In creating the deliverables list, as noted above, NHS Scotland Assure utilised a document known as 'BG 6 Design Framework for Building Services' (BG 6) **(A36853347 – BSRIA allocation of design responsibilities – BG 6-2018 Concept design-4 - Bundle 13, Volume 5, Page 2454)** as the starting point**.** It

is not a healthcare specific document so we supplemented this with other requirements, such as requirements noted within SHTM documents, including a design risk assessment for water services.

85. I refer to **(A46192243 - RIBA Plan of Work 2020 – Bundle 13, Volume 5, Page 2289)**. During a KSAR we assess the level of detail relevant to the RIBA stage as it is prescribed in SCIM for each of the key stages that the workbooks are utilised. RIBA itself describes the Plan of Work as follows:

"The RIBA Plan of Work organises the process of briefing, designing, constructing and operating building projects into eight stages and explains the stage outcomes, core tasks and information exchanges required at each stage. Guidance in the RIBA Plan of Work 2020 overview is based on nearly seven years of feedback gathered by RIBA from the construction industry, and it now includes an expanded glossary in comparison to international Plan of Work equivalents, and guidance on the following core strategies; conservation; cost; fire safety; health and safety; inclusive design strategy; planning strategy; plan for use strategy; procurement strategy; and sustainability strategy."

86. Not everything featured in the Plan of Work is represented within the scope of the KSAR. The RIBA Plan of Work is more architecturally focused in nature. BSRIA looks through BG6 to expand on that from a more technical engineering perspective.
The important point is that the RIBA Plan of Work is recognised in industry as good practice. It provides a logical way in which to develop the technical requirements of a particular project. It builds stage upon stage through a project's lifecycle, from the early stages through to a fully constructed building. BG6 and the RIBA Plan of Work are not mandated documents.

87. BSRIA itself defines the purposes of BG6 (within BG6 2018) as:

"The purpose of BG6. There is a variety of activities required to produce the necessary level of detail and information as well as the output documents. The role of BG6 is to provide a platform where the activities can be identified and

allow them to be allocated to individual organisations or roles within the project team. It is vital that each party knows what they are expected to do in terms of design activities, responsibilities and deliverables, and using this approach also ensures that all necessary activities are identified and allocated and that there are no gaps between or duplication of responsibilities." **(A36853347 – BSRIA allocation of design responsibilities – BG 6-2018 Concept design-4 - Bundle 13, Volume 5, Page 2454)**.

88. Health Boards which have undertaken multiple KSARs and been through the information exchange process are now well versed in it. Health Boards who are going through the process for the first time tend to require more support and guidance on the mechanics of the KSAR process. For those Health Boards we would hold a series of workshops leading up to the commencement of the formal part of the KSAR workbook review. During the workshop, people representing the Health Board tend to look for support in identifying whether a particular document may suitably answer a particular KSAR question and ask if that mirrors what we see from other Health Boards. At this juncture we would share learning from previous KSARs to help them formulate their response.

89. Some Health Boards submit written reports to accompany their KSAR response, as they feel this can help to contextualise how they believe they can provide assurance on their project.

90. This is not currently a mandated requirement of the KSAR process as we are conscious of the Health Boards' time in responding to the KSAR. However, in my experience, such a document can prove beneficial and may in the future become a requirement for the KSAR process. This can help where the assurance provided by the Health Board is formed of multiple documents where there may be no obvious linkage initially – a report or file note from the Health Board - can help to sign-post these to the NHS Scotland Assure KSAR team and allow an expedient review of the information.

91. Ultimately, it remains the sole responsibility of the Health Board to provide evidence of assurance related to the core topics of the KSAR workbook.

The Gap Analysis and Review Phase

92. Following the information exchange phase there is a gap analysis phase, prior to commencement of the formal "review phase" of the KSAR. The gap analysis phase looks to confirm a successful transfer of documents from the Health Board to NHS Scotland Assure, rather than reviewing the documents themselves. NHS Scotland Assure also use this phase to make sure that we can successfully access the documents. That allows us, during the review phase, to focus our time on the important issues rather than seeking further records and documentation. Investing time in the gap analysis part of the process allows us to focus more on the technical detail during the review phase.

93. NHS Scotland Assure currently uses Microsoft Teams as an information transmittal portal. We have set up a series of standard folders which are aligned to the KSAR questions and to the deliverable items. This allows Health Boards to effectively "drag and drop" information across by way of response to our requests. We then take a copy of that onto our main server, in accordance with our own information governance protocols.

94. The Health Board submits a transmission log during the information exchange and gap analysis phase, which provides a record of the evidence the Health Board is submitting in response to the KSAR.

    When making observations in the KSAR report we will reference any of the Health Board's documents that are relevant to the observation.

95. It is during the gap analysis phase where we will agree collaboratively with the Health Board about whether we are ready to move onto the review phase. Only once we agree that we have the relevant documentation to start the review, would we start the review itself. It is important to then be able to see the review phase through to a conclusion and provide a "snapshot in time" view of the assurance provided by the Health Board. We tend not to accept further information during the review phase as this may delay the overall KSAR

process. Where the Health Board identifies further evidence, we may choose to make an exception and consider it within the KSAR, or it may be deferred to later and considered as part of the Health Board's action plan. The action plan also provides a documented audit trail of the decision-making process around the resolution of any observations raised in the KSAR.

The Review and Report Phase

96. After the information exchange process is complete, the KSAR moves to 'the review period.' That period can vary in duration depending on the size and complexity of the project build. The larger the project, the more documents there will be and the longer that stage will take. The final phase of a KSAR is the publication of the report. There is a cycle of quality assurance before the final report is issued to the Health Board and SCIG. This includes issuing a draft report to the Health Board for a factual accuracy review. That needs to be done because there is a lot of complex information contained within the report. We then allow the Health Board a final opportunity to review the report to make sure that it agrees with the findings, prior to us then finalising the report. Finally, we issue the report in parallel to colleagues at the Scottish Government via the SCIG and the Health Board itself.

Sharing of the Results of the KSAR Process / Action Plans

The Dashboard

97. I have been asked by the Inquiry how Health Boards respond to each area within the workbooks. I outlined earlier in this statement the relative parts of a KSAR, and these are also outlined within the project dashboard document. The dashboard is something we provide to all the Health Boards on all KSARs. The format of the dashboard (a blank template has been provided to the Inquiry) **(A44600860 – 2023-06-13 – Redacted Example of KSAR Dashboard V1.0 pack number 10 - Bundle 13, Volume 5, Page 2462)** is common for all projects. The detail contained within the template will be generated by the

KSAR lead to contain project specific data, relative to how the KSAR is progressing.

98. The dashboard provides a snapshot in time as to how the KSAR is progressing, including a high level “RAG” (red / amber / green) status. Red would represent that there are risks/gaps in the information being provided by the Health Board, and thus there is a risk that the project may receive an “unsupported” status from NHS Scotland Assure if no evidence of assurance is forthcoming. Occasionally it may also be used if concerns have emerged relative to the KSAR programme or collective NHS Scotland Assure/Health Board resource relative to the KSAR process. Amber would be used to represent similar concerns, albeit these may be emerging or of a lesser concern (hence the lower rating). Some of that might be down to our understanding of the information that the Health Board has provided and, as such, we may seek further clarifications on these through the review period. We occasionally might allocate an amber status to a project if we feel that the programme is starting to slip (for example, we found during COVID that staff had either been unavailable on our side, or on the Health Board’s side as a result of ongoing pandemic response priorities). If there are no concerns overall, then a green status would be applied. The dashboard template is a controlled NHS Scotland Assure document. Any changes to the dashboard document template would need to be approved by myself or the Assistant Director for Engineering & Assurance.

99. It is unlikely that the dashboard would be coloured red in the lead up to a KSAR, as the Health Board will not yet have provided their evidence for review. The exception to this would be if a project was “unsupported” at a previous stage and the Health Board had not yet provided assurance they had resolved the key issues via their action plan. We might look to allocate an amber if we were starting to think that the Health Board may not be able to provide the information on time, which might consequently impact on the availability of the KSAR team or Health Board key stakeholders to undertake the KSAR relative to the originally agreed dates.

100. NHS Scotland Assure aims to be as transparent in our processes as we can. If concerns emerge during a KSAR in terms of the project itself, or if we are growing concerned around the actual KSAR process, we have found that the dashboard document provides a really good high-level snapshot that can be shared with Health Boards. It is a document that we can provide to senior colleagues at Health Board level to explore what they, and we, may need to do in response to the issues identified. The document might not necessarily just be about highlighting risks around the project itself. For example, if a key stakeholder in a particular KSAR is not available, it can limit the ability of the KSAR to progress within the timescales. That could have a significant impact on the Health Board going to the Scottish Government for funding approval. Maintaining visibility on progress is vital.

101. There would not be any detailed technical observations provided within the dashboard as this document is not intended for that purpose (it is essentially acting as a KSAR progress tracker). It might note, for example, “we have emerging concerns on compliance with SHTM 03-01”, or “we have identified a non-compliance with SHTM 03-01” or “there is a lack of detail to support a derogation to SHTM 03-01”. The detail would be notified to the Health Board by means of a separate communication and detailed within the KSAR report.

102. If a significant concern was identified during a KSAR then an escalation pathway would be followed, and we would seek to engage with the Health Board further.

