Scottish Hospitals Inquiry

Royal Hospital for Children and Young People/ Department of Clinical Neurosciences

Closing Statement by Counsel to the Inquiry

Hearing commencing on 26 February 2024 covering the period from financial close to the Opening of the Hospital

Introduction

1. These closing submissions cover the period from financial close until the opening of the Hospital. They seek to address the issues highlighted by the Chair in Direction 6. They do not repeat the points covered in our submission of 2 June 2023.

2. The closing submissions shall address:

    1. The task of the Chair and the approach to the evidence

    2. An overview of the themes which emerge from the evidence

    3. The list of topics

    4. The questions posed in Terms of Reference 1-12 ("the TOR")

    5. Potential recommendations

3. The Chair is invited to make findings in fact based on the analysis in sections 3 and 4. We have not included a separate section on findings in fact to avoid duplication.

4. In addition to the witness evidence and associated documentation considered at the hearing diet, a further five provisional position papers (PPPs) have been produced by

the Inquiry Team. A lot of detailed background information is set out in these documents. The PPPs, and the responses from Core Participants, should be considered by the Chair in addition to these closing submissions.

5. The submissions focus on the issue of ventilation (air changes and pressure parameters), which was covered at the hearings diet. Other ventilation issues that had the potential to impact on patient safety and care are set out in the Note to PPP 7. Other non-ventilation issues, concerning the built environment, that had the potential to impact on patient safety and care, are set out in PPP 7. The Chair is invited to find that the issues covered in PPP 7 and the accompanying Note had the potential to impact adversely on patient safety and care but were not the cause of the delay in the Hospital opening and that these issues have been rectified.

6. We wish to highlight at the outset that it is not the function of the Inquiry to make any determination about parties' rights and obligations, or to resolve disputes between them as to the meaning of documents, particularly the correct interpretation of contractual provisions.

Executive Summary

7. The genesis of the problems that ultimately resulted in the RHCYP/DCN not opening as planned was an error in a technical spreadsheet called an environmental matrix. The status of that document in the final contract is controversial. Ambiguity in the terms of the final contract contributed to a situation where there was a disconnect between what NHSL wanted the ventilation system to achieve and what the successful tenderer believed the ventilation system required to achieve. A misunderstanding as to whether the environmental matrix was a fixed brief (intended to form the basis for the design of the ventilation system) or a document upon which no reliance could be placed by IHSL, Multiplex and Wallace Whittle is at the heart of the matter. That issue continued to cause significant problems in the period after financial close.

8. The Project Agreement reflected the unresolved status of the environmental matrix. The matrix was included in it as a schedule, and the Board's Construction Requirements

prima facie required compliance with it. An express derogation in the contract excused that compliance because the matrix was known to feature anomalies. As reviewable design data, the matrix was, after financial close, to be submitted by Project Co (IHSL) to NHSL for approval. The schedule which gave the matrix status as reviewable design data suggested the matrix was part of Project Co's Proposals. By treating the matrix in part as if it were one of NHSL's requirements, and in part as if it were one of the contractor's proposals, the Project Agreement reflected the confusing presentation of the matrix in the tender documents.

9. This was an unsatisfactory basis for finalising the ventilation design. There was a lack of clarity in terms of whether the document was the brief or the design solution to the brief. The lack of a finalised document clearly setting out the technical requirements for the ventilation, at financial close, was at the root of the problems with the project. The project exemplifies the difficulties associated with making significant changes to technical specifications after financial close in revenue funded projects.

10. In the period after financial close, a dispute arose between NHSL and IHSL in relation to the pressure regime in certain rooms. The dispute was resolved and the resolution recorded in Settlement Agreement 1 ("SA1"). This clarified the pressure and air change rates to be achieved in the disputed rooms. NHSL were assisted by Mott MacDonald Limited ("MML") in drafting the technical schedule. However, MML informed NHSL that it could not take design responsibility for the revised solution set out in the agreement. Once again, there was a lack of clarity in terms of whether the parties were setting out NHSL's brief (for which it would be reasonable for NHSL to expect assistance from the technical advisors that had been engaged since the reference design stage of the project) or agreeing a design solution to that brief (which the technical advisors could not assist with without a change to their remit and a fundamental departure from the standard risk profile of the revenue funded model which places design risk with the project company).

11. It would be understandable for MML to refrain from taking design responsibility for the contractor's solution. It is less clear why MML would not take responsibility for a brief it was assisting a client to draft. That is particularly so given that MML had, at an earlier stage in the project, assembled the reference design documents and confirmed

(based on confirmation from Hulley & Kirkwood) that the environmental matrix complied with all relevant guidance, including SHTM 03-01. A situation appears to have arisen whereby NHSL considered it was getting technical advice and assurance from MML (albeit MML were not shadow designers and were not therefore taking full design responsibility) while MML considered it was not providing any such assurance as doing so would be contrary to the principles of the NPD model and would involve MML going beyond their remit.

12. This links in to a wider theme on the project. It was not always clear exactly what precise role MML were playing. In particular, it was not clear whether MML were providing NHSL with formal advice at various key stages of the project, including on the technical requirements set out in SA1.

13. NHSL's infection prevention and control team ("IPC") were heavily involved at the early stages of the project. The extent of their involvement post-financial close, the advice they gave on aspects of the project (if any), and the information basis on which they did so is, however, unclear and not formally recorded. IPC do not appear to have been consulted on the final technical solution agreed for the multi-bed rooms, or on the other ventilation technical solutions recorded in SA1. There was a failure to fully implement the "*partnership*" model of working, set out in SHFN 30, under which all relevant disciplines should be involved in key decisions on a project.

14. SA1 was signed on 22 February 2019. However, agreement in relation to the works to be carried out to the ventilation system was reached in 2018. The works on the ventilation system were completed by IHSL in 2018. On 31 January 2019, IHSL issued a letter stating that there was compliance with SHTM 03-01. The letter reflected NHSL's understanding of the position, subject to derogations of which they had been made aware for ventilation in the neutropenic ward and for the mixed mode strategy under which the recommended 6 air changes were reduced to 4. In those circumstances, and given the terms of the letter, it is not surprising that NHSL did not seek further assurance. The Chair may wish to consider whether some independent advice should have been sought on the technical resolutions in SA1 before it was signed or whether that would have been unnecessary and disproportionate.

15. SA1 was signed against a backdrop of financial pressure on IHSL. The company had significant debt obligations it required to service but, due to project delays, no regular income to service the payments. There was a risk of the company entering insolvency, which could ultimately have resulted in NHSL or the Scottish Government having to pay £150m for the hospital.

16. NHSL failed to follow the HAI-SCRIBE procedures. SA1 was concluded, and the hospital was handed over to NHSL, without the Stage 4 HAI-SCRIBE procedure being completed. The Stage 4 HAI-SCRIBE procedure should have been completed before handover. Further, the fact that SA1 involved technical resolutions to briefing and design issues, NHSL should arguably have gone back and completed the Stage 2 HAI-SCRIBE procedure.

17. The hospital was due to open on 9 July 2019. NHSL's IPC team insisted on seeing a report that confirmed compliance with SHTM 03-01 before they could complete the stage 4 HAI-SCRIBE. Testing was carried out by IOM Limited which identified that certain rooms in critical care did not have positive pressure and 10 air changes per hour. As a result of this testing, the stage 4 HAI-SCRIBE report could not be signed off at that time.

18. When steps were taken to complete the Stage 4 HAI-SCRIBE in June 2019, the issues with the hospital ventilation system were detected. Had the HAI-SCRIBE procedure been completed before SA1 was signed, there is the possibility that the issues with the ventilation system would have been detected sooner than they were (in February 2019 instead of June 2019). Therefore, the failure to follow the standard procedure can be viewed as a missed opportunity. However, by that point in time, the system had already been built. Earlier detection might have mitigated the disruption to some extent, but it would still have been necessary to carry out remedial works.

19. The Cabinet Secretary made the decision not to open the hospital on 4 June 2019. This was on the basis that non-compliance with SHTM 03-01 was equated with a risk to patient safety.

20. In the period that followed, a further settlement agreement was concluded. The final requirements for the ventilation system are set out in High Value Change Notice 107 ("HVC 107") and Settlement Agreement 2. HVC 107 and Settlement Agreement 2 required the ventilation system in the critical care and haematology/oncology bedrooms to achieve 10 air changes per hour with positive pressure. The final system was tested by IOM Limited and was found to be achieving these parameters. This is confirmed by Mr Maddocks in his expert report. The ventilation system fully complies with SHTM 03-01. The hospital provides a suitable environment for the provision of safe and effective patient centred care.

21. The Inquiry has seen no evidence indicating any deliberate concealment or failure to disclose wrongdoing. There were changes that were made to Guidance Note 15 of the environmental matrix. These changes were not expressly drawn to the attention of NHSL. However, the Chair is not invited to find that this amounts to deliberate concealment or a failure to disclose wrongdoing.

22. The issues on the project arose from a lack of clarity in the brief. The problems with the specification were not detected through the process of developing the ventilation solution, or when SA1 was signed. The issue was detected at a late stage, after handover, as the standard HAI-SCRIBE procedures were not followed before handover. However, the problems were identified, before patients were admitted to the hospital, as a result of NHSL's belated implementation of the HAI-SCRIBE procedure. The non-compliance with published guidance has been rectified and the hospital is safe for patients.

1. The task of the Chair and the approach to the evidence

23. We addressed the task of the Chair at paragraphs 24 to 32 of the closing submissions dated 2 June 2023. Those comments apply equally to this submission.

24. Many witnesses gave evidence by written statement and oral evidence. It is submitted that all witnesses were endeavouring to assist the Inquiry.

25. Mr Brian Currie, NHSL's project director, provided a written statement but was unable to give oral evidence. This was through no fault of Mr Currie, the NHS's Central Legal Office or the Inquiry Team. Mr Currie would likely have provided a counterpoint to the evidence of several other witnesses (particularly witnesses that worked for IHSL and Multiplex). As a matter of fairness, the Chair should bear this in mind when assessing the evidence.

26. A number of witnesses gave evidence in relation to the meaning of the Project Agreement and the two settlement agreements. Witnesses did this to seek to be helpful to the Inquiry and to provide context to the wider views expressed. However, while the views of witnesses on the intention behind certain provisions may be relevant to the issues the Chair requires to determine, we would respectfully submit that the Chair should disregard the subjective views of witnesses in relation to the meaning of various documents. These should be assessed objectively.

27. The Chair will require to consider contractual documents, including the Project Agreement and the two settlement agreements, to address the TOR. The Chair should avoid making any determination on any liability arising under any contract or otherwise (Inquiries Act 2005 (the "2005 Act"), section 2(1)). However, the Chair should not be inhibited in the discharge of his functions by any likelihood of liability being inferred from facts he determines or recommendations he wishes to make (2005 Act, section 2(2)).