103. It might be something that we can address through the weekly meetings we have with the Health Board or in a separate technical workshop. If it requires further escalation, we would typically liaise with the Health Board project director and / or the SRO in order to identify what the appropriate course of action should be. The dashboard would only provide a summary of the concern. The detail would be formally recorded through our final KSAR report or in intermediate written correspondence with the Health Board. The dashboard is effectively a progress tracker where we can monitor concerns.

104. The frequency of issuing the dashboard to the Health Boards can vary depending on the stage of the project. The minimum period is typically quarterly, when we are not in the "review phase" of the KSAR. As the KSAR ramps up, the frequency will increase and during the review phase it will be issued weekly. We notify the Health Board immediately if we come across any issues that give us concern. We don't want to sit on something that could be rectified there and then. If a case or process takes twelve weeks, and we uncover something on day one, it is not in anyone's interest for us to sit on that until completion of the KSAR. We want to get out in front of that and notify the Health Board timeously.

105. The dashboard will typically be issued to the project director and the SRO at a particular Health Board. They will then be able to monitor any recommendations or instructions through the dashboard.

Weekly Meetings, Other Meetings and Technical Workshops

106. In addition to the project dashboard, during the review phase of a KSAR, we have a regular weekly catch-up with the Health Board. At these meetings there is a weekly agenda which identifies any key themes that are starting to emerge from the KSAR or any points that we would look to clarify. For example, we may note "We have not found any evidence of your ventilation strategy. Here is where we have looked (relative to the evidence provided by the Health Board). Can you point us in the right direction?" We may be directed to a particular document by the Health Board, and we can move on with the review.

107. Other times it could be "We have reviewed your ventilation strategy, and we think that there is a lack of supporting evidence. Is there anything else that you can provide in support of that?" Quite often it is difficult at the weekly meetings to intimate whether that is going to lead to a project being 'supported' or 'unsupported'. We will not give a definitive 'supported' or 'unsupported' status until we are content that we have a ratified position. By that I mean that we have reviewed all the evidence that has been provided by the Health Board and we are content that we have a factually accurate observation. We may convene

other more specific meetings in addition to the weekly meetings if we feel these would be of benefit to the health board or the wider project team.

108. At the midpoint of the KSAR "review" phase, we undertake in-depth technical workshops with the Health Board and its project team (typically consisting of the contractors, designers and relevant project stakeholders). These present an opportunity to discuss any points identified in the review in more detail. Attendees are typically identified in conjunction with the Health Board to ensure that the personnel with the relevant knowledge are present. We would typically have a dedicated workshop for each of the KSAR topics.

Action Plans

109. The Health Board creates an action plan at the end of every KSAR, which is monitored through future KSARs. If a project is 'supported', the Health Board may still have actions. These could include items the Health Board should consider for future stages and to help ensure successful project outcomes. If a project is 'unsupported', then the action plan becomes important as it is through this medium that the Health Board would be required to demonstrate how it intends to address our observations and thus provide further assurance.

Communication with Health Boards, the SRO, SCIG and the Scottish Government

110. Health Boards are provided with an overview of KSAR progress through the project dashboard and through meetings and workshops, as described earlier in this statement.

111. Only once a Health Board has provided assurance would a project become 'supported.' Health Boards and SCIG are notified in writing as to whether a project is supported or unsupported. The mechanism is usually emailed correspondence, originating either from myself or the Assistant Director for Engineering and Assurance. The email would go to the Scottish Government (SCIG) and the Health Board in parallel. For the projects that have an 'unsupported' status it may also be sent to their Chief Executive – this will be

dependent on whether further escalation is required within the Health Board. In the event of an unsupported KSAR, we will continue to engage with Scottish Government and the Health Board around resolution timescales and actions.

Contact after KSARs are Published

112. Since the launch of the KSAR process in 2021, NHS Scotland Assure has evolved the approach for engagement with Health Boards following the issue of the KSAR report. In the past, NHS Scotland would maintain limited engagement with a Health Board if it was a supported project – the onus would be on the Health Board to monitor the resolution of items within the action plan. If a project was 'unsupported', an active level of engagement would be maintained, as ultimately the Health Board would be required to provide assurance to reach a "supported" KSAR status. We tended to get less involved if it was a 'supported' project as generally this would mean there were no significant project risks identified in the KSAR previously. We now continue to liaise with a health board following all KSARs until a project is complete – this allows them to provide evidence at a point in time to demonstrate resolution of action plan observations. This revised approach has also supported health boards in preparing for the next KSAR stage.

113. The KSAR process is not intended to be a burden, rather it is a supportive process for Health Boards. The continued involvement between Health Boards and NHS Scotland Assure following a KSAR report being issued has been positive as it maintains an insight into how Health Boards are addressing the key recommendations of the KSAR process – which is important learning to help inform future projects and development of the KSAR process.

114. We have shared key learning outcomes via a series of presentations to the NHS Scotland Assure Learning Network, which is a platform that Health Boards can attend to share experiences and knowledge.

KSAR and Disagreements

115. I have been asked by the Inquiry whether I have encountered differing opinions or disagreements during a KSAR. Thankfully, we have not got to a point where a Health Board has not accepted the factual accuracy of a KSAR report. I like to think that is a result of the processes that we have put in place. By acting in a transparent manner there are no surprises, because the Health Board should know if there are going to be any key findings in the report before we publish it. There have been differing opinions at times around some of the recommendations. However, through the weekly meetings and technical workshops, we have always been able to reach a consensus with the health board.

116. The way we present recommendations and observations through the KSAR process is also a contributory factor as to why Health Boards have accepted the reports as factual. We always reference observations back to the evidence that the Health Board has provided, or a piece of guidance or statutory requirement in our findings. We take any subjectivity out of the process.

117. I meet with SCIG colleagues monthly and run through the active KSAR project list. It is through this process that we give the Scottish Government an early indication of progress on the KSAR process on each project, including an early insight into any emerging issues that may impact on our ability to "support" a project.

118. I think NSS and NHS Scotland Assure's structure is effective when it comes to potential disagreements and their resolution. The typical escalation pathway within NHS Scotland Assure on a KSAR project would firstly see any concerns raised with me in both my capacity as Head of Engineering and as being responsible for overseeing the day-to-day delivery of the KSAR process. Should further escalation be required, this would initially be through the Assistant Director for Engineering & Assurance. Ultimately, the escalation path would go via the Director of NHS Scotland Assure and in certain instances to the NSS Chief Executive.

119. As Head of Engineering, I would look to initially try and resolve any disagreement with the Health Board, whether that be through the project director or the SRO. If I could not reach resolution in that first instance, I would look to escalate that to the Assistant Director and even up to Chief Executive level. Typically, the escalation pathway does not require to go further than myself or the Assistant Director. There have been examples though where the escalation to senior colleagues has been required and worked well, including one large National Treatment Centre project.

120. Another example was where the project was allocated an 'unsupported' status following the Commissioning and Handover KSARs, and due to concerns over the time until the first patient was due to be treated within the building, the NSS Chief Executive was briefed on the significance of the issue. This allowed her to liaise with the Chief Executive of the Health Board and to ensure that actions were collectively prioritised. It also maintained the open and transparent ethos behind the KSAR process and ultimately the Health Board addressed the concerns identified, received a "supported" KSAR status and opened on time.

121. In the unlikely event that a resolution could not be reached between NHS Scotland Assure and a Health Board, we would escalate this via Scottish Government. The KSAR presents an objective position and is linked back to guidance and the evidence provided by a Health Board. We would present the risks to Scottish Government to help them identify an appropriate resolution pathway. Thankfully, we have never had to go fully down that route.

KSAR at Outline Business Case (A43494374 – KSAR Outline Business Case Workbook – Bundle 9 – Page 120)

122. As noted earlier in this statement, the KSAR at OBC will consider if the Health Board can provide assurance that the designs have been developed to a RIBA Stage 2 level of detail. The KSAR will also consider whether the Health Board can provide assurance that it has a comprehensive knowledge and understanding of the type of patients who will use the facility, and that the

project team consider how appropriate quality and safety standards will influence the design. The Health Board should also be able to evidence that the project is suitably developed to be able to proceed to the FBC.

123. The Health Board at OBC, should be able to demonstrate the governance processes it has in place to support decision making, including for example how they it has engaged with clinical and IPC colleagues. NHS Scotland Assure would also seek assurance from the Health Board that solutions had not been developed in silos (e.g. without full and transparent consultation with stakeholders) and that appropriately competent personnel had been engaged in the Health Board's respective processes. An example of a KSAR question at OBC is "Does the Health Board continue to demonstrate service and clinical input in design decisions?" If we only receive the clinician or the service lead's perspective on the design, and we do not receive the engineer's or the project management team's perspective, then we would look to probe the Health Board to determine if it can demonstrate a full alignment of understanding across the project team. For example, this could be in the form of a design approval document with signed approvals from relevant stakeholders.

124. If the KSAR identified concerns around an integrated approach to design decisions, NHS Scotland Assure would probe further to establish how the Health Board ensured that clinical requirements and engineering strategies (for example) were compatible. We may for example probe topics such as "The clinical team has outlined certain requirements, but your engineers were not in the room when that was discussed, so how was that conveyed to your engineers?"

125. How have these requirements informed their outline ventilation strategy?; How have these requirements informed the briefing documents that you have developed for your ventilation?; If it is an isolation room, for example, have you applied the correct guidance for an isolation room?; Do you understand the clinical function of that room? and If you do not understand the clinical function, how can you design the engineering?" NHS Scotland Assure will consider the Health Board's project approach to understand if all the relevant stakeholders

are talking to each other. We want to see whether there is a clear linkage between a Health Board's clinical briefing requirements and the development, evolution, and implementation of their technical briefings. This is part of the reason why the workbooks are structured in the way they are. We often find that where a Health Board cannot demonstrate adherence to a defined governance process in this respect, that we need to probe further in terms of the technical information requested in other sections of the workbook.

126. Dependant on the procurement route of a project there may or may not be a construction partner appointed at OBC. Where a project doesn't have a construction partner, NHS Scotland Assure would probe how a Health Board was assessing the "buildability" of the concept solutions. We would also review how the Health Board had considered and defined any risks in that respect, including how they planned to integrate with a construction partner in subsequent stages of the project.

Technical Review of the Specifics of the Design Solution at the Outline Business Case Stage

127. NHS Scotland Assure implements a common approach to the review of design solutions presented by Health Boards as part of its KSAR response, regardless of the stage of the project. We will effectively appraise both the design solution and the project briefing requirements. We have to consider whether the Health Board provides assurance that the technical solutions presented are relevant and appropriate to the type of facility that is being built. In terms of our processes, that begins with a review of the Health Board project requirements. The KSAR team needs to understand what it is that the Health Board is setting out to achieve through their construction project before we delve into the intricacies of the technical detail. We would then assess whether the technical solutions had been developed to the appropriate level (relative to the stage of the project, as noted earlier in my statement) and in accordance with the project requirements.

128. NHS Scotland Assure considers how the Health Board has defined the project requirements at this stage, how it has reached key decisions and who was involved in that process. We would assess governance around that early stage and whether the Health Board is setting expectations and requirements through the project briefing documents. We would further assess how is that being used to inform the design. At the OBC stage, we would be looking at an assessment of the concept technical solutions that are being proposed. That process would involve obtaining and reviewing a number of different documents. Those documents could include technical specifications, drawings, schedules, notes of meetings, various briefing documents and others.

129. I have been asked by the inquiry how the KSAR considers the requirements for commissioning at OBC. I have included a wider explanation of this for all KSAR stages later in this statement but note here the specific considerations at OBC. At this stage of a project, we would seek assurance that a Health Board has commenced planning for commissioning, including for example whether a designer's commissioning brief for ventilation and water had been commenced in accordance with SHTM requirements. Health Boards should also provide assurance that they can demonstrate how they have assessed the appropriate standards that need to be applied. The KSAR will consider who was involved in that process and how that was reflected through the project documentation. One specific aspect for example would be - has the Health Board defined roles and responsibilities for commissioning? We would also consider whether the project programme has appropriate time allowances for commissioning (noting that a detailed commissioning programme may be provided during later stages of the project).

130. The Health Board at this stage should also be able to demonstrate an awareness of any commissioning dependencies (for example ensuring that building fabric works are complete before commencing microbiological air quality sampling) and whether they were captured in appropriate risk registers, programmes, etc. The Health Board should also be able to demonstrate it has appropriate governance controls in place and sufficient project documents in place to support the actual implementation of that commissioning, including

considerations of its own internal resources to support the commissioning process.

KSAR at Full Business Case (A43494373 - KSAR Full Business Case Workbook – Bundle 9 – Page 151)

131. The KSAR at FBC will consider if the Health Board can provide assurance that the designs have been developed to a RIBA Stage 4 level of detail. The KSAR process at FBC stage is similar to the process at OBC stage, as this helps to ensure a commonality of approach when undertaking a KSAR. At this stage we would expect the Health Board to have concluded its detailed design and there be confidence that the project can move onto the construction stage.

132. The RIBA Plan of Work 2020 notes:

"Stage 4 is about developing the information used to manufacture and construct the building. This requires information from the design team and the specialist subcontractors employed by the contractor, regardless of which procurement route is used." **(A46192243 - RIBA Plan of Work 2020 – Bundle 13, Volume 5, Page 2289)**.

The FBC KSAR is the last review before construction. We expect a lot more detail in the information that is being provided and a lot less information stating itself as "still to be developed at the next stage." We would expect all room data sheets (RDS) to be in place at this stage. Any gaps in such information can impact on the coordination, viability, and functionality of a build.

Furthermore, it may potentially impact the time, cost, quality, and safety of the build. We would only review a sample of the room data sheets' as we are not a shadow design team.

133. If a project had previously been subject to a KSAR at OBC, NHS Scotland Assure would initially look to assess whether the Health Board had evidenced resolution of the action plan from the previous KSAR. The KSAR team would

also look to understand what (if any) changes had been made to the project in terms of briefing requirements, to ensure the subsequent FBC review was fully informed. Where changes were identified, either as advised by the Health Board or through the KSAR itself, we would seek assurance from the Health Board as to how it had assessed the change. The KSAR team would consider, for example, whether the change fundamentally impacted any of the core principles that were signed off. We would also consider how the Health Board project governance protocols had been implemented in managing the change.

134. In terms of the information provided by the Health Board at FBC, we would expect a greater volume of information to be provided (than at OBC) and that the information be of a detailed technical nature, reflective of the stage of the project. This will both inform how the building is to be constructed and, from an engineering perspective, how the building will be commissioned and validated.

135. The FBC KSAR remains a rigorous process. Some documents may remain unchanged from a previous stage and we would not necessarily need to review them again if there were no significant changes to the project briefing requirements.

Design Calculations

136. It states within the FBC workbook **(A43494373 - KSAR Full Business Case Workbook – Bundle 9 – Page 151)** that there will be a check of design calculations. As NHS Scotland Assure is not a shadow design service or a checking service, this will not extend to a check of all calculations on a project – rather it will be a sample of calculations. The sample size will vary on the size and complexity of a project and be established by the KSAR team on a project by project basis. Our involvement does not change the liability on the project. The ultimate legal responsibility and project liability, in terms of the accuracy of the design information and calculations, is retained solely by the Health Board and its Project Team.

137. When reviewing a calculation, the KSAR team would firstly assess whether the usage/performance criteria of a space had been defined (and thus how it would inform the calculation). This could then include an assessment of the type of patient that would go into the space, which had informed the decision, how that decision was recorded, how the Health Board had developed the environmental parameters for that space, how it had undertaken the calculations, what software it had used, who had checked it, who had validated it, whether it aligned with the guidance and whether there were any associated derogations. The KSAR team will then assess the accuracy of the calculation. For example, if reviewing a Health Board's ventilation calculation we consider how the Health Board demonstrates the way that calculation relates back to the patient cohort, how the outputs have been validated (e.g. does the air change rate meet SHTM or briefing requirements), how that calculation is then used to inform the ventilation design strategies (such as fan sizing).

138. The KSAR will also consider the process a Health Board and its Project Teams have in place for checking and approving design calculations. We would seek assurance it has a demonstrable process for checking and validating calculations and that it identifies the individuals with respective responsibilities – for example who are the checkers? Who are the verifiers? If the Health Board and the Project Team can demonstrate they have robust audit processes in place for checking all their calculations, then this reduces the potential for errors to have been made. We would expect similar processes to be in place for documents such as an environmental matrix (an environmental matrix is a tool, typically spreadsheet based, that project design teams and health boards can use to record the environmental parameters relevant to their specific project

– note this does not supersede the requirement to use Activity Data Base (ADBs) on projects as per Scottish Government's "A Policy for Design Quality for NHS Scotland' issued under CEL 19 (2010) **(A37215536 – Chief Executive Letter (2010) "A Policy on Design Assurance for NHS Scotland 2010 Revision" – 2 June 2010 – Bundle 13, Volume 5, Page 2234)** or room data sheets.

139. In my opinion, a robust quality assurance process that incorporates peer reviews and validation, in addition to a self-checking process, promotes good quality outcomes and reduces the potential for errors to go undetected.

KSAR at Construction Stage (A43494368 - KSAR Construction Workbook - Bundle 9 – Page 183)

140. The KSAR review at the Construction Stage is the first to be undertaken once the building is “out of the ground” and takes place during the RIBA Plan of Work Stage 5. During this KSAR we consider both how the construction activities are progressing relative to the project requirements (inclusive of the detailed design proposals and Health Board requirements), in addition to how any outstanding design activities have been concluded.

141. Whilst most design activities should be concluded at RIBA Stage 4 and within the FBC stage, there are “contractor design portions” that may not have been developed by the end of RIBA Stage 4 and as such fall within the Construction Stage of the project. By way of context, during the FBC KSAR stage we would seek assurance from the Health Board that there was an appropriate level of detail within the project documentation to inform those contractor design portions.

142. We would not expect any contractor design portion to have a fundamental impact on the form, function and the coordination of the building. BSRIA BG6 provides an overview of the subtleties between particular packages. The KSAR would seek assurance from the Health Board and the Project Team that none of those contractor design portions had altered the signed-off detailed principles approved by the Health Board at RIBA Stage 4/FBC.