2. Key Themes

28. The following Key Themes/ Issues emerged at the hearing:

    1. The lack of a clear brief set by NHSL

    2. The status of published guidance

    3. The interpretation of published guidance

    4. Compliance with published guidance

    5. The role of advisors

    6. The role of infection prevention and control

    7. Adequacy of Governance – NHSL

    8. Adequacy of Governance – Scottish Government

    9. The suitability of the NPD model

1. The lack of a clear brief set by NHSL

29. Many of the problems that arose after financial close resulted from events prior to financial close. The Project Agreement contained contradictory provisions in relation to NHSL's requirements. These issues became acute post-financial close. There was a lack of clarity in the relationship between the Board's Construction Requirements and the Environmental Matrix. This problem began at the procurement stage and continued after financial close through the reviewable design data procedure.

30. When the parties agreed a compromise to the dispute over pressure, there was confusion as to whether it was a change to the brief itself or a change to the solution to meet the

brief. Had the brief been clearly stated before financial close, such issues would not have arisen.

2. The status of published guidance

31. SHTM 03-01 is published guidance. It sets out a range of parameters for hospital ventilation, including pressure cascades and air changes per hour. There is no absolute legal obligation to comply with it. This was a matter of the parties' contract which contained ambiguous and contradictory provisions.

3. The interpretation of the published guidance

32. A common theme that emerged at the hearings was the difficulty of taking published guidance and requiring compliance with it in a contract. That is due to the fact that guidance can be open to interpretation and require difficult judgments to be made on what the guidance requires. Stating that there must be "*compliance*" with a document that is open to interpretation will not always provide sufficient certainty about the necessary requirements.

33. The Chair may wish to address whether the requirements of SHTM 03-01 for critical care and isolation rooms were ambiguous, and open to differing interpretation, such that this was at the root of the problems with the project.

34. Mr McKechnie had a particular interpretation of SHTM 03-01. Mr McLaughlin of HFS disagreed with the interpretation. Mr Maddocks also disagreed and accepted the description of Mr McKechnie's views as an outlier.

35. In our submission, Mr McKechnie's interpretation is difficult to reconcile with the natural meaning of the words used in the guidance. In our submission, the problems with the project did not arise due to a lack of clarity in the published guidance for critical care areas.

36. If, however, the Chair rejects this position and were to consider the guidance was reasonably open to different interpretations, he may consider that this issue was at the very heart of the problems with the project.

4. Compliance with published guidance

37. The version of SHTM 03-01 in force during the project was unclear about when a health board could depart from its recommendations. It was unclear about how any derogation should be assessed and documented, and by whom.

38. SHFN 30 Part B: HAI-SCRIBE sets out a 4 stage "HAI-SCRIBE" procedure. HAI-SCRIBE stands for "Healthcare Associated Infection System (for) Controlling Risk In the Built Environment". The procedure has been developed as a framework to identify, manage and mitigate issues in the built environment impacting on infection prevention and control risks. The stage 4 check requires to be completed before a hospital is handed over to a health board.

39. The Stage 4 HAI-SCRIBE was not completed by NHSL prior to the hospital being handed over. This resulted in NHSL accepting, and paying for, a hospital that it could not use.

40. NHSL still intended to complete the check prior to the admission of patients, albeit after handover. NHSL's justification for non-compliance with HAI-SCRIBE was that the hospital was already late, it was not sufficiently complete to allow the required checks to be carried out, and IHSL was in financial distress. By accepting practical completion, and handover of the hospital in its incomplete state, NHSL triggered its obligation to pay IHSL, alleviating the risk of the latter's insolvency.

41. This decision resulted in NHSL accepting a hospital that it did not know was safe for patients to occupy. When NHSL progressed with the Stage 4 HAI-SCRIBE assessment, after the hospital was handed over to NHSL, the issues with the ventilation system were identified.

42. The decision to accept the hospital without the Stage 4 HAI-SCRIBE being completed was made by NHSL without input from IPC personnel. The guidance in SHFN 30 outlines the need for a "*partnership*" approach (between clinicians, IPC, estates, and engineers, etc) on projects. This partnership approach was not achieved on all aspects of the project.

43. A general theme that emerges from the evidence is the need to follow set procedures – at the correct time – and to fully implement the partnership model. Otherwise, there is a risk that a hospital will be accepted by a health board that does not provide a safe environment.

5. The role of advisers

44. The lack of clarity on the role of advisors, and the lack of any clear procedure for instructing and recording advice from technical advisors, is a theme that emerges from the evidence. It is an issue that was highlighted by Grant Thornton in their report on the project.

45. NHSL appointed MML as technical advisers. NHSL considered that MML was providing a range of advice on technical issues after financial close. It is often difficult to identify precisely what MML was requested to do by NHSL, what MML were required to do, and what MML were actually doing, on the project during this period. In particular, it is difficult to discern whether MML were giving advice on key technical issues. NHSL's project team may not always have fully understood that MML considered it was providing a more limited level of advice and assistance on technical matters.

46. The agreement reached on the terms of SA1 is a good example of the confused position.

47. NHSL's position is that it was receiving advice and assistance on the requirements of SA1 from MML. Members of NHSL's project team thought that MML had confirmed that the technical solution set out in SA1 was adequate and appropriate.

48. MML do not accept that they were giving any technical advice on the adequacy of the solution recorded in SA1. MML accept that they were providing advice on compliance with SHTM 03-01 during the project. MML accept that they were assisting NHSL with *ad hoc* advice on technical issues after financial close. MML also accept that they assisted NHSL in drafting the technical schedule to SA1. However, MML maintain that they were not a shadow design team and could not provide NHSL with any assurance on the adequacy of the proposed design solution.

49. On MML's analysis, there was no technical advice or assistance provided to NHSL on the solution set out in SA1 as MML could not agree to take on design responsibility.

50. There are no clear, contemporaneous, documents that record what MML was instructed to do by NHSL in relation to SA1. NHSL considered that MML were providing technical advice and assistance. However, there is no clear instruction recording what advice was sought. Moreover, there is no clear record of any advice that was tendered.

51. The evidence indicates that there was a lack of clarity in relation to the role of technical advisors and of appropriate procedures for recording the instruction of technical advice and the advice received.

6. The role of infection prevention and control

52. IPC personnel were involved in the project. IPC were consulted in the context of the risk assessment process underlying SA1. However, they were not consulted on the technical solution documented in it or the way it was drafted. That is because SA1 was regarded as a commercial matter. As the issues were viewed as commercial rather than clinical or technical, IPC were not asked for advice on whether it would be appropriate to accept the hospital without the Stage 4 HAI-SCRIBE procedure being completed.

53. The guidance in SHFN 30 stresses that collaboration is key (Bundle 13, Volume 3, p464; 468; 470). A collaborative partnership needs to be at the heart of a multi-disciplinary team (p472). The lack of consultation with, and participation of, IPC in the documentation of SA1 and the decision not to complete the Stage 4 HAI-SCRIBE procedure before the agreement was signed are missed opportunities. Had the guidance

in SHFN 30 been followed, and had IPC been engaged in the decision-making process around SA1, the problems with the ventilation system could potentially have been spotted at an earlier stage.

54. A wider theme that emerged in the evidence was an acute shortage of IPC personnel. IPC are increasingly being asked to take a more active role in aspects of the built environment. However, there is a shortage of staff to undertake these roles.

55. There is no role specification as to what is required from IPC on projects. IPC staff often feel they are being asked to undertake inappropriate tasks for which they have no specific knowledge or training.

7. Adequacy of Governance – NHSL

56. NHSL had a governance structure in place that complied with the set requirements for a project of this nature. This was not a situation where there was no oversight or governance. The Chair will wish to consider whether there was sufficiently robust challenge to key decisions.

57. The approval of SA1 is a good example. The settlement was approved by the Finance and Resources Committee and the Board of NHSL. Both took comfort from assurances purportedly provided by technical advisors. However, MML's position is that it was not acting as a shadow design team and was not able to take design responsibility for the design solutions in SA1. Statements that advisors were happy with the technical solution were effectively taken on trust with no paperwork or reports provided to the governance bodies vouching statements concerning the technical advice purportedly being provided. This could, on one view, be viewed as a weakness in the governance and oversight procedures.

58. However, the only way that the problems would have been detected is if a full technical audit had been insisted upon by the governance bodies. The Chair will require to reflect on whether such a step would have been proportionate.

8. Adequacy of Governance – Scottish Government.

59. Scottish Government provided the finance for the project. It provided significant public funds for SA1. Significant further funding required to be provided to complete the HVC 107 and Settlement Agreement 2 works.

60. Scottish Government provided no challenge in relation to technical matters at the stage of SA1. This resulted in a situation where public funds were utilised to install a ventilation system for balanced/ negative pressure at 4 ac/hr with the system subsequently being replaced with a system that had positive pressure at 10 ac/hr.

61. The Chair will require to consider whether more should have been done by the Scottish Government. On one view, they could have asked Health Facilities Scotland ("HFS") to conduct a review in advance of providing funding. That could have potentially detected the issue. However, similar issues arise in relation to the governance by NHSL. The only way that the problems would have been detected is if a full technical audit had been insisted upon by the governance bodies. The Chair will require to reflect on whether such a step would have been proportionate given the respective split in roles between NHSL (which had overall responsibility for the project and technical compliance) and the Scottish Government (which had overall responsibility for the NHS but its key role on the project was financial rather than technical).

9. The suitability of the NPD Model

62. A key theme is whether the NPD model, and revenue funding in general, are appropriate for healthcare projects. The substantial risk transfer to the private sector under a revenue funding model includes a large element of design risk, but this transfer may transpire to be more theoretical than real. Further, it is difficult to make changes to specifications after the contract is concluded, as this project demonstrates. That is due, in part, to the complex structure involving the project company, sub-contractors and lenders. Such difficulties may arise for reasons unassociated with an incomplete brief at financial close – such as developments in healthcare science. Several witnesses gave evidence indicating that, in their view, the NPD model is unsuitable for healthcare projects. The Chair will require to consider whether the funding structure contributed to the issues that arose on the project.

3. List of Topics

63. We address in this section the findings that the Chair is invited to make in relation to each topic.

1. The development of the design of the ventilation system for critical care rooms and isolation rooms in the period after financial close (February 2015)

64. Much of the detailed background to this topic is set out in PPP 8 and the Core Participants' responses to it. This section of our submission may be more readily understood with the benefit of having read those first. Our submission takes account of those sources, together with the witness statements supplied for the 2024 hearings and the oral evidence heard at them.

1.1 The input (if any), provided by Clinicians, Infection Prevention and Control (IPC), Estates, and Technical Advisors, in relation to the design of the ventilation system for critical care and isolation rooms, in the period after financial close.

65. As discussed in sections 1.2 to 1.4 below, NHSL clinicians, members of the NHSL IPC and Estates Teams, and NHSL's technical advisers (MML), were involved in the development of the ventilation design in the period after financial close.

66. As discussed in section 1.3 below, they were involved in the development of the technical solution for multi-bed rooms.