143. Over the course of the KSAR construction review we would consider how the Health Board and Project Team have managed the evolution of contractor design portions and how they continue to maintain an appropriate level of stakeholder engagement. Even though the project has passed the design

stage, the Health Board stakeholders still have an important role to play in terms of the implementation and finalisation of those strategies. That is particularly so when it comes to approval of contractor design portions.

144. As with the FBC KSAR, if a project had previously been subject to a KSAR, NHS Scotland Assure would initially look to assess whether the Health Board had evidenced resolution of the action plan from the previous KSAR. The KSAR team would also look to understand what (if any) changes had been made to the project in terms of briefing requirements, to ensure the subsequent review was fully informed. Where changes were identified, either as advised by the Health Board or through the KSAR itself, we would seek assurance from the Health Board as to how it had assessed the change. The KSAR team would consider whether the change fundamentally impacted on any of the core principles that were signed off. We would also consider how the Health Board project governance protocols were implemented in managing the change. For example, if it had been as a result of a value engineering exercise (this could include where project specifications, designs or material selections have to be changed for affordability purposes), we would be looking to establish who had been consulted. We would seek evidence from the Health Board that it had the right stakeholders involved and that there was transparency around what they were doing.

145. The KSAR will also seek assurance from the Health Board and Project Team that there is an appropriate level of supervision on site, to make sure the physical build is progressing in accordance with the project requirements (including any statutory processes).

146. The KSAR will also assess how the Health Boards and the appointed Contractor are managing the supply chain, particularly where sub-contractors are employed for specialist packages, to ensure that quality and safety on the project is not compromised. As part of this we will consider what briefing information has been provided to the contractors/sub-contractors, particularly if they were not appointed during the design stage of a project and may therefore be initially unfamiliar with the project requirements.

147. I have been asked by the Inquiry whether the briefing information provided would include Room Data Sheets (RDS). I would note this could include but not be limited to RDS. We would also expect additional information to be provided. This may include for example technical specifications provided by the design team. It all depends on the scope of work and the function of the subcontractor, as well as the scope of their duties. It wouldn't specifically be the ADB. The ADB is the start of the journey in creating an RDS. The briefing documents are an evolution of that and are specific and bespoke to any given project and its requirements. Essentially, the Health Board and the Project Team should be able to demonstrate that roles and responsibilities for all sub-contractors are fully defined and that all individuals are appropriately briefed on the requirements of the project.

148. The KSAR would also consider the processes Health Boards and Project Teams have in place for appointing Contractors and Sub-contractors, to ensure they possess the relevant experience, competencies and qualifications to work within the healthcare built environment. Healthcare buildings present very specific challenges and nuances, for example a water system in a hospital is different to a water system in a school, particularly as the water may be used in clinical procedures or certain patients may be more susceptible to waterborne organisms than the general public. By way of further example, if an individual plumber had no demonstrable experience of working on a healthcare project, we would want to know how they had been considered competent to work on the project.

149. The Construction KSAR will also consider how the Health Board and the Project Team continue to prepare for the commissioning of the facility, as even decisions made early in the Construction phase can impact on the outcomes of later stages. An example of this is assessing how the Health Board and the Project Team are looking to manage the water system through the Construction phase, including when & how water will be safely introduced into the system. If the project involves connecting into an existing healthcare building, there will be a lot of additional considerations compared to a brand-new build with no

interfaces to existing infrastructure. We would also assess how the contractors are interfacing with Infection Control, with Estates, and how they are considering any existing safe systems of work or policies that Health Boards may already have in place, for example permitting systems (which would be required to gain authorisation to work on a particular system) or water management protocols.

150. The KSAR will also consider whether the Health Board can demonstrate a coordinated approach at all levels across the Project Team. The KSAR seeks assurance that the Health Board has systems in place to ensure that there is a commonality of approach. This is true for all stages within a healthcare project, however, at Construction stage we are getting to the point where patients and staff members are ever closer to using the facility, with an ever-decreasing ability to amend anything that may not be correct. The KSAR seeks assurance that systems are being commissioned appropriately, and in accordance with the aims and objectives of the design.

151. The Inquiry has referred me to the use of the term “correct standard” with regard to design within the Construction Stage workbook. As referred to earlier in this statement, the Health Board and its Project Team are ultimately responsible for specifying the standards to which a project should be designed and constructed, notwithstanding any statutory or legal obligations placed upon a project. The KSAR will seek assurance as to whether the Health Board has a process in place to establish this in terms of a project briefing or specification. The standards to which the project is subject should also be documented. This is considered at all KSAR stages and is not exclusive to the Construction KSAR. If a project had undertaken a previous KSAR to this point, one would assume that it had a supported status and that there was assurance around the project.

152. Whilst a KSAR may highlight ambiguities in applied standards, ultimately the process for resolving any ambiguities in standards would rest with the Health Board. The KSAR process requires a Health Board to prepare an action plan in response to observations made and, within that document, we would expect the

Health Board to outline how it planned to address the ambiguities and then ultimately evidence that such had been addressed. The specifics of this evidence would depend on the nature of the ambiguities. NHS Scotland Assure has in the past been asked for support by Health Boards in addressing such matters, which we would support where possible, albeit without affecting the overarching obligations/responsibilities which remain with the Health Board.

Derogations at Construction Stage (Through Variations)

153. A variation at the Construction stage may not necessarily lead to a derogation. What is key is the nature of the variation. A variation could include a change in manufacturer or product, if the original specified requirement is no longer available or unable to be procured in the timescale required. At the opposite end of the variation, it could be a result of a change in the Health Board's projects requirement, such as change in use or it could be something else that is completely unrelated. All of that would need to be assessed by the Health Board to identify whether a derogation was required. As part of the KSAR, should such changes be apparent, the Health Board should provide assurance that it has conducted a full technical appraisal of the changes, to establish if a derogation was required.

154. The Health Board should be able to demonstrate that it has not just assumed that any change is not going to have an impact. It needs to be able to demonstrate a process that proves that there is not going to be an impact on compliance with guidance, safety, risk and reliability. Time and cost may also be considered.

155. If, for example, there has been a change in manufacturer, we would seek assurance that the Health Board and the Project Team have considered if the change will impact on performance and reliability or is it a true "like-for-like" change. We would seek evidence as to how they have assessed that, for example whether they had looked at product data sheets, who looked at the product data sheets and whether it was a demonstrable like-for-like change.

156. We would seek assurance on the change control processes implemented by the Health Board. The Health Board should be able to provide assurance that an appropriate level of due diligence had been applied when considering that variation. Depending on the nature of that change, that absolutely should include clinical and IPC involvement. They are subject matter experts in their field, and they must be consulted if the change may impact on IPC strategies.

157. The workbooks throughout all stages promote good project governance and technical due diligence by competent people. Whilst there is always potential for variations on any project, if Health Boards can provide the assurance outlined in the KSAR workbooks at all stages of a project, it would, in my opinion, reduce the potential for a variation to be required to address an error in design. If a Health Board can demonstrate appropriate levels of governance, appropriate levels of technical due diligence being applied, if they are following a prescribed framework for developing the design (like a RIBA Plan of Work for example), the potential for those errors to exist should, in theory, be reduced.

KSAR at Commissioning (A43494367 – KSAR Commissioning Workbook – Bundle 9 – Page 213)

Commissioning and Validation

158. I note paragraph 1.8 on page 14 of the Commissioning Workbook which asks the question

"How does the Health Board ensure that Commissioning results are witnessed and agreed as acceptable including independent validation where required?"

Commissioning is the process of advancing a system from physical completion to an operating condition. Commissioning is normally undertaken by a specialist commissioning contractor working in conjunction with equipment installers. It may also be undertaken by specialist personnel within a particular company who may be trained in commissioning of a particular system.

159. Validation is subtly different from commissioning. The purpose of validating a system is to assess the complete installation to ensure that it performs to the desired level and parameters. Validation is a process of proving the system in its entirety is fit for purpose and achieves the operating performance originally specified. SHTM 03-01 for example, recommends that it should be a condition of contract that the system will be acceptable to the client if, at the time of validation, it is considered fit for purpose and will only require routine maintenance for its projected life. Effectively, validation proves that a system (or systems) is ready to be put into service, whereas the commissioning may only include elements of that in isolation.

The KSAR Process at Commissioning Stage

160. The Commissioning KSAR takes place towards the very end of the Construction Stage of a project and prior to the Handover Stage. At this time the building works will be substantially complete and system commissioning complete (or nearing completion). As with all KSARs we will establish whether a KSAR had been undertaken previously and assess whether the Health Board had evidenced resolution of the action plan from the previous KSAR. The KSAR team would also look to understand what (if any) changes had been made to the project – the process for which I have described earlier in this statement.

161. The overarching aim at this stage is to seek assurance from the Health Board that all commissioning activities have been successfully completed and that it continues to prepare for the facility being put into service. The Health Board should also provide assurance that the building is fit for purpose and safe from foreseeable risks. If any residual risks are identified we would look for assurance that those had been properly documented, mitigated and accurately assessed. The KSAR will assess who was undertaking the commissioning and who would be validating that commissioning, particularly critical care areas or areas of significant complexity. The KSAR will also consider how the Health Board has implemented any independent validation of particular systems, such as critical ventilation for example.

162. Often the Commissioning KSAR and Handover KSAR are undertaken back-to-back, given the project will be close to completion.

163. There should not be any design activities remaining when a project reaches the Commissioning KSAR because the systems should be fully installed and commissioned. If there is still design ongoing then that would be viewed by NHS Scotland Assure as a risk.

164. If we identified such a risk we would look to probe this further with the Health Board to establish how it was assessing the risk – for example how is it reviewing the impact of the outstanding design work against the physical site works and commissioning progress to date?; how is it assessing the safety of the facility relative to the design work?; how is it assessing compliance against relevant standards, including SHTMs?

165. The Commissioning KSAR builds on previous stages and will assess whether Health Boards and their Project Teams have defined their aims, objectives and standards to be followed for commissioning. I would stress that this will not be the first time that the KSAR process considers this question – but it is revisited during the Commissioning KSAR. I have also been asked by the Inquiry as to whether there may be mandatory commissioning activities. There will be certain activities that are mandated through law or a statutory process, such as compliance with the building regulations. For other "good practice" activities that may be outlined in guidance, these would typically only become mandated through a contract.

166. The KSAR will also consider whether commissioning activities have been completed in an appropriate sequence and the results documented, checked and approved by relevant stakeholders.

167. I have been asked by the Inquiry if the commissioning is now carried out against published guidance, such as SHTM's, regardless of what the contract states. Through the KSAR process, we would be considering how Health

Boards had defined the standards to which the building should be commissioned and validated. At the commissioning stage of a project there should not be any ambiguity between a contract and the technical specifications. We would seek assurances from a Health Board that it had developed those documents in an appropriate manner and was able to demonstrate its governance processes in relation to this, through the KSAR process.

168. Use of SHTMs themselves are not mandated by default – they would, for example, tend to become mandated through a contract. For a healthcare facility they would typically be seen as good practice. Should a Health Board choose not to implement a SHTM, through the KSAR process we would seek assurance as to the rationale behind such a decision, including evidence that there would be no impact on the safety, risk or reliability of the given system or facility. We would also seek evidence from the Health Board that such requirements were outlined within the project information, such as briefing documents, specifications, etc.

169. There may be instances where an alternative approach may be entirely justified and this would be fully considered as part of a KSAR – for example a healthcare facility within a prison may present instances where a derogation from a SHTM may be required due safety & security considerations. Provided the Health Board can demonstrate that doing something a different way hasn't compromised the safety of the person within that space, be that a patient or a member of staff, then it may be an acceptable approach – but it must be evidenced, as noted earlier in this statement. There should be no ambiguity in existence because the project documentation should be robust enough to demonstrate what a building needs to achieve and why it needs to achieve it.

170. As part of a KSAR, NHS Scotland Assure would not necessarily review the contract where any potential ambiguities are identified. The contract would remain the responsibility of the Health Board. The KSAR observations made by NHS Scotland Assure may point out specific issues that the Health Board

needs to address, such as clarifying the scope of works for a particular role or organisation on a project.

171. If we identified a scenario where a contactor was not doing something in accordance with a SHTM and the Health Board believed that they should, we would seek clarification from the Health Board as to what its contractual requirements were or what the project briefing requirements were, and probe as to how the Health Board was monitoring the quality & performance of the Contractor to ensure they were discharging their duties accordingly.
Where a gap was identified we would seek assurance from the Health Board as to how it proposed to address that gap. We would recommend that it document what the relative risk was that it was facing and how it proposed to mitigate & address that risk. Ultimately, that might result in a significant remedial measure, or it might not. It is the responsibility of the Health Board to assess that risk relative to the situation that it is facing. Contracts and technical documents are complex; however, the Health Board and its Project Team must make sure that such documents are suitably formed to ensure successful project outcomes.

172. I have been asked what independent validation involves, by reference to SHTM-03-01 Part A 2022, **(A37301627 – Scottish Health Technical Memorandum 03-01 (Interim Version) – Part A: The Concept, design, specification, installation and acceptance testing of healthcare ventilation systems: February 2022 – Bundle 13, Volume 5, Page 2463).** Sections 12.4 and 12.5 of this guidance document note that

"In order to ensure that the complete system operates correctly it will be necessary to validate it as a whole from the air intake through to the extract discharge. It is unlikely that the client's in-house staff will possess the knowledge or equipment necessary to undertake this process. Validation should therefore be carried out by a suitably qualified competent engineer appointed by the client. The validator would be the client's AE(V) (see Chapter 2 in Part B of Scottish Health Technical Memorandum 03-01) **(A37301626 – Scottish Health Technical Memorandum 03-01 – Part B: The management,**

operation, maintenance and routine testing of existing healthcare ventilation systems: February 2022 – Bundle 13, Volume 5, Page 2690) *or someone of similar standing who is familiar with the ventilation requirements for healthcare facilities. They will be completely independent of the system designers, contractors, suppliers, installers, commissioners and those who will subsequently operate and maintain the system… To retain independence, the validator should be appointed and paid directly by the client.*
The validator will act as the client's representative to inspect the system, check its performance and recommend acceptance, or not, to the client."

Relating back to the KSAR process, NHS Scotland Assure will seek assurance from the Health Board in relation to the processes and procedures they have in place in that respect.

173. The mechanics of the KSAR process will entail a review of the Health Board and Project Team processes, as well as a review of the outcomes/outputs. The processes themselves would typically be designed to outline the governance associated with commissioning & validation activities. It is important for the Health Board to provide assurance that these are robust and being adhered to.

174. The Commissioning KSAR includes a site visit to gain a general understanding of the site conditions during the construction and commissioning stage. This visit could, for example, include an inspection of the air handling unit installation, to check if the condensate traps are clear and running free and to make sure that there is no visible contamination within the respective chambers of the Air Handling Unit (AHU). We may also check the protection of the sanitary ware, the water services pipework and inspect fire safety measures that are installed. It is important to note that this is not intended to act as a replication or replacement of a clerk of works or site supervisor. The site visit can also offer perspective relative to the Health Board's quality control processes – for example if we attend the site and observe quality issues, that would potentially lead to a further probing of the quality controls in place on the project.

175. The Commissioning Stage KSAR will also consider the assurance provided by the Health Board in relation to the structure and competency of the workforce involved in the commissioning process.

176. In response to the Commissioning Stage KSAR, the Health Board would typically provide evidence including risk assessments, method statements, commissioning programmes and documentation, to demonstrate engagement with the relevant stakeholder groups such as the water safety group, the ventilation safety group and other such specialist groups.

177. Following a review of the governance and workforce arrangements, the KSAR will then look at the detail of the commissioning results and information provided. This includes an assessment of the commissioning data relative to the design and functional requirements, in addition to considering how the Health Board itself has assessed the data to ensure it is within the required tolerances. The KSAR will also consider how the various organisations involved in the commissioning process are collating this information for the Health Board at handover. We recognise that a lot of the responsibilities will start to shift onto the health care provider at that point. The project is moving from a construction project to a live health care environment.

178. As with any KSAR, the Commissioning KSAR does not change the liability on a project. It remains with the Health Board and its Project Team. As already stated, NHS Scotland Assure is not a shadow design team – if that function is required it would need to exist within the Project Team itself. The KSAR process is designed to receive assurance from Health Boards that they have appropriate governance and quality control processes in place and that they are being discharged by competent personnel. The KSAR also considers the level of supporting evidence in relation to this, including technical documentation. It is important that a Health Board can provide demonstrable evidence, otherwise this can represent a risk to it.

179. The workbooks identify different types of evidence that may be applicable to a project in order to provide assurance – the evidence types are not intended to

be exhaustive. The KSAR team uses its own experiences to expand on areas to probe, as required, but ultimately these are related to the core KSAR topics. The Health Board must provide evidence through its KSAR response that it has fully considered the safety, risk and reliability of a facility as it is put into service. That is what the questions in the workbooks are trying to tease out. From my perspective, I view the workbooks as being self-explanatory. They set out the areas to probe and identify how they will be assessed during the review. There is explanatory text at the beginning of every single workbook that sets out the aims and objectives of the KSAR process.

KSAR and the Handover (A43494370 – KSAR Handover Workbook – Bundle 9 – Page 249)

180. The KSAR review at the handover is a point of transition in the project life cycle, moving from a construction project to an operational healthcare facility. The focus of the handover KSAR is the detail around the "handshake" between the contractor, the wider project team (including the designers) and Health Boards. It generally marks the transition to Health Boards taking on full ownership of the facility/works and any associated risks. The KSAR will consider the level and quality of information provided by the contractor, subcontractors and technical specialists to the Health Board, to ensure that the Health Board can provide assurance that it has all the relevant information in place to safely operate the facility. The KSAR seeks assurance from the Health Board that all the commissioning activities have been completed, that the outputs have been reviewed and approved by the relevant stakeholders and that it meets the requirements of the design. As noted previously, the handover and commissioning KSAR go back-to-back in terms of a typical project timeline, with the time between completed commissioning and a facility handed over being short (in comparison to the time between other milestone stages such as OBC to FBC).

181. As with all KSARs, we will establish whether a KSAR had been undertaken at a previous stage of the project and assess whether the Health Board had evidenced resolution of the action plan from the previous KSAR. The KSAR

team would also look to understand what (if any) changes had been made to the project. We might not necessarily undertake a site-based audit at the handover stage.