67. *Clinicians:* when NHSL risk assessed the pressure regime in multi-bed rooms, it consulted its clinicians. They expressed a preference for balanced or negative pressure. There is no indication that they expressly considered or were asked to advise upon the air change parameter.

68. *The IPC team:* NHSL appear to have consulted an IPC team member when considering the appropriate pressure regime for multi-bed rooms. There is no formal or clear record of what she was asked to advise upon or what advice she gave, except to address the question of whether multi-bed rooms were, for the purposes of applying SHTM 03-01

guidance, akin to single rooms or general wards. There is no indication that she was aware the rooms in question included rooms in the critical care department or that she was asked to advise upon the air change parameter. She could not, by July 2019, remember having been asked to advise on ventilation in the critical care department (Bundle 7, volume 1, page 123). There is therefore no indication that IPC were asked to consider the core question, of the air change rate needed for clinical purposes in the critical care multi-bed rooms.

69. Neither the clinicians nor the IPC team appear to have participated in correspondence or meetings with IHSL, Multiplex or Wallace Whittle about the development of the technical solution for pressure in the multi-bed room. NHSL were represented in that correspondence and those meetings by members of their project team[1], their estates team, and by their technical advisors, MML.

70. NHSL's IPC team was not consulted about SA1 or the way in which the technical ventilation solutions were expressed in it (Goldsmith, Transcript, 49; Inverarity, Guthrie).

71. *The Estates team*: were involved throughout the process. This included Mr Henderson being sent a copy of the 2017 risk assessment when he was informed by email that one of the rooms was in critical care (Bundle 13, vol 8, page 449). Estates were involved in the development of the ventilation system throughout the project but did not spot the non-compliance with SHTM 03-01.

72. *Technical advisors*: provided input primarily by way of a sample review of the reviewable design data. Engineers (including Colin MacRae) and project managers (including Mr Greer) attended meetings and were copied in to key correspondence regarding the development of the design. While MML were involved in the process, it is not clear precisely what advice (if any) they were providing. Moreover, there is a lack of contemporaneous documentation as to what they were instructed to do, and what advice (if any) they provided.

[1] NHSL's representatives at these meetings included the project clinical director, Ms MacKenzie, but not the clinicians she had consulted in relation to the risk assessments.

1.2 The development of the environmental matrix in relation to critical care and isolation rooms, including changes made to guidance note 15.

Development of the environmental matrix generally

73. At financial close, both the ventilation design and the environmental matrix were unfinalised and subject to the contractual process for reviewable design data ("RDD") (2023 Bundle 5, pages 860, 869).

74. The contractors and designers (Multiplex and Wallace Whittle) expected review of the environmental matrix to be limited to the points recorded against it in the Project Agreement. They were surprised by the range and number of comments made about it by, and on behalf of, NHSL. That surprise reflected their understanding that the environmental matrix constituted NHSL's brief on the matters it contained. They understood NHSL in substance to be changing their brief.

75. Under the terms of the Project Agreement's reviewable design data procedure, the only contractual effect of NHSL's approval was to confirm that the approved item satisfied NHSL's requirements for Operational Functionality. Operational Functionality is a concept defined by the Project Agreement and is limited in scope (Bundle 5 for the 2023 hearing, page 167). Put short, it is concerned with the layout of the hospital insofar as it bears upon its use for the health board's services. The limited effect of NHSL's approval reflects the fact that under an NPD contract, design risk (including responsibility for ensuring compliance with applicable guidance) rests with the project company.

76. Mr McKechnie, the lead for Wallace Whittle's design team, was unfamiliar with the concept of Operational Functionality – as defined in the Project Agreement - until asked about it by the Inquiry. He did not realise that NHSL's approval under the RDD process was limited to it. Rather, he treated NHSL's approval as confirming, in a much broader sense, that they were happy with the proposals: as "*an acknowledgement by the client that what we were putting forward met with their expectations*" (Transcript, page 6). Mr Hall of Multiplex had a similar understanding (Transcript, page 130 to 132). Mr Pike of Multiplex was familiar with the concept of Operational Functionality but still

saw the RDD process as in part confirming NHSL's agreement to parameters such as air changes (Transcript page 10 to 26). Mr McKechnie saw himself as engaged in a process of attempting to clarify what NHSL wanted and was frustrated by the number of comments made on the matrix and the number of revisions it went through without reaching a finalised form.

77. NHSL, and their technical advisers MML, approached the RDD process with an attitude which more closely reflected the design risk allocation of the Project Agreement. In particular, they noted that NHSL's approval was limited in its effect to matters of Operational Functionality. Notwithstanding the origins of the environmental matrix in NHSL's reference design, they did not regard it as NHSL's brief, but as part of IHSL's design response to that brief. They considered themselves free to comment on the matrix, including to highlight what they considered to be non-compliances with SHTM guidance, but did not consider themselves obliged to do so or as being in any way responsible the compliance of its contents with guidance. In the words of Mr Greer of MML, they intended these comments to be "*helpful pointers*".

Development of the environmental matrix: Guidance Note 15

78. In the particular case of rooms in the critical care department, the environmental matrix at financial close contained an inherent ambiguity. The room-specific entries for multi-bed and single rooms in the critical care department specified an air change parameter of 4 per hour (2023 Bundle 5, page 1454 onwards). The matrix also, however, included a guidance note (number 15) which read, inter alia:

> "*Critical care areas – Design Criteria – SHTM 03-01 – Appendix 1 for air change rates – 10ac/hr Supply …*".

79. In the course of the RDD procedure, in a revised version of the environmental matrix dated 26 November 2015, Wallace Whittle amended that guidance note by adding the words "*for isolation cubicles*" (Bundle 13, volume 2, page 101).

80. The effect of this was to limit the requirement for 10 ac/hr from critical care areas generally to isolation cubicles only. Unlike other changes to the matrix made by

Wallace Whittle at the same time, this change was not highlighted in red text. According to Mr McKechnie, the change reflected his understanding of the guidance (that is, that the recommended parameters for critical areas in Appendix 1 of SHTM 03-01, including the recommended 10 ac/hr, applied only to isolation rooms) (Mr McKechnie, Transcript, from page 28). Therefore, as far as he was concerned, Mr McKechnie was tidying up the guidance notes to ensure that the wording matched the proper construction of the guidance set out in SHTM 03-01.

81. In our submission, this is not a satisfactory explanation for proceeding in this way. Even if Mr McKechnie's interpretation of the guidance was a reasonable one (and we submit that it is difficult to reconcile with the natural meaning of the words used), there is no good reason for Wallace Whittle to have treated this change differently from others.

82. By highlighting other changes but not this one, Wallace Whittle created the impression there had been no change to the guidance note and thereby prevented NHSL and MML from being aware of it. The change was on any view significant, since it removed an important contradiction from the matrix. By proceeding as they did, Wallace Whittle denied NHSL the opportunity to consider at that relatively early stage whether they wanted 10 air changes for the critical care rooms (as per the guidance note) or 4 (as per the room specific data).

83. Even if one accepts Mr McKechnie's interpretation of the guidance to be correct, the guidance was plainly open to the opposite interpretation (that the recommendation for critical care areas was not confined to isolation rooms) and by proceeding as they did Wallace Whittle closed down an opportunity for NHSL to consider which interpretation of the guidance they preferred. Mr McKechnie (and Mr Hall) relied upon correspondence about isolation rooms as supporting Wallace Whittle's amendment of the guidance note, but there is nothing in that correspondence to justify a conclusion that NHSL (if asked) would have resolved the contradiction in the matrix by selecting 4 air changes in critical care rooms (Mr McKechnie, Transcript, pages 40 to 45); Mr Hall, Transcript, page 123).

84. Wallace Whittle's decision to make this change unilaterally is difficult to reconcile with their position that the environmental matrix was a fixed client brief. Mr Maddocks gave

evidence indicating that a client brief should not be changed without the approval of the client.

85. Wallace Whittle do, however, appear to have made the change in good faith, based on their understanding of NHSL's wishes and the guidance (McKechnie, Transcript, page 36).

86. Development of the environmental matrix thereafter proceeded in a generally unsatisfactory way. Wallace Whittle were frustrated by what they perceived as the difficulty in getting NHSL to confirm their agreement to its parameters. NHSL and MML were frustrated by what they perceived as a failure by Wallace Whittle to bring the parameters into line with those recommended by guidance. The most serious disagreement in this regard concerned the pressure arrangements for multi-bed rooms, which is discussed more fully in section 1.3 below.

Air change parameter for rooms in critical care left unchanged

87. Importantly, throughout the development of the environmental matrix after financial close, there was no active disagreement over the air change parameter for rooms in the critical care department. For single and multi-bed rooms in that department, the room-specific sections of the environmental matrix throughout specified 4 air changes per hour. Given Mr McKechnie's interpretation of the guidance (that its recommendation of 10 air changes per hour and 10 pascals of positive pressure applied only to isolation rooms), he did not consider there was any reason to change it. Despite the scrutiny applied by NHSL and MML to the contents of the environmental matrix, the detailed comments they made about it, and the fact that those comments included concerns about the matrix specifying parameters which were non-compliant with SHTM 03-01 guidance, they never raised any concern about the air change parameter for the critical care rooms.

88. When (during the procurement phase) the reference design documentation was produced, MML had confirmed that the documentation complied with published guidance, including SHTM 03-01. Despite (during the post-financial close phase) having identified a purported non-compliance with published guidance, no thought appears to have been given to whether there may have been more extensive errors in

the environmental matrix. It appears that NHSL simply assumed that all other parameters, including air changes, were correctly specified in the environmental matrix (Bundle 7, vol 3, page 143).

89. NHSL and MML seek to explain this on the basis of the risk allocation of the Project Agreement, under which responsibility for the design and its compliance with applicable guidance rests with IHSL: they emphasise that it was not their responsibility to detect any non-compliance. They also rely on an interpretation of the Project Agreement under which the environmental matrix included in it was not to be read as their brief but as a contractor's proposal for meeting it. In other words, any non-compliance with guidance which went undetected by NHSL or MML, in contractual terms, remained IHSL's problem to resolve.

90. In our submission, NHSL may well be correct in this interpretation of the Project Agreement (although it is not for this Inquiry to definitively resolve that question). There is, however, an air of unreality about it given the origins of the environmental matrix in NHSL's reference design, the way in which it was used in the procurement process, and the fact it was embedded in the Project Agreement.

91. NHSL may also be correct, in contractual terms, to say that their approval of items submitted under the RDD process was confined to a confirmation that it met their requirements for Operational Functionality and that, despite that limitation, they were nonetheless entitled to make other comments about the matrix and the ventilation design without altering the risk allocation of the contract. The wider point of significance to this Inquiry, however, in our submission, is that this approach (whether consistent with the contract risk allocation or not) failed to achieve what ought to have been achieved: a hospital which at handover was indisputably compliant with guidance.

92. In our submission, the operation of the RDD process in relation to the environmental matrix and the ventilation design was unsatisfactory. The parties approached it at cross-purposes. The matrix was an important foundation for the ventilation design yet remained under constant review and its contents were a source of contention. The ambiguity and confusion about its status that began during the procurement process persisted through the period after financial close. Whatever the correct interpretation of

the Project Agreement (which is not a matter for this Inquiry to resolve), the provision by NHSL of an environmental matrix which had been prepared for them, and its inclusion in the Project Agreement, was apt to lead to its adoption as a starting point for the design and to the understanding that it reflected NHSL's wishes about the way the hospital would be used.

Wallace Whittle checked environmental matrix for compliance with guidance

93. It should be noted, too, that Wallace Whittle maintain that they checked the environmental matrix for compliance with guidance, and concluded that it was compliant (Mr McKechnie, Transcript, page 23). Indeed, on the most controversial issue (the air changes required in the critical care department multi- and single-bed rooms), Mr McKechnie maintains even now that 4 air changes was compliant with the guidance. Given that position, a different outcome could only have been achieved on the RHCYP/DCN project if NHSL had specified, whether in the environmental matrix or during the process of reviewing it, that they wanted 10 air changes in those rooms, and insisted upon it over the views of Wallace Whittle. They had the opportunity to do this – Wallace Whittle sought a line-by-line review of the matrix with NHSL/MML to "*agree that the parameters that we had then recorded in the matrix was the client's brief*" (Mr McKechnie, Transcript, page 81; Hall, Transcript, page 154; PPP 7, Bundle 11, page 217), but that offer was declined by MML on behalf of NHSL. That was a decision to trust in the designer to comply with the guidance, and (insofar as the guidance was open to interpretation) to accept the designer's interpretation of that guidance. That approach was consistent with the design risk allocation under the NPD Project Agreement and is therefore defensible in that context. It is, however, more difficult to defend in the wider circumstances of NHSL having put the environmental matrix into circulation in the first place. It contributed to the failure to detect the air change issue until after the ventilation system had been installed and the hospital handed over to NHSL. This issue links in to the wider theme of whether the NPD model is suitable for healthcare projects.

94. We submit that Mr McKechnie's interpretation of SHTM 03-01 (that the entry in Appendix 1 for critical care areas applies only to isolation rooms) is difficult to reconcile with the language used. However, the chair may consider there to be some

force in the view that nothing in SHTM 03-01 compelled a change from the ventilation parameters set out in the environmental matrix for the critical care single and multi-bed rooms. That is because SHTM 03-01 is guidance for health boards which they were free to depart from in the exercise of their own judgment. Accordingly, if one proceeds (as Mr McKechnie did) on the basis that the environmental matrix set out NHSL's preferences it is, perhaps, legitimate to say that SHTM 03-01 did not compel a change from them, even if they were not consistent with the recommendations which it made. This raises the question of whether or not it is meaningful for a contract to require compliance with guidance which is not, in and of itself, prescriptive.

Single rooms

95. The environmental matrix at financial close made provision for 4 ac/hr in single rooms, including those in the critical care department (2023 Bundle 5, page 1454). A derogation for single rooms was agreed in SA1 (Bundle 13, volume 1, pages 797 and 805, Item 13). The derogation is from 6 ac/hr to 4 ac/hr. It is not therefore intended as a derogation from the SHTM 03-01 recommendation for critical care areas (for which the recommendation is 10 ac/hr). The derogation is justified by the mixed mode ventilation philosophy, which was based upon the availability of openable windows to provide a passive means of ventilation. Such an approach was not suitable for the critical care department.

96. There is disagreement about whether or not the derogation applied to rooms in the critical care department. This is a matter of contractual interpretation, which it is not for the Inquiry to resolve. Mr Pike of Multiplex was unable to identify anything apart from the wording of the derogation itself to confirm it was intended to apply to rooms in the critical care department (Transcript, page 46). The fact that the purpose of the derogation was to confirm the basis on which 4 ac/hr had been selected for the single rooms may be seen as an indication that it was intended to apply to all single rooms for which 4 ac/hr had been specified (whether in the critical care department or elsewhere).

97. The position in relation to air changes in the single bed rooms therefore appears to be the same as for the multi-bed rooms (discussed in section 1.3 below): throughout the period after financial close, and until IOM Limited's inspection, nobody considered the possibility that single rooms in the critical care department were, by virtue of that

location, subject to particular ventilation parameter recommendations in SHTM 03-01; and the derogation was agreed in ignorance of that possibility (see, e.g., Mr Pike, Transcript, page 49). The single rooms in the critical care department were simply treated in the same way as single rooms outside of that department.

98. The environmental matrix at financial close made provision for the single rooms in critical care to have balanced pressure (2023 Bundle 5, page 1454). That was contrary to the recommendation of positive pressure made by SHTM 03-01 for critical care areas, and was reversed by HVC 107 (Bundle 1, page 2992). Our submission following the 2023 hearings addresses the origin of the balanced pressure requirement for the single rooms at paragraphs 154 to 160. We are not aware of the issue having been revisited after financial close, until Settlement Agreement 2.

1.3 Issues that arose concerning the pressure regime. In particular, risk assessments relating to the pressure cascades in four-bedded rooms in various different departments of the hospital and whether implications for critical care rooms were considered.

99. The financial close environmental matrix, which formed part of the Project Agreement, specified positive pressure for the multi-bed rooms throughout the hospital, including in the critical care department (2023 Bundle 5, page 1454).

100. NHSL wanted to be able to use the multi-bed rooms to treat children with similar infections in the same space. They considered that this clinical use required the rooms to be at negative or balanced pressure compared to the adjoining space. Such a pressure arrangement would tend to keep pathogens within the ward, whereas a positive pressure arrangement (all other things being equal) might spread them beyond.

101. Appendix 1 to SHTM 03-01 (2014) specified ventilation parameters for different room types. It did not include an entry for multi-bed rooms, but did include entries for single rooms and general wards. For general wards, no recommendation was made for the pressure arrangement. For single rooms, the recommendation was for balanced or negative pressure (Bundle 1, page 1173).

102. A debate arose between NHSL and IHSL about which entry applied to the multi-bed rooms. NHSL, having taken advice from HFS in June 2016 (PPP 8, Bundle 11, page 183, paragraphs 9.4.22 to 9.4.23), considered the multi-bed rooms to be analogous to single rooms (such that they were therefore subject to a recommendation for balanced or negative pressure). That view supported their clinical preference for such a pressure arrangement in the multi-bed rooms. IHSL considered the multi-bed rooms to be akin to general wards (such that they were subject to no recommended pressure arrangement, and that there was therefore no obstacle in the guidance to the positive pressure which had been specified in the environmental matrix).

103. This debate formed the basis for a serious dispute about the contractual requirements. In simple terms, the dispute was on the following lines. NHSL considered IHSL to be obliged to deliver the balanced or negative pressure, regardless of any contrary requirement being set out in the environmental matrix, because of the requirement in the Project Agreement to comply with SHTM guidance. IHSL considered that they were obliged to deliver the parameters specified in the environmental matrix even if they contradicted SHTM guidance. Wallace Whittle's view, furthermore, was that the parameters specified by the environmental matrix for the multi-bed rooms did not in any event conflict with SHTM guidance. IHSL were content to deliver the pressure arrangement which NHSL required, but the dispute bore upon who would carry the additional cost of doing so. IHSL therefore initially declined to progress development of a design for NHSL's preferred pressure regime until NHSL issued a formal change notice to that effect, which NHSL declined to do.

104. NHSL threatened litigation over this in March 2018 (Bundle 13, volume 9, pages 92, 96). The threatened litigation would have sought court orders against IHSL to produce a ventilation design for the multi-bed rooms which achieved a balanced or negative pressure arrangement in specified rooms, including three in the critical care department. (As the draft summons noted, the fourth multi-bed room in that department had already been designed with balanced or negative pressure.) The litigation sought interim orders to that effect on the basis that the project had already been delayed and that a design for the multi-bed rooms was necessary if progress was to be made. The basis for seeking balanced or negative pressure was articulated in the draft summons to

be the need to inhibit the spread of infection from the multi-bed rooms. The approach in the litigation was based on the position which had been developed in the NHSL project team with input from MML (Goldsmith, Transcript, page 7), and was supported by an affidavit from Mr Greer of that firm. NHSL's Finance and Resources Committee had approved litigation, the NHSL board was aware of it, and the Scottish Government were informed (ibid., page 15).

105. The threat of litigation was withdrawn following a proposal from IHSL on 22 March 2018, to which NHSL agreed, for balanced or negative pressure in fourteen of the multi-bed rooms, at 4 air changes per hour (Goldsmith, Transcript, page 29). A proposal along these lines had been under discussion at the project team level since January 2017 as the Wallace Whittle Multi-Bed Room Ventilation Amendment Proposal (McKechnie, Transcript, page 45 onwards; Bundle 13, volume 2, page 666 to 674). At a meeting on 24 February 2017, NHSL had identified the rooms in which it considered the pressure solution to be essential (including the four multi-bed rooms in the critical care department: Bundle 13, volume 2, page 686). Reflecting the high-level agreement reached in March 2018, the Wallace Whittle proposal was approved by NHSL at level A under the RDD process in July 2018 (Bundle 13, volume 2, page 1279 to 1282).

106. This technical solution to the multi-bed room pressure issue was one of many issues formally documented in SA1, which was executed in February 2019 at the culmination of a detailed negotiation and drafting process (Goldsmith, Transcript, page 29 onwards).

107. The issue at the core of the multi-bed room pressure dispute (that of which recommendation in the SHTM guidance applied to multi-bed rooms) is of some significance to this Inquiry, because it demonstrates that the recommendations made by the guidance can be open to interpretation and debate in the context of a particular project, at least when the parties specify a room type which is not in terms the subject of particular recommendations. The parties spent significant time and effort debating this point.

108. It is important, however, to recognise that that debate did not concern the particular issue which led the Cabinet Secretary to postpone the opening of the hospital (the number of air changes in the critical care rooms). That issue formed no part of the parties' dispute. Nor did the parties' dispute concern the particular question of the pressure gradient recommended for critical care rooms (positive, rather than the balanced or negative arrangement which the parties had agreed). The point of direct significance to this Inquiry is that the multi-bed room dispute led the parties to consider in detail the recommendations made by the guidance for the rooms in question, but did not lead them to identify that the guidance made particular, and different, recommendations for rooms in critical care areas, of positive pressure and 10 air changes per hour.

109. The reasons for this require some explanation. The short explanation is that no one involved in the development of the ventilation system after financial close drew any distinction between multi-bed rooms in the critical care department, and multi-bed rooms in other departments in the hospital; and there was no explicit discussion of the possibility that the former might be subject to a different recommendation in SHTM 03-01.