182. If we had already been to site and assessed that during the commissioning stage, there may only be a difference of a few weeks in the process. For much larger complex projects, we may have to go back to site at that point. It is all dependent on the nature of the project.

183. As stated, the KSAR team adopts a common approach across all KSAR stages and the Handover stage is no different. The KSAR team will review the evidence provided by the Health Board that outlines its handover processes. We would then look to review this information to establish whether the Health Board has provided assurance that all the statutory and key health and safety information is in place, and whether all commissioning & validation information has been reviewed and confirmed to be within tolerance. "Within tolerance" could mean for example a range of values relative to the design specification or it could be an overarching requirement, such as disconnection times for electrical circuits, in accordance with the Wiring Regulations BS7671. It would be very much dependent on the type of system.

184. The KSAR would also probe whether any out-of-specification results were identified in the conclusion of the commissioning and seek assurance that the Health Board and its Project Team had reviewed and addressed the results appropriately.

185. The KSAR will also seek assurance from the Health Board that it has a process in place for managing any defects at completion, and where defects are present it must evidence that such defects will not fundamentally impact the safety or performance of the facility in operation. If any long-term risks were identified by the Health Board we would seek assurance that it had documented plans in place to manage that risk. The fundamental objective here from a KSAR perspective is for the Health Board to provide assurance that defects would not

compromise patients, staff or visitors or the Health Board's ability to maintain the facility.

186. The KSAR at handover will also consider the assurance provided by the Health Board as to how it has discharged its statutory obligations or obligations under guidance at the point of handover, and also consider how it proposes to move forward into the operational phase and maintain that compliance. For example, what may be considered is whether existing Health Board operational policies (such as electrical safety policies) will cover the new facility or whether amendments to existing or new policies are required.

187. In addition to Health Boards' documentation, we will also seek assurance that the contractor (& sub-contractors) have ensured that they have prepared an appropriate package of information at handover for the Health Board, and that there is a clear audit trail in place showing who has taken ownership. In historic KSARs we have seen contractors also provide a "letter of comfort", typically on their company-headed paper, signed by an appropriate person within their organisation, in order to provide further evidence in respect of who has taken ownership. This is important as it brings individual accountability from a decision-making perspective.

188. The Inquiry has referred me to the directorate letter, DL (2023) 03 **(A43494372 – Letter Dated 6 February 2023 from Alan Morrison, Deputy Director of Health Infrastructure, Investment and PPE to NHS Board Chief Executives and others – Bundle 9 – Page 75)**. The recommendation in that DL from the Scottish Government is that no building should open without support from NHS Scotland Assure. At handover, if there are any critical areas where further assurance is required, we would continue to be involved until such time as the Health Board provides the additional assurances required to allow us to allocate a supported status to the project. There may still be some minor residual actions at this point, however these would very much be within the ownership of the Health Board.

189. Once a project is “supported” at handover that would typically signal the end of NHS Scotland Assure’s mandated involvement. It would only be if the Health Board asked us for further support that we would continue to be involved.

190. Effectively, that would fall under ‘business as usual’ activities for NHS Scotland Assure, through the provision of Subject Matter Expert support. If a Health Board asked us for support, we would assess that request, relevant to capacity, and the nature of the requested support, to determine under our terms of service whether that was something that we could support.

Derogations

191. Within current Scottish guidance there is no standard derogation template or form. Health Boards tend to develop their own templates. I am aware that Health Boards share ideas and knowledge through forums like SETAG.

192. The KSAR process will consider how Health Boards provide assurance that they have a robust process in place for identifying and managing derogations. The KSAR will seek assurance from Health Boards that any derogations have been fully reasoned, transparently discussed and the implications understood, recorded and signed off by relevant members of the Health Boards and their Project Teams.

193. For example, the KSAR will probe whether a Health Board can demonstrate a derogations process flow. The Health Board would typically be asked to provide evidence to demonstrate how they assess derogations, how they record them, how they assess them and ultimately who (within the Health Board) approves them. The KSAR process will also seek assurance that Health Boards have considered safety, risk, and reliability in their derogations assessment. We require assurance that the Health Board is not going to compromise the safety or the reliability of a particular service. We would further look to assess how the Health Board defines supporting mitigations, where they have identified risks or where they believe they demonstrate compliance by another manner.

194. Often, one person alone in the Health Board may not have the required knowledge and competency to assess all facets of a particular derogation. It is therefore important within the KSAR process to assess who has reviewed and approved any derogation within the Health Board and who has been consulted in the process. Given the complexity of a healthcare project there needs to be a collaborative effort across all the stakeholders. It is important that competent people are used in assessing the derogation. That includes engagement with relevant technical subject matter experts such as IPC colleagues, clinical colleagues and finance colleagues.

195. Not all derogations will require full input or review from IPC teams, however we would seek assurance that Health Boards have reviewed whether a derogation may result in a consequential impact on infection control measures or risk assessments. If the derogation does impact on these control measures or risks, then I would expect IPC colleagues to be fully consulted on the derogation.

196. There are dedicated questions within the KSAR workbooks that look to probe the derogations process on a project.

197. Different Health Boards take different approaches to management of derogations, as often the approvals process will be linked to their own internal governance structures. For example, Health Boards may have different roles within their Estates Departments and job titles might be different. Ultimately, what the KSAR is looking for is assurance that the Health Board's derogations process is encompassing of all relevant stakeholders.

Evaluation of Commissioning Plans

198. As noted earlier in this statement, "guidance" is not necessarily mandated, however it can become mandated through a contract, or where it is related to a statutory process. An example of the latter would be the electrical testing required to meet the requirements of the Building Standards Technical

Handbook. If it is not a statutory requirement, we would typically consider the guidance to be described as good practice.
Recommendations for commissioning may be contained within a SHTM or other relevant industry guidance, for example through Commissioning Codes published by CIBSE.

199. Another example of a “mandated” commissioning process would be those linked to processes such as receiving an occupation certificate, for example, from Building Control. There may be commissioning activities required in order for a Health Board to meet legal requirements – for example the Control of Substances Hazardous to Health Regulations 2002 (COSHH).

200. The KSAR process seeks assurance as to how a Health Board has outlined its requirements for commissioning. This begins at an early stage of a project (it is considered from the OBC KSAR workbook onwards) and a Health Board should be able to demonstrate that as its project progresses through the respective RIBA stages, the level of detail in support of the commissioning proposals increases. It is important to seek assurance on the commissioning of a facility from an early stage, as it could have a fundamental impact on buildability and the ability to comply with the required/recommended technical standards. The KSAR would also consider whether roles and responsibilities associated with commissioning have been defined by the Health Board.

201. We often see projects engage a specialist commissioning manager whose role it is to oversee the commissioning process. Responsibilities under such a role would include (but not be limited to) coordinating activities, to make sure that they were appropriately sequenced, looking at programming and looking at the types of parties that may need to be involved in the commissioning . The most recent CIBSE guide for commissioning management “Commissioning Code M: Commissioning Management”, which was published in 2022, **(A47201177 – Commissioning management - Commissioning Code M (2002) - Bundle 13, Volume 4, Page 1335)** promotes engagement with a specialist commissioning manager from an early stage of the project. Historically, it was common that this role would not be appointed until much later in a project. The

importance of the role has evolved over time and is now recognised through other industry bodies' guidance.

202. It is the responsibility of the Health Board to demonstrate how it proposes to resolve any ambiguities we identify through the KSAR. If 'document A' is competing with 'document B', then this would be recorded as an observation within the KSAR report. Our recommendation would be that the Health Board should assess and demonstrate how it is responding to that ambiguity. Depending on the nature of the observation, we may be able to make a more specific technical observation. Ultimately, the responsibility for the resolution would sit with the respective Health Board and its Project Team.

Environmental Matrices, ADB, Room Data Sheets and CEL 19 (2010)

203. The use of an environmental matrix is not something that is mandated in SHTM Guidance. An environmental matrix is a tool that can be used by designers and contractors to develop various engineering solutions and strategies, including input into calculations. Where there are a number of designers using spreadsheet-based calculations, they can utilise data from an environmental matrix in their manipulation and assessment of particular figures. NHS Scotland Assure does not consider an environmental matrix to be a direct equivalent to ADB, because the ADB contains more than just engineering information. The ADB is used to inform an environmental matrix. An environmental matrix is referenced within the KSAR workbook as it is a tool we often encounter in projects.

204. I have been asked if RDS produced using ADB is now a mandatory briefing tool for all projects. The use of the ADB is mandated. It is a database from which information can be obtained to populate a RDS, which would in turn become a project-specific document. The ADB will contain a lot of information relative to various different technical standards and requirements. It is not limited to engineering technical data. The Health Board should look at how that information matures into a project-specific requirement and the ADB should be

used in conjunction with all other relevant technical guidance, and not in isolation.

205. Where an environmental matrix is provided by a Health Board as part of the KSAR response, NHS Scotland Assure would not undertake a full line-by-line check on the environmental matrix. As stated previously in this statement, it is not within the scope of our service to act as ‘a shadow design team’ in that respect. Our role is to assess the Health Boards’ processes in setting up the document, which includes an assessment of its quality control and assurance processes. I fully acknowledge that to make a mistake is only human. However, if you have a robust quality control process then that reduces the potential for such errors to go undiscovered. The KSAR would consider for example, whether the Health Board and its Project Team were implementing a peer-checking process followed by a review and approval process, by appropriately competent individuals. If the data were reviewed on multiple levels then the probability of an error going unidentified reduces. Ultimately, if a Health Board has a robust and iterative quality control process in place at each stage of the design, this goes a long way to reducing the potential for an error to go unspotted.