110. In our submission, the starting point is to note that no distinction was drawn in the environmental matrix between multi-bed rooms in critical care, and multi-bed rooms elsewhere in the hospital. The room-specific part of the matrix specified the same pressure and air change parameters for all multi-bed rooms, whether they were in the critical care department or not. That may have encouraged the belief that all multi-bed rooms were to be treated as normal patient bed spaces, whether they were in the critical care department or not. In other words, the environmental matrix may have encouraged the parties, when debating the issue of pressure in multi-bed rooms, to start and proceed from the assumption that all multi-bed rooms were the same. If this assumption was made, it is likely to have been reinforced by Wallace Whittle's unhighlighted amendment of guidance note 15.

111. The next important point, in our submission, is that NHSL sought the balanced/negative pressure arrangement in the multi-bed rooms for a particular clinical purpose: the cohorting of patients with similar infections. This was described by Ms

MacKenzie as a very common practice in paediatrics (Transcript, day 1, page 216). This was a clinical decision which an engineer would be unlikely to second-guess.

112. Further, NHSL conducted clinical risk assessments in support of their preference. In July 2017, Ms MacKenzie led a risk assessment into the use of positive pressure in the multi-bed rooms (as the environmental matrix then proposed) (Bundle 13, volume 8, page 449). She was aware that some of the multi-bed rooms under consideration were in the critical care department, and her risk assessment took explicit account of that (e.g., Transcript, page 220; Bundle 13, volume 8, pages 449 and 455). The risk assessment was explicit that it proceeded on the basis that the then current multi-bed room ventilation design, in providing for positive pressure, was not compliant with SHTM 03-01 recommendations. That statement was not correct for the multi-bed rooms in critical care if, as NHSL later came to consider, they were governed by the SHTM 03-01 recommendation for critical care areas. Ms MacKenzie's evidence was that the assessment took full account of the views of the children's clinical management team and had been discussed with (and approved by) Janette Richards (Rae) of NHSL's infection prevention and control team. The risk assessments were circulated to, amongst others, the NHSL Project Director Brian Currie, representatives of MML, and NHSL's commissioning manager, Ronnie Henderson. In the email circulating the risk assessment, Ms MacKenzie stated that at least one room was in critical care. According to Ms MacKenzie, none of the recipients (or, indeed, anybody) told her that, since some of the rooms were in the critical care department, they were subject to the SHTM recommendation of positive pressure which applied to critical care areas. Ms MacKenzie's recollection was that the statement in the risk assessment about the positive pressure regime for multi-bed rooms being non-compliant with SHTM 03-01 was based on advice from Colin Macrae, a mechanical and electrical engineer employed by MML, NHSL's technical advisers on the project (Transcript, Day 1, page 227; Day 2, page 1; statement, paragraph 20). The risk assessments gave no consideration to air change rates.

113. The risk assessments were reviewed in January 2018 (Bundle 6, page 14). The revised assessments proceeded on the same assumption that a positive pressure arrangement was not compliant with SHTM 03-01, including for multi-bed rooms in the critical care department. Again, they did not consider the air change rates.

114. NHSL therefore developed their requirement for balanced or negative pressure in multi-bed rooms in the critical care department having erroneously failed to take account of the fact that SHTM 03-01 recommended positive pressure for such rooms. There is no indication of MML pointing out the error.

115. There is no indication the risk assessments were shared with IHSL, Multiplex or Wallace Whittle (McKechnie, Statement, paragraph 54; MacKenzie, Transcript, Day 2, page 11; Henderson, Transcript, page 91).

116. Shortly thereafter, a MML table was circulated to members of NHSL's project team with extracts from the environmental matrix showing positive pressure and supply at 4 air changes per hour for the multi-bed rooms in critical care. The fact the rooms were in critical care was apparent from the use of the department code, B1, and the reference to them being in "PICU and HDU" (Paediatric Intensive Care Unit and High Dependency Unit) (Bundle 13, volume 5, page 1243).

117. Wallace Whittle responded to NHSL's requirement for balanced/negative pressure in the multi-bed rooms with a proposed solution for achieving it. This initially involved reducing the supply air change rate from 4 per hour (Bundle 13, volume 2, page 667; 31 January 2017). The proposal applied to rooms in several departments, including critical care. Whilst it did not explicitly say the rooms were in that department, that fact ought to have been readily apparent to anyone familiar with the project through the use of plans identifying the rooms' location and the "B1" department code used to identify the affected rooms (Bundle 13, volume 2, page 668). The proposal was circulated widely amongst the project teams, including to Brian Currie and Ronnie Henderson of NHSL, and Kamil Kolodziejczky and Colin Macrae of MML, and went through seven versions (Bundle 10, pages 179 to 182). There was a page within the environmental matrix that stated that B1 was the code for critical care (see, e.g., the financial close version: 2023 Bundle, volume 5, page 1460).

118. The designer and contractor team must have been aware that some of the multi-bed rooms under consideration were in the critical care department (not least because the documents dealing with the pressure proposal used the department reference "B1"

for the critical care department). The evidence of Mr McKechnie was that Wallace Whittle drew no distinction between the multi-bed rooms in critical care and the multi-bed rooms elsewhere in the hospital. Furthermore, he maintains that there is nothing in any guidance to require any different approach. On his interpretation, the SHTM recommendation for critical care areas only applies to isolation rooms and not to other bed spaces. Mr McKechnie has been consistent in his position: e.g., Bundle 7, volume 1, page 308, 11 July 2019. That interpretation of the guidance accounts for Wallace Whittle's failure to apply the SHTM recommendation to the critical care rooms.

119. It is not, however, clear that the rationale underlying Wallace Whittle's ventilation design was applicable to critical care rooms. A document prepared by them for Multiplex on 21 February 2017 concluded following a review of the design that the then-current designs for single rooms and multi-bed rooms were "*fully in compliance with SHTM 03-01*" (McKechnie, Transcript, page 60 onwards). It referred to the mixed-mode ventilation philosophy under which a mechanical air change rate of four per hour was combined with natural ventilation. As expressed in that document, that philosophy was based upon opening windows which were not appropriate for critical care rooms. That consideration does not appear to have influenced Wallace Whittle's approach.

120. Mr Greer's evidence was that the discussion around pressure in the multi-bed rooms proceeded on the assumption that all of the rooms, including those in critical care, were "*effectively normal bedrooms, all normal multi bedded rooms*" (Transcript, page 132). He accepted that his colleague, Colin Macrae, would have realised that some of the rooms were in the critical care department, and that he himself was copied in to correspondence in which that was explicit (ibid., pages 134, 137, 141). He did not recall any conversations to the effect that some of the rooms, being in the critical care department, were subject to different ventilation recommendations (ibid.). He pointed to the activities on the room data sheets for the critical care rooms being more akin to those expected in a normal bedroom, and to that being a difference from the activities listed in the ADB sheet for such rooms (ibid. page 133). A Design Issues Report prepared by MML in June 2017 addressed the parties' disagreement about whether or not the ventilation design for single and multi-bed rooms complied with SHTM guidance, but drew no distinction between rooms in the critical care department and

rooms elsewhere in the hospital again because all were being treated as normal bedrooms (Greer, Transcript, page 147).

121. Mr Hall likewise recalled no discussion, in the context of the review of pressure in the multi-bed rooms, about the possibility that, because some of the rooms were in critical care, they might be subject to different SHTM recommendations for air changes and pressure parameters (Transcript, page 150). When (on 5 July 2018) he circulated an extract of the environmental matrix for comment to MML and NHSL, showing the parameters agreed for the multi bed rooms including 4 air changes and positive pressure for the rooms in critical care, he received no objections (Transcript, page 175).

122. Mr Pike saw no issue with four air changes on the basis that, as he understood it, the contract already required that via the environmental matrix (Transcript, page 43).

123. Mr Henderson, the commissioning manager in NHSL's estates team, was familiar with the table of recommended ventilation parameters in SHTM 03-01, and (contrary to the interpretation placed upon the guidance by Mr McKechnie) understood the recommendation for critical care areas to apply to such areas as a whole and not to be restricted in its application to isolation rooms. If he had known that something other than the recommended parameters of 10 air changes per hour and 10 Pascals of positive pressure were being proposed for a critical care area, he would have queried it as a non-compliance with guidance. He therefore had sufficient experience, knowledge of the guidance, and confidence to challenge the use of non-compliant parameters. He did not do so on the RHCYP/DCN project, however, because he did not realise that any of the multi-bed rooms under consideration were in the critical care department. That is despite the fact that information to that effect was readily available to him. For example, when Ms MacKenzie emailed the risk assessment to him in 2017, she made reference to one of the rooms being in critical care in the covering email (Bundle 13, vol 8, p449). Documents about the proposal used room codes and plans from which the location of some of the rooms in critical care could have been discerned, and others included explicit reference to some of the rooms being in the critical care department. He was unable to explain how it was (as he put it) that "*the dots weren't joined*", but pointed to that proposal being very narrowly focused on the pressure arrangements and to the responsibility of others to point it out. He proceeded throughout the multi-bed room

proposal on the mistaken assumption that none of the rooms were in the critical care department (Transcript, pages 71 to 125).

124. Ms MacKenzie signed off NHSL's approval of the multi-bed room ventilation solution under the Project Agreement RDD process on 26 July 2018 (Bundle 10, page 182). She expected MML to have thoroughly reviewed it before she did so (Transcript, Day 2, page 27). Her sign-off came after NHSL's threatened litigation to enforce their preferred pressure arrangement had been called off on the basis of IHSL's proposal to implement it. Although she knew some of the rooms were in the critical care department (and she had led a risk assessment particular to the proposed ventilation pressure in those rooms), neither she nor the clinicians she consulted were aware that the proposed solution would involve a derogation from SHTM 03-01, for either the pressure regime or the air change rates (Transcript, Day 2, page 4). Nobody explained that to her. She was unaware of the SHTM guidance for critical care rooms. Her state of knowledge was, therefore, on these issues, the converse of Mr Henderson's.

125. In the course of development of the multi-bed room pressure proposal, NHSL took independent expert engineering advice from David Rollason Associates, a firm of consulting engineers (Bundle 13, volume 9; page 30; report dated 1 November 2017). The scope of Rollason's instruction was dictated by what was understood by the parties to be the key aspect of their dispute – what pressure arrangement, if any, was recommended by SHTM guidance for multi-bed rooms and the associated question of whether a multi-bed room was akin to a single room or a general ward. Rollason were not asked to advise upon air change rates. Their report noted that NHSL had concerns about IHSL's proposed air change rates, but this does not appear to have been a specific concern related to air change rates in the critical care rooms (Henderson, Transcript, 139). The report did not draw attention to the SHTM recommendations for critical care areas and appears to have proceeded on the assumption that these were not relevant to the parties' dispute. Rollason do not appear to have been asked to take account of the fact that some of the rooms were in a critical care department, although they do appear to have had papers which identified some of the rooms as being there (Bundle 13, volume 9, page 72, entry for "*PICU and HDUs*").

126. NHSL were aware, in the context of the development of the multi-bed room pressure proposal, that four air changes proposed for the haematology/oncology ward (a neutropenic patient area) would be contrary to SHTM 03-01 recommendations for neutropenic patient wards (which, in respect of air change rates and pressure regimes, were the same as for critical care areas; those recommendations appeared in adjacent lines of SHTM 03-01 (Bundle 1, page 1173)). This issue was discussed amongst NHSL, MML, Multiplex and Wallace Whittle. It led to a discussion amongst NHSL's clinicians who, having been told that any change to the air change rates would involve a significant amount of work, cost and delay, decided to accept what they understood to be a ventilation arrangement for those rooms that was non-compliant with SHTM 03-01 on the basis that risks could be managed operationally. This did not prompt any consideration about whether or not the same air change rate was consistent with SHTM 03-01 recommendations for critical care areas (PPP 8, paragraphs 9.6.23 to 9.6.47; Bundle 11, from page 193; Henderson, Transcript, 131).

127. In summary, the pressure proposal for the multi-bed rooms was developed at length and in depth without any of the parties involved realising that some of the rooms were in the critical care department and were thereby subject to SHTM recommendations with which the proposal did not comply.

128. Following agreement on the technical solution for the multi-bed rooms, it was incorporated along with other technical solutions in SA1. The decision-making leading up to the execution of SA1 is discussed below.

1.4 Correspondence, including an email chain on 18 April 2018, where NHSL indicated that 4 air changes per hour were required for areas in the hospital. In particular, whether this requirement included the multi-bed wards in critical care and, if so, the basis for including those rooms.

129. In an email exchange on 18 April 2018 concerning ventilation in the multi-bed rooms, Ronnie Henderson of NHSL said *"...we are seeking design for 4 Air Changes*

to all 14 rooms. Can you confirm that this is the brief to WW". Ken Hall of Multiplex, in his reply, said "*4ACH is the brief...*" (Bundle 1, page 2042).

130. This comment referred to revision 5 of Wallace Whittle's proposal for achieving balanced or negative pressure in multi-bed rooms. That proposal, as explained above, included rooms in the critical care department (Bundle 13, volume 2, page 1248). Mr Henderson's reference to seeking four air changes therefore did concern those critical care rooms.

131. In the agreed proposal which resolved NHSL's threat to commence litigation in March 2018, there is similarly agreement by NHSL to a resolution at four air changes per hour (Goldsmith, Transcript, pages 16 to 34).

132. These might be read as an explicit instruction by NHSL, or at least confirmation of a requirement by NHSL, for four air changes per hour in the critical care multi-bed rooms.

133. In our submission, however, this correspondence should be read and understood in its context.

134. The multi-bed rooms were under discussion because NHSL wanted them to have negative or balanced pressure. Discussions were driven by this desire to change the pressure parameter and not by any desire to change the air change parameter.

135. The air change parameter specified for these rooms in the body of the environmental matrix was 4 ac/hr. Early proposals by Wallace Whittle to achieve balanced or negative pressure in the multi-bed rooms involved lowering the air change rate within the rooms – that is, reducing it from the 4 air changes stated in the environmental matrix. This lowered air change parameter was Wallace Whittle's proposed means of achieving NHSL's desired pressure arrangement and not something which NHSL themselves had asked for.

136. The discussions, and decisions, on multi-bed rooms therefore involved confirmation of an air change rate of 4 per hour, including for the multi-bed rooms in

the critical care department, but this was in the context of 4 air changes having been the parameter applied by the environmental matrix, from financial close and indeed before that, to all multi-bed rooms.

137. Mr Henderson's request for confirmation that 4 air changes would be used for multi-bed rooms was therefore no more than a reminder that the technical solution to achieve balanced or negative pressure in the multi-bed rooms was not to involve any reduction in the air change rates already forming part of the design. It was not intended as a change by NHSL to their brief or as an instruction by NHSL to override IHSL's design solution. In our submission, the agreement to IHSL's proposal to resolve the threatened litigation should be viewed in the same way.

138. The origin of the explanation for having 4 air changes in the multi-bed rooms in the critical care department therefore lies, in our submission, not in the discussions around the multi-bed rooms but in the fact the financial close environmental matrix specified that parameter. The discussions around the multi-bed rooms were, however, a missed opportunity to change it to a 10 per hour air change rate for the critical care rooms.

139. Discussions on the multi-bed room proposal were conducted on the understanding that all multi-bed rooms in the hospital were to be treated in the same way, with no special requirements for those in the critical care department (McKechnie, Transcript, page 57, page 99).

140. Mr McKechnie gave evidence that he considered even if the air changes were reduced below 4 per hour, the design would be consistent with SHTM 03-01 (Transcript, 47). This would not in our submission be compliant with SHTM 03-01 for rooms in the critical care department, given the recommendation in Appendix 1 (Bundle 1, page 1173).

1.5 Correspondence sent by IHSL to NHSL on 31 January 2019 confirming that that the ventilation systems had been designed, installed and commissioned in line with SHTM 03-01 together with further correspondence on this issue in February and March 2019.

141. On 25 January 2019, prompted by awareness of emerging issues at the Queen Elizabeth University Hospital, Glasgow ("QEUH"), Paul Gray, the then Director General of Health and Social Care, wrote to Scotland's health boards seeking confirmation that certain controls were in place and working effectively. These included that all critical ventilation systems were inspected and maintained in line with SHTM 03-01 (Bundle 13, volume 1, page 762).

142. This prompted confirmation from Multiplex to IHSL on 31 January 2019 that, inter alia, all ventilation systems at the RHCYP/DCN had been designed, installed and commissioned in line with SHTM 03-01 "as required" (Bundle 13, volume 1, page 764 and 766). IHSL wrote to NHSL in similar terms on the same date (Bundle 4, page 9). The letter addressed design, installation and commissioning instead of inspection and maintenance because, whilst the ventilation systems at the RHCYP/DCN had been installed by this time they were not yet in operation. According to Mr Pike, the words "as required" were intended to reflect the fact that the design and installation had been done to the contractual standards (Transcript, page 66). However, at that stage, SA1 had not been signed and its technical schedule did not reflect the contractual position between the parties.

143. NHSL understood by this stage that the ventilation system as designed and installed deviated from the recommendations in SHTM 03-01, in relation to the use of 4 air changes per hour throughout the hospital in place of 6 and in relation to the neutropenic ward (where NHSL recognised the as-built 4 air changes was a departure from the SHTM 03-01 recommendation for 10). Otherwise, however, they were under the impression there was full compliance, including for the multi-bed rooms (Henderson, Transcript, page 145; Goldsmith, Transcript, page 70).

144. On 12 February 2019, IHSL sought further written assurance from Multiplex that engineering systems (including ventilation) had been designed and were being

installed and commissioned to meet current guidance and statutory requirements (Bundle 13, volume 1, page 769).

145. Multiplex responded on 6 March 2019 to confirm that the engineering systems had been designed and had/were being installed and commissioned to meet "*the relevant Construction Contract standards, as varied by the Settlement Agreement*" (Bundle 13, volume 1, page 771). This was as much assurance as Mr Pike, who drafted the letter, felt able to give (Transcript, page 75).

146. By the date of Multiplex's letter of 6 March, SA1 had been executed and contained the technical solutions which the parties had agreed, including on ventilation.

2. The decision making and governance concerning the agreement reached between NHSL and IHSL on 22 February 2019 (Settlement Agreement No 1)

2.1 Why NHSL agreed to enter into the agreement.

147. SA1 documented dozens of agreed resolutions to disputed issues which were set out in a technical schedule (Bundle 4, page 38). These included the agreed resolutions to disputes about ventilation (items 4, 7 and 13). The ventilation system was installed by late 2018 in accordance with those resolutions, although SA1 was not itself signed until February 2019. Part of the function of SA1 was to formally record the basis on which the parties had resolved these disputes.

148. SA1 also recorded the Independent Tester's readiness to issue a certificate of practical completion for works, under exception of certain categories of work to be carried out thereafter (Bundle 4, page 13, recital D).

149. A major commercial reason for the parties entering into SA1 when they did was to alleviate financial pressures which had built up on IHSL (Goldsmith, Transcript, page 58 onwards; Templeton, Transcript, 173 onwards; Pike, Transcript, 57 onwards). IHSL's funding arrangements were based on the assumption it would start receiving

payment from NHSL of the unitary charge (which fell due once NHSL accepted the completed hospital) in July 2017. Delays in completion of the hospital meant these payments had not begun on time, placing pressure on IHSL's ability to meet its financing obligations. By early 2019, IHSL was at risk of defaulting on its loans which presented the further risk of its funders stepping in to replace IHSL with another project company leading to further delay. There was the possibility of NHSL (or the Scottish Government) having to pay £150m to repay the debt and take on the hospital themselves – funds which neither had. NHSL agreed to SA1 and to accept practical completion of the hospital to avoid these risks.

150. NHSL agreed to this in the knowledge that the construction work had not been completed and would have to continue thereafter. It planned to carry out its commissioning work in parallel with completion of the building works. This was done with the aspiration of concluding all work in time to facilitate the opening of the hospital in summer 2019. The prospect of opening the hospital after the delays which had affected the project was a source of relief (Goldsmith, Transcript, 51, 59).

151. This arrangement meant it was not possible to carry out the stage four HAI-SCRIBE process at the time of the handover and it had to be deferred until a later stage (ibid.), although this does not appear to have been the subject of conscious consideration at the level of NHSL's board (ibid., page 57). Moreover, there does not appear to have been any input from IPC.

152. This issue links back to wider theme of whether SA1 was a change to NHSL's brief or a design solution to that brief. If it was a change to the brief, arguably, NHSL should have gone back to stage 2 of the HAI-SCRIBE procedure. That this was not considered may be due to the lack of input from IPC. It demonstrates that difficulties may arise if the partnership approach set out in SHFN 30 is not followed.

153. NHSL took comfort from the Independent Tester having issued its certificate, on the assumption that this could be taken as confirmation of compliance with guidance (Goldsmith, Transcript, 60). However, in reality, the Independent Tester was making an assessment against an interpretation of the parties' contract rather than the guidance itself.

154. Furthermore, IHSL had by the date SA1 was executed (22 February 2019) confirmed compliance with SHTM 03-01 in the design, installation and commissioning of the ventilation systems, and in the maintenance of those systems such as to ensure compliance at handover (letter of 31 January 2019, Bundle 4, page 9). That letter was written, not as a formal element in the project governance, but in response to the Scottish Government's letter to all health boards based on their emerging concerns about ventilation at the QEUH. NHSL took assurance from IHSL's letter, but it merely confirmed what they already understood to be the case and it does not appear to have been relied upon by NHSL in deciding to execute SA1 (Goldsmith, Transcript, page 70). At the level of the project team, it was understood that there had been certain departures from SHTM guidance but not in relation to critical care rooms (Henderson, Transcript, page 145; MacKenzie, Transcript, page 44).