206. I am aware that there has been evidence presented to the Inquiry to suggest that there is the potential for transcription errors in environmental matrices. However, I would stress again that the role of NHS Scotland Assure is to seek assurance from the Health Board that it has in place appropriate quality control processes to minimise the potential for such errors to occur.

207. During a KSAR, NHS Scotland Assure will consider the tools used by a Health Board in informing their project requirements, including room data sheets and, where provided, environmental matrix type documents. We will identify a core sample for review based on the size and complexity of the facility, with a particular focus on key/critical clinical areas. This will help to inform our more detailed assessment of the technical strategies presented in relation to the other KSAR workbook questions or topics.

208. I have been asked by the Inquiry if I can explain what information is required regarding stakeholder input into ventilation strategies. From a KSAR perspective, NHS Scotland Assure would look to understand how the Health Board had defined the requirements for particular rooms. We would seek assurance from the Health Board that its briefing requirements had been developed relative to the patient cohort and room function and that multi-disciplinary stakeholder input had been provided. Typically, we would expect the clinical and IPC stakeholders to have helped to inform the room briefing requirements, then to see these developed into technical solutions by the design team members (not just from a ventilation perspective, but for other engineering services, architecture, acoustics, fire safety, etc). We would seek assurance that all facets of the design were being developed in a co-ordinated manner and that this could be demonstrated at each stage of a project. As noted previously, this could include the development of ADB into project specific room data sheets or other documents, such as an environmental matrix. The Health Board should be able to provide assurance it has in place a coherent and co-ordinated approach for developing the requirements for the particular space with all relevant stakeholders. The KSAR would also seek assurance that ventilation strategies had been reviewed and approved by the relevant stakeholder groups, such as the Ventilation Safety Group, clinical and IPC colleagues, estates colleagues, and others.

209. I have been asked by the Inquiry whether, where a room function is required, would it be a clinician and / or an IPC professional who would provide input on the patient group and function. I would expect both a clinical representative and an Infection Control professional to be involved in defining requirements. The KSAR workbooks and the types of evidence they call for stress the need for this collaborative approach. The KSAR would, for example, seek assurance that a clinical lead had approved the room requirements, but also seek assurance that IPC had been engaged in the process – this could be in the form of identifying the lead Clinical Consultant and the IPC Doctor/Nurse. A healthcare building is complex.

It is important that all the stakeholders come together at a point in time to assess the requirements as a collective and not in isolation. That helps make sure that there are no unintended consequences as a result of reaching a decision in isolation.

210. The Inquiry has brought to my attention that the KSAR workbooks state that CELs need to be complied with and that it is mandatory to use the Activity Database. The Inquiry has asked me why is ADB mandatory? I was not involved in the formation of the CEL so I cannot comment on that.

Guidance

211. The Director for NHS Scotland Assure is ultimately responsible for the duties that we discharge. NHS Scotland Assure produces guidance covering many different topics and dependant on the nature of the topic, the formation of individual pieces of guidance will be led by different divisions of NHS Scotland Assure relative to their specialism.

212. In my role as Head of Engineering I manage and direct the production of technical engineering documents within NHS Scotland Assure, for national use. This includes identifying appropriate best practice and priority actions. I look to develop and implement national strategies, guidance and operational policies to ensure that publications are accurate. That work primarily relates to the SHTMs, with a particular focus on the engineering suite of documents. Those documents in the main pertain to electrical services, water services, ventilation, and medical gas systems. There are also a number of specialist SHTMs including lifts and pressure systems.

213. The Head of Engineering is the corporate record owner for the engineering SHTM guidance within NHS Scotland Assure. NHS Scotland Assure has its own corporate governance protocols for updating guidance, with associated timescales. My role is to make sure that we, as a department, are fulfilling our role in terms of guidance update cycles. In practice, it is my role to co-ordinate the delivery programme to ensure that guidance is updated timeously.

214. The Principal Engineering Managers effectively take on the day-to-day role of managing the actual development of individual pieces of guidance documentation relative to their engineering specialism.

215. NHS Scotland Assure is the primary technical author of the engineering guidance we produce. We maintain overall responsibility for that guidance. Our approach, when it comes to updating engineering guidance, is very much a collaborative one. By way of a particular example of our processes, SHTM 06-01 is for electrical services. The specialist electrical Principal Engineering Manager will oversee the development of that document and I will liaise regarding the programme required. I will also make sure that we are following our own internal governance protocols and working with the NHS Scotland Assure Information Officer, to ensure that we have supporting paperwork in place. We discuss how we are going to engage with the wider stakeholder network and work through the development cycle associated with reviewing, updating, and getting the guidance document approved.

216. NHS Scotland Assure works with the Scottish Engineering Technology and Advisory Group (SETAG) in the production of guidance. Underneath SETAG there are a number of National Advisory Groups. Those groups include the National Water Safety Advisory Group, the National Heating and Ventilation Group, the National Electrical Advisory Group, and the National Medical Gas Advisory Group. Those are the primary National Advisory Groups that contribute towards the development of guidance. Each of the groups contain subject matter experts from across all the Health Boards in Scotland. That structure makes sure that all the Health Boards have a voice in the development of guidance. The SETAG terms of reference also note “SETAG will be responsible for Health Facilities Scotland’s (HFS) range of operational engineering and technical guidance material, advice, training courses and seminars”.

217. NHS Scotland Assure also works very closely with our devolved nation healthcare colleagues in NHS England, NHS Wales and NHS Northern Ireland.

This is to help ensure a unified approach to the production of guidance. Historically, NHS England have typically taken the lead on producing a piece of engineering guidance, which would then be reviewed by NHS Scotland Assure (formerly HFS) and SETAG, to adapt to any specific NHS Scotland requirements. There can be nuances in the production of “local guidance” – for example as a result of Building Regulations in Scotland being different from Building Regulations in England. There are times when Scotland has taken the lead on pieces of guidance. It depends on where we are relative to the guidance document update cycle.

218. When a guidance document is produced in Scotland, NHS Scotland Assure will be responsible for delivery of the programme, supported by SETAG and the National Advisory Groups. We work with the devolved nations to identify, through collective dialogue, any additional expertise that we may require to produce a particular piece of guidance. Our aim is to make sure that the guidance is informed and technically accurate. We take a collaborative approach, which spans across both industry and academia. This may include engagement with research partners, academic partners, and partners from industry, to support the production of a particular guidance document.

219. When producing engineering guidance, NHS Scotland Assure will undertake a scoping exercise in conjunction with Health Boards and other key stakeholders, to identify any areas that need to be changed or clarified within the guidance. The scoping exercise is important as it allows Health Boards an opportunity to share their knowledge in relation to the guidance’s practical application and what they have learned. We sometimes must update guidance to reflect changes in statutory requirements or where new standards have been identified. At other times we require to update guidance where there has been an unintended consequence due to the last piece of guidance.

220. After the scoping exercise is complete, NHS Scotland Assure, in conjunction with SETAG, will assess who is the most appropriate author to write or amend a section. Following the section being drafted or amended, NHS Scotland Assure will then undertake an internal quality assurance process.

221. Through that process we work with colleagues to undertake accessibility checks and review the technical accuracy of the document. The document would then be put to SETAG, the NAGs and the identified stakeholder group for the particular piece of guidance, for review & approval prior to formal publication. It is my role, as Head of Engineering, to make sure that we are following the information governance protocols. As part of that I will review the content of the guidance and provide my feedback.

222. NHS Scotland Assure aims to review each piece of engineering guidance on a five-yearly cycle. That cycle has been significantly impacted due to the COVID response. The availability of stakeholders has been extremely limited. The updates for guidance were delayed when NHS Scotland Assure (formerly HFS), SETAG and the NAGS were focused on the pandemic response. Because of that we worked in conjunction with SETAG and the NAGs on a priority program to try and identify the priority for updating the existing suite of guidance documents. For example, SETAG and the NAGs identified that SHTM 03-01 Ventilation for Healthcare Premises was an immediate priority in 2021. That resulted in an interim version of SHTM 03-01 being published in 2022, with the support of SETAG and the National Heating & Ventilation Safety Advisory Group. Another example of a priority piece of guidance following the pandemic is that NHS Scotland Assure is currently working on SHTM 06-01 “Electrical Services Supply and Distribution”. That guidance is now eight years old. The wiring regulations (BS7671) have been updated and we hope to get a revised SHTM document to reflect these changes out as a priority in 2024.

223. I note that the Inquiry has heard that a lot of guidance, including SHTM-03-01, is open to interpretation. I have been asked if this requirement to comply with the guidance still leaves ambiguity in terms of what is required. My former colleague, Eddie McLaughlin, has previously noted to the Inquiry that compliance with SHTM guidance is not mandatory – I have also explained that within this statement. However, quite often it becomes mandated through a contract. Therefore, ambiguity is removed when the guidance becomes a contractual requirement. We assess the potential for ambiguity during a KSAR

by reviewing what the Health Board defines as the requirements for the project. We would assess the standards the Health Board sets for its designers, its contracting partners and anyone else who is involved in the project from a design and construction perspective.