155. The letter is also relevant to the issue of governance. NHSL had documentation confirming that the ventilation system complied with published guidance. While there is a dispute between NHSL and IHSL as to what the words "as required" mean in the letter, the Chair may consider this is a minor semantic issue. If Mr McKechnie had been asked whether the design solution for critical care areas fully complied with SHTM 03-01, he would have said that it did. Viewed in this way, the Chair may consider that the issues that arose on the project did not arise from a failure in governance on the part of NHSL or the Scottish Government. The only way that the governance procedures could have detected the issues with the critical care ventilation system would be if they had required an independent audit of the technical solution. The Chair will wish to consider whether that would have been necessary and proportionate in terms of governance of the project.

2.2 Why the ventilation parameters set out in the agreement were deemed adequate and appropriate by NHSL and IHSL, with particular regard to their application to critical care rooms.

156. The process by which NHSL and IHSL reached agreement upon the technical solutions for ventilation is explained in section 1 above. In short, those technical

solutions were agreed without any party considering, or realising, that some of the rooms to which they applied, by virtue of their location in the critical care department, were the subject of particular recommendations in the guidance with which the technical solution did not comply.

2.3 The input (if any) obtained by NHSL from Clinicians, IPC, Estates and Technical Advisors on the ventilation requirements to be included in Settlement Agreement No 1, for critical care rooms, in advance of the agreement being concluded.

157. The involvement of NHSL's clinicians, IPC team, estates team and technical advisors in the development of the ventilation technical solution for critical care rooms is set out in section 1 above. In short, all were involved albeit the IPC team involvement was relatively limited by the time of the finalisation of the technical schedule to SA1. The precise nature of IPC involvement in the period up to SA1 is not clearly documented.

158. Once the technical solutions had been agreed, they had to be formally documented in SA1. MML drafted the technical schedule to SA1. Graeme Greer of MML raised concerns with NHSL's Project Director, Brian Currie, that the way in which the agreement was expressed could disturb the design risk allocation of the Project Agreement in relation to those solutions. This was a reference to the standard design risk allocation of an NPD contract, under which design risk rests with the project company except in relation to operational functionality, the risk of which rests with the health board. In that context, Mr Greer emphasised that, although MML were NHSL's technical advisers, they were not designers and were not therefore in a position to provide design assurance to NHSL in relation to the technical solutions (Bundle 13, volume 5, page 1272; 4 June 2018; Greer, Transcript, page 162).

159. Although it was understood in NHSL's project team that MML were not the designers, or a shadow design team, there was nonetheless a belief that they were providing assurance to NHSL about the technical solutions (Goldsmith, Transcript, page 46; MacKenzie, Transcript, Day 2, page 33; Henderson, Transcript, page 145).

160. Mrs Goldsmith was alert to the need to avoid any risk transfer to the board and referred to legal advice being taken to ensure that did not happen (Transcript, 36; see Bundle 10, page 156). NHSL proposed an approach which involved treating the agreed technical solutions in accordance with the existing procedures in the Project Agreement (Bundle 13, volume 9, page 184). That approach is reflected in the technical schedule of SA1, where each of the ventilation solutions (4, 7 and 13) is referred to as approved under the Project Agreement procedure for RDD (Bundle 4, pages 40 to 46). That is a process under which NHSL's approval constitutes no more than confirmation that the proposed design meets their requirements for operational functionality.

161. Whether or not this approach was successful in treating these agreed technical solutions as part of IHSL's design solution for which they bear the whole design risk is a matter of contractual interpretation, but there is once again an air of unreality about treating the ventilation solutions in that way. There had been serious dispute between the parties about the ventilation and SA1 resolved it following detailed involvement by technical experts on both sides. The solution for the multi-bed rooms featured a pressure arrangement which, whilst contrary to the recommendation for rooms in a critical care department, was based upon a risk assessed, clinical preference of NHSL's paediatric clinicians. It was one which NHSL were prepared to litigate to obtain, and they had taken additional expert advice in support of it. In our submission, the process leading up to SA1 therefore involved clarification by NHSL of their ventilation brief (Goldsmith, Transcript, 39).

162. On any view, and whatever the contractual implications, SA1 set out the technical basis on which NHSL had agreed to installation of the ventilation system. Even if the project company bore the contractual risk of ventilation parameters not complying with guidance, NHSL would suffer the disruption of the hospital opening being delayed for rectification works if the agreed technical solution proved to be non-compliant with guidance.

163. The need for clarity in relation to the ambit of technical advisors, and the need for a clear record of advice being tendered, were highlighted in the Grant Thornton report commissioned by NHSL. Mrs Goldsmith acknowledged a need for greater clarity

when technical advisers were providing formal advice, and explained that NHSL had undertaken work to improve processes around that issue, as had been recommended by Grant Thornton (Transcript, page 48). While these steps have been taken by NHSL, there does not appear to be any similar processes or procedures embedded in the wider NHS. The Chair may therefore consider that there is a risk of other health boards experiencing similar problems on future projects.

2.4 Whether the design parameters for the ventilation system set out in Settlement Agreement No 1 were appropriate for critical care rooms.

164. The agreed ventilation parameters for the multi-bed rooms in the critical care department included negative or balanced pressure and 4 air changes per hour. Both of these are contrary to the SHTM 03-01 recommendation for critical care areas.

165. The pressure parameter was, however, the considered and risk-assessed preference of NHSL's clinicians based on their intended use of the space. A negative or balanced pressure arrangement, as opposed to a positive one, is a comprehensible choice for rooms in which children with similar infections are to be cared for together: all other things being equal, negative or balanced pressure would tend to limit the spread of respiratory viruses better than positive pressure (Inverarity, Transcript, page 152).

166. After IOM Ltd reported in 2019 on the non-compliance of the critical care ventilation with guidance, and the Cabinet Secretary had determined that compliance with IOM's interpretation of the guidance was essential, NHSL's clinicians were initially concerned as to whether reversal of their preference for negative or balanced pressure would be safe. This led to a great deal of discussion between NHSL's infection prevention and control team and the clinicians, and informal consultation with third party experts, to determine whether the use of positive pressure would indeed be safe for NHSL's intended clinical use. The conclusion ultimately reached was that the guidance-compliant arrangement (positive pressure and 10 air changes per hour) would be safe for that use, but that the balanced or negative pressure arrangement could have

been used without an increase in the risk of infection (Inverarity, Transcript, page 161 to 165).

167. The air change parameter, of four air changes per hour, by contrast was not specifically chosen by NHSL for clinical reasons and was not explicitly considered in their risk assessments. As a departure from the recommended 10 air changes, this increased the risk of infection transmission but it was not possible to quantify that increase (Inverarity, Transcript, page 115 onwards. Dr Inverarity's evidence was consistent with the evidence of Professor Humphreys).

168. No risk assessment was undertaken to assess the risk of having 4 air changes as opposed to 10 air changes. This issue was superseded by the Scottish Government's instruction in early July 2019 that the hospital was required to comply with the guidance (ibid.). There was not therefore any concluded assessment of the risk presented by the ventilation system as installed (balanced/negative pressure at four air changes per hour) compared to the ventilation parameters recommended by the guidance and insisted upon by the Government (positive pressure at ten air changes per hour). There were, however, indications that the lower air change rate might be unsatisfactory (such as information informally supplied to Dr Inverarity by Dr Inkster about ventilation issues at the QEUH (Dr Inverarity, Transcript, pages 124 to 149)), and that achieving slight increases through short-term modifications would come with unacceptable compromises (ibid.)).

169. It was recognised at the time that there was sub-optimal evidence in the scientific literature about ventilation air changes and clinical outcomes. There are challenges in researching these matters. The air change parameters recommended in SHTM 03-01 reflect a broad consensus across the developed world (Dr Inverarity, Transcript, page 45 onwards), and an approach in which critical care areas are better ventilated than general wards (Prof Humphreys, quoted in Inverarity, Transcript, page 146).

170. The Cabinet Secretary's decision to insist on compliance with the guidance was, in respect of air changes, a defensible and rational one given that the guidance recommendation reflected a consensus agreed by experts and the absence of any risk

assessment, or clinical need, justifying a departure from it. It had the consequence that a new and unused ventilation system was replaced at significant cost and disruption, but given the uncertainties of the underlying science it is unlikely that any more detailed investigation would have generated comfort that 4 air changes was appropriate for the critical care department. In our submission, it was reasonable and appropriate to treat the guidance as a default standard in the absence of any risk-assessed, clinical choice for something lower (see Dr Inverarity, Transcript, page 58).

171. The subsequent experience of the Covid pandemic has improved awareness of the risks of low ventilation air change rates, particularly for staff (Inverarity, Transcript, pages 52, 143).

172. There remains disagreement over whether or not the SA1 technical solution for single rooms applied to single rooms in the critical care department. That solution was not, in any event, appropriate for such rooms. It was contrary to the SHTM 03-01 recommendation for critical care areas. It had not been risk assessed for them. It was based on the mixed mode ventilation strategy which relied on openable windows which was not appropriate for critical care rooms. It assumed the existence of en suite WCs which the critical care single rooms did not have.

2.5 Whether the design parameters for the ventilation system in critical care and isolation rooms conformed to statutory regulation and other applicable recommendations, guidance and good practice.

173. The design parameters for the critical care rooms (balanced/negative pressure and 4 air changes per hour) were inconsistent with the recommendation made by SHTM 03-01 for critical care areas.

174. Our submission of 2 June 2023 addressed the matter of the interpretation of SHTM 03-01 in that regard (paragraphs 162 onwards). Whilst Mr McKechnie has consistently maintained a different interpretation, that was not supported by any other

witness and in our submission the Chair should accept Mr Maddocks' characterisation of the interpretation as being an "*outlier*".

2.6 Whether NHSL agreed to a formal derogation from the requirements of SHTM 03-01 and, if so, whether any prior risk assessment was conducted.

175. As explained above, NHSL carried out a risk assessment of the pressure arrangement in multi-bed rooms which included some rooms in the critical care department. Whilst the risk assessment considered the pressure parameter, it did not consider the air change parameter. The pressure parameter for the multi-bed rooms in critical care was therefore risk assessed, but the air change parameter was not.

176. Since nobody involved in the development of the pressure solution for the multi-bed rooms realised that, to the extent it included rooms in the critical care department the solution was not compliant with SHTM guidance for critical care areas, there was no formal derogation from that guidance.

177. The technical solution agreed in SA1 for the single bed rooms was for 4 air changes per hour, and this was explicitly stated to be a departure from the SHTM 03-01 recommendation of 6 air changes per hour for single rooms (Bundle 4, page 45; Bundle 10 page 69). This was therefore a formal derogation to that extent. The Inquiry is not aware of any formal risk assessment having been carried out in support of that derogation in advance of that agreement being documented in SA1.