224. Eddie McLaughlin has also said that it is not possible to produce guidance that can cover every particular scenario that may exist. I fully agree with that. There are a huge number of possible scenarios that exist within healthcare buildings and it would simply not be practicable to produce guidance to cover every possible scenario. In the course of a KSAR we will consider how the Health Board has applied the principles of the guidance. We look for any ambiguities, when they were identified and how the Health Board looks to address them. We will assess whether the Health Board has provided assurance that it is achieving its statutory requirements. If, at any point in a KSAR, we discover that something does not comply with the guidance, as currently written, we look to assess how the Health Board provides assurance that the resulting solution has not compromised the safety, risk, or reliability of that particular project.

225. On a project, should a Health Board indicate that extant guidance does not cover a particular situation, we would request assurance from the Health Board as to how it can make that assertion and request detail as to how it developed its technical proposals. This would also involve consideration as to whether the Health Board contacted NHS Scotland Assure for any clarification on the guidance, whether it sought to meet with the relevant NAG, or whether it considered other guidance that may be applicable to the topic. A review of the project contract is not within the scope of KSAR.

226. I have been asked by the Inquiry what processes are in place at NHS Scotland Assure to assist prospective tenderers to interpret guidance in relation to technical requirements and aspects of hospital builds. There are various mechanisms which Health Boards can use to approach us for support. One of our core functions is to provide Health Boards access to Subject Matter Experts to give support in technical matters of that nature. This function exists regardless of whether a project is going through a KSAR or not.

227. There are opportunities within a KSAR and the NDAP when a Health Board is setting out its briefing requirements where Health Boards can approach NHS Scotland Assure for support in developing them – the responsibility though remains with the Health Board.

228. NHS Scotland Assure aims to provide support to Health Boards and we always encourage a spirit of collaboration with them. The extent of support provided, particularly with respect to engineering services, can be either accessed directly via a Health Board request or via existing technical knowledge sharing platforms. For example, NHS Scotland Assure engineering and ARHAI colleagues attend NAG meetings, which have representation from various colleagues within Health Boards. NHS Scotland Assure also facilitates a Learning Network platform and regularly holds presentations within that forum to support the sharing of knowledge between Health Board colleagues. NHS Scotland Assure also works closely with Health Board colleagues on workforce development, where colleagues look to work with partner organisations, such as NHS National Education for Scotland (NES).

229. I have been asked what plans NHS Scotland Assure has in place to address and overcome issues where published guidance is open to interpretation. In response, I would re-emphasise the processes we have in place currently and how they are designed to provide Health Boards and wider stakeholders with an opportunity to collaborate in the production of guidance. Stakeholders must use the platforms available to them to share learning and to inform the future of guidance. I would also stress that guidance goes through a rigorous quality control process. The process involves the Health Boards and key stakeholders. If a particular individual can demonstrate to us that something can be misinterpreted, or could benefit from further detail, then that is considered by the cohort of subject matter experts that are assembled to create the guidance document. I would also reiterate that it is impracticable for guidance to cover every eventual scenario that may present itself on a project.

230. I have been told that the Inquiry has heard evidence that several parts of published guidance, including SHTM 03-01, are open to interpretation. As noted previously, it is not possible to produce guidance that is applicable to every circumstance. Engineering guidance documents typically frame a set of overarching aims and objectives to be achieved through the design, construction, commissioning, validation and operation of a facility. Sometimes guidance can be explicit if it is linked to a statutory requirement. Legionella and water, for example, have a set of standard tests that must be undertaken. In other cases that is not the case. Guidance should be implemented by appropriately competent people. That should be reinforced by Health Board's governance processes. The KSAR process seeks this assurance.

Authorising Engineer

231. Health Boards may also engage with their Authorising Engineers to support with interpretation of guidance. Typically, they would possess the required knowledge, experience and competence to advise on such matters. They may also be able to provide a Health Board with support in reviewing competencies of designers and/or contractors in relation to project appointments for their specialist discipline.

Design

232. I have been asked by the Inquiry what guidance is in place for prospective tenderers surrounding the use of the ADB system or its equivalents and how Health Boards can demonstrate, where equivalents are used, that it is of equivalent value. ADB is not something that falls under my core responsibilities. I do not actively provide any training or support around ADB. It would be other colleagues within NHS Scotland Assure who would look after that. Any questions with respect to engineering systems would either come to me or my team.

233. I have been asked by the Inquiry about CEL 19 (2010) and whether that will be updated. I cannot comment on what plans are in place around CEL 19 (2010)

and whether it is going to be reconsidered or refreshed. That would be an area that my colleagues in another part of NHS Scotland Assure would be able to answer.

234. I have been asked by the Inquiry what NHS Scotland Assure's position and practice is in relation to RDS produced using ADB and what work is being done to create standard rooms for Scotland. I have responded to the position on ADB earlier in this statement. NHS Scotland Assure in conjunction with the Scottish Property Advisory Group's (SPAG) sub-group Building Design & Construction (BDaC), are looking at repeatable rooms guidance. There is representation on that group from the Engineering and Property & Capital Planning teams of NHS Scotland Assure, in addition to the various Health Boards across Scotland. The production of repeatable rooms is important for a variety of different reasons, including whether it be from a repeatability, construction efficiency or compliance perspective.

235. I have been asked by the Inquiry what role NHS Scotland Assure has at the procurement stage in terms of assessing design and briefings for a project. The "procurement" stage of a project could mean several different things that range from a health board procuring an external design team, advisor or contractor through to the procurement of equipment, land or other assets. The NDAP and KSAR processes are designed to assess design and briefings for a project (irrespective of the procurement route of a project). This assessment will be based on the design development journey of a project as opposed to being centred solely on procurement.

The Grant Thornton Report

236. I have been asked by the Inquiry about the Grant Thornton report. I was not employed by NHS Scotland Assure at the time of the RHCYP build project and the level of my personal awareness about the Report is limited to recent dialogue with colleagues in NHS Scotland Assure.

My understanding from such dialogue is that NHS Scotland Assure has no record of receiving a copy of the Report out with the course of this Inquiry.

Would KSAR Have Prevented Events Surrounding RHCYP/DCN?

237. I have been asked by the Inquiry whether the KSAR process would have prevented occurrence of the issue of non-compliance with SHTM 03-01 on the RHCYP/DCN project. I would not be willing to say categorically "Yes, it would have." Although I am aware of some of the learning concerning the RHCYP/DCN project, I was not party to the project at the time. I can, however, explain what NHS Scotland Assure would do now to try and address the emerging learning from that project.

238. NHS Scotland Assure has, through the KSAR process, identified issues with ventilation on projects, including issues with air change rates. Some of those issues are simplistic in nature such as 'typos' in documents. Other issues have involved a lack of evidenced discussion and dialogue regarding the patient cohort. I would not wish to be arrogant by saying that we would have prevented what happened in Edinburgh by use of the KSAR process. I am not party to all the information relating to the Edinburgh project, therefore it is not possible for me to give a definitive yes or no answer.

239. It is worth reiterating that NHS Scotland Assure is not a shadow design team and we are not a checking service. We do not check every line of every calculation or document that is provided to us. We have neither the time nor the resources to do that in our scope of service. We consider, first and foremost, what assurance the Health Board have provided and whether they have robust protocols in place. We look for assurance around how they have assessed the patient cohort and how they have looked at what the actual functional clinical requirements of that space would be, in order to inform an engineering design. We consider if they have a clear and common understanding of that patient cohort and what they are going to require in terms of relevant guidance.

240. As a further example, we might be looking for things like project minutes or decision trees in support of this.

241. I noted earlier in this statement that the KSAR would also be used to look at the scrutiny and the processes that Health Boards have in place in terms of their own checking and validation. As much as it is not within the scope of KSAR to check every single line of a document or to check every line of calculation, it is someone's job to do that within the Health Boards' Project Team. We would be looking for assurance that the Health Board could demonstrate that it had been undertaken. From a quality assurance perspective, a process aligned to the principles of ISO 9001 (a certified quality management process) would be considered good practice. I would expect Health Boards to have some form of a self-check, a peer review, and peer approval. We would be looking for them to evidence this scrutiny, because the more robust that process is, the less likely it is that error will occur.

242. The importance of the initial briefing information must not be underestimated. That is particularly the case around the requirement from a clinical perspective as to what the facility is required to deliver. It is at this point that health boards and their project teams can identify the appropriate piece of guidance and how the project strategies required to be developed to comply with that guidance. That is where a Health Board can start to tell the story of the evolution of the design briefing information from the early-stage concept design, through to the detailed technical design and then, ultimately, into commissioning. That is why NHS Scotland Assure puts a lot of scrutiny into the briefing process. The more robust Health Boards' processes are, the more likely they are to achieve successful outcomes on their projects.

243. I have been asked by the inquiry if the procedures in place now are likely to eliminate any change that does not comply with guidance unless there is a risk assessment justification. In a high level sense we would look for Health Boards to be able to demonstrate the processes they have in place to prevent such an occurrence from arising. The KSAR workbooks are something a Health Board can use to complement their own processes.

Declaration

244. I believe that the facts stated in this witness statement are true. I understand that this statement may form part of the evidence before the Inquiry and be published on the Inquiry's website.