178. There remains uncertainty and disagreement, however, about whether or not this derogation applied to single bed rooms in the critical care department. The Inquiry is not aware of any evidence that NHSL consciously intended the derogation to apply to single rooms in the critical care department, and the derogation does not purport to be a derogation from the SHTM recommendation of 10 air changes per hour for critical care areas. It seems likely that, as was the case for the multi-bed rooms, the parties proceeded on the basis that all single rooms were to be treated in the same way without any realisation that the rooms in the critical care department were the subject of

different recommendations. Whatever the correct interpretation of the derogation (that is, whether or not it includes single rooms in the critical care department), it would follow that there was no formal, conscious derogation from the SHTM recommendation of 10 air changes per hour. The Inquiry is not aware of any risk assessment to assess the risks arising from a departure from 10 air changes per hour in the single bed rooms in the critical care department, and given the departure appears to have been inadvertent there is unlikely to have been one.

179. For the single bed rooms in haematology/oncology, the technical solution in SA1 was for these rooms to have balanced pressure at 4 air changes per hour. This was an agreed derogation from the requirements of guidance and, although not the subject of a written risk assessment, was risk assessed at a meeting on 13 February 2017 (PPP 8, paragraph 9.10.42 and NHSL comment in response: Bundle 11, page 108; Bundle 12, volume 1, page 85).

2.7 The procedure followed by NHSL for the approval of Settlement Agreement No 1. In particular, the consideration of the issue by the Finance and Resources Committee and the Board of NHSL.

180. The Board of NHSL delegated to its Finance and Resources Committee the authority to undertake oversight and responsibility on its behalf of matters pertaining to SA1. The Finance and Resources Committee thereafter approved the business case for SA1 on 25 July 2018, upon which the Scottish Government agreed (by letter dated 8 August 2018) to provide the additional capital funding of £10m in support of SA1. The Finance and Resources Committee received further updates about, and confirmed its support for, SA1 through the latter part of 2018 and early 2019, and provided a report for the main board about it dated 23 January 2019. On that basis, NHSL's board approved SA1 on 6 February 2019, having been asked "*to receive assurance that all negotiations on the terms of this settlement agreement had been supported by the Board's legal and technical advisers*" (Bundle 13, volume 7, pages 1049 to 1163; Bundle 10, page 153).

181. A member of the NHSL board sought clarification of the assurance which had been received in relation to technical advice, and was referred to the settlement agreement having been supported by the board's technical advisers (ibid., page 1163, paragraph 37.3). The minute does not record the Board being told about the limitations which, according to Mr Greer, he explained to NHSL's project director (Brian Currie) were inherent in MML's role as technical adviser.

182. However, this should be viewed in context. Mr McKechnie maintained, and still maintains, that the design fully complied with SHTM 03-01. If the Board had insisted on receiving additional assurances, Mr McKechnie would have confirmed that, in his view, the design fully complied with published guidance. MML would have refused to accept design responsibility and would therefore not have confirmed formal agreement or disagreement. Therefore, the only way this issue could have been detected through the governance procedures would be if the board had insisted on an independent review of the design. That would likely have involved HFS or a third-party independent contractor reviewing the design and reporting upon it. At the relevant time HFS had very limited engineering resources. The evidence indicated they had between 1 and 3 engineers. The Chair may wish to reflect on whether HFS could have provided the type of assurance that would be required, without incurring the cost of an external consultant. The Chair will also wish to reflect on whether the instruction of an independent review of the technical solution would be appropriate, and proportionate, for a project that was structured on the basis that all design risk sat with the private sector project company.

2.8 What assurances (if any) were sought by and/ or provided to the Scottish Government that: (i) it was appropriate for NHSL to enter into Settlement Agreement No 1; and (ii) that the specification complied with published guidance and best practice.

183. The resolution captured in SA1 necessitated around £10m of additional funding from the Scottish Government. NHSL briefed the Scottish Government on the objectives of SA1. The Scottish Government was aware that the settlement resolved around 80 technical issues and that these included issues relating to the ventilation

systems. It was aware of the financial challenges affecting IHSL. It wanted to avoid the risk of the Scottish Government having to pay £150m to acquire the hospital for NHSL if IHSL became insolvent and its lenders called up the debt obligations, although it considered that to be a remote risk. It was motivated by a desire to get the hospital open, given the delays which had already affected it. NHSL submitted a business case to the Scottish Government on 25 July 2018, which approved it on 8 August 2018 (PPP 8, paragraph 9.10.40; Bundle 11, page 233). This was on the basis that it appeared to be the best solution in the circumstances (Morrison, Transcript, pages 106 to 127).

184. In approving NHSL's entry into SA1, the Government took steps to satisfy itself that NHSL's governance arrangements around it were adequate. It did not carry out, or instruct, any assessment of its own of the technical solutions SA1 contained and instead relied on NHSL having secured sufficient input from its own technical advisors. Mr Morrison, who was NHSL's main point of contact within the Scottish Government, accepted that with the benefit of hindsight it would have been reasonable for the government to ask HFS for a review of the technical solutions before approving NHSL's entry into SA1. He candidly accepted, again with hindsight, that it was a failure of governance on the part of the Scottish Government not to do so (ibid.), although said that the approach to decision making was in line with the division of accountability between government and health boards at the time (ibid., page 125). He was unaware that the approval of SA1 led to NHSL accepting handover of the hospital without the stage 4 HAI SCRIBE checks being carried out (ibid., page 123).

185. The Chair may wish to consider the points made at paragraph 182 above in relation to HFS. At the relevant time, HFS had a limited number of engineers. The evidence indicates it had between 1 and 3 engineers. Instructing a view from HFS would likely have involved an external engineer being instructed at significant cost. The Chair may wish to reflect on whether that would have been a necessary and proportionate step to take in the context of a project where design risk was meant to sit with the private sector. The Chair may also wish to reflect on whether any scrutiny of technical solutions is appropriate or proportionate at government level, given the division of accountability between health boards and government.

186. SA1 was not signed until February 2019, by which time the Scottish Government was aware of emerging concerns about the ventilation systems at the QEUH (Mr Gray having written to health boards about that on 25 January 2019). This raises a question about whether or not the Government knew enough at that time that it ought to have insisted on greater scrutiny of the technical solutions. We do not consider the Inquiry to have enough evidence to reach a view, as it depends on the level of knowledge held by the Government at that time about the emerging issues at the QEUH. The Chair may wish to consider asking the Scottish Ministers to address this point in their closing submissions. He may also wish to re-visit it when further evidence has been led in relation to the QEUH and on the timing of issues being raised with the Scottish Government.

2.9 Why NHSL agreed that the certificate of practical completion could be issued at the point Settlement Agreement No 1 was concluded.

187. The recitals to SA1 record the parties' understanding that the Independent Certifier was, subject to certain provisions, ready to issue a certificate of practical completion (Bundle 4, page 11). Practical completion was in fact certified on 22 February 2019, being the same date on which SA1 was executed (Bundle 4, pages 37 and 223). SA1 and the certification of practical completion were therefore linked.

188. As explained above, practical completion of the hospital allowed NHSL to carry out their commissioning works, resulting in progress towards the hospital opening, and triggered payment of the unitary charge to IHSL, which alleviated the financial pressure they were under.

2.10 Whether the organisational culture within NHSL allowed individuals to raise concerns and issues in relation to the proposed agreement.

189. This matter is addressed in chapter 36 of PPP 9 (Bundle 11, page 619). In short, throughout the time period with which the Inquiry is concerned, NHSL maintained policies designed to ensure individuals with concerns were able to raise them. The

Inquiry has seen no evidence to indicate that anyone was aware of problems with the building engineering systems in the RHCYP/DCN yet inhibited or precluded from raising them. There is evidence of individuals raising concerns without difficulty. For example, Dr Inverarity and Ms Guthrie raised concerns about the lack of a validation report. As explained elsewhere in this submission, the problem in the case of the critical care ventilation was, rather, that nobody realised its specification and design were contrary to the SHTM recommendations for critical care areas.

3. The financing of the RHCYP/DCN

3.1. Whether the financing arrangements for the project contributed to issues and defects in the hospital. In particular, whether there was a perceived need for the building to be certified as practically complete as soon as possible to ensure the solvency of the project company.

190. The financing arrangements are set out in detail in PPP 10 (Bundle 11, page 625).

191. In our submission, the financing arrangements did not directly contribute to issues and defects in the hospital. The Inquiry heard evidence that other revenue funded projects were delivered without significant issues. Moreover, the QEUH was capital funded and significant issues arose.

192. This submission is controversial and a contrary position is taken by NHSL in its response to PPP 10 (Bundle 12, page 530). The Chair should carefully consider PPP 10 and the responses from Core Participants before making any findings on this issue.

193. Although we submit that the financing arrangements did not directly contribute to the defects, there were clearly problems that arose from the deal structure. That gives rise to an issue as to whether the revenue funded model is suitable for future hospital projects. Several witnesses gave evidence indicating that they do not consider that revenue funding is appropriate for hospital projects given their complexity and the

difficulties that arise if changes need to be made to technical solutions after the contract is signed.

194. The NPD model seeks to place most design risk onto the private sector. That is an understandable aspiration given the private sector is financing the hospital. However, the effectiveness of the risk transfer relies on two factors: (1) the clarity of the brief; and (2) the solvency of the special purpose vehicle. The project highlights problems with both aspects.

195. Changing the brief after a contract is signed is problematic. There is a nexus of contracts that sit underneath the Project Agreement. These include arrangements with the principal building contractor, their sub-contractors, and the lenders. Any changes to the Project Agreement have implications for these associated agreements. Witnesses gave evidence of NHSL effectively having to negotiate with IHSL's contractor (Multiplex) despite there being no contract between the parties. Therefore, any changes are problematic and result in complicated negotiations to resolve issues. For a project to be successful, a very clear brief requires to be set out before the Project Agreement is concluded. That creates challenges for a complex project such as a hospital where the relevant science and technology is often evolving. This indicates that the model – in which changes can be problematic – is potentially not fit for purpose.

196. The added risk factor in an NPD project is the solvency of the special purpose vehicle. In the project, there were a range of delays. IHSL required to start making debt payments before the hospital was practically complete. NHSL were not making payments under the Project Agreement. IHSL therefore had significant debt payments to make with no regular, guaranteed, income stream. The problem was initially alleviated by damages payments made by Multiplex. However, there came a point where Multiplex stopped making payments as it considered that it was not responsible for the delays. If a resolution had not been reached, IHSL would have faced insolvency.

197. An inherent risk in revenue funded projects is that the special purpose vehicle incurs obligations but has no revenue as a result of delays. That is what happened on the project. By 2018, there was a real risk of insolvency. Any insolvency would have created significant delays for the project. It could have triggered a requirement for

NHSL to repay £150m. That was the commercial backdrop to SA1. It meant that a deal had to be struck.

198. The commercial pressure to reach a compromise resulted in standard procedures not being followed. HAI-SCRIBE Stage 4 was not completed before the hospital was handed over due to the need for the payments to be made to service the debt. Dr Inverarity described the Stage 4 review as the last chance for a health board to be assured a hospital is safe. Had the Stage 4 review been completed before the agreement was concluded, there was the opportunity for the issues with the critical care rooms to be spotted before NHSL committed to paying for remedial works and before NHSL was bound to pay the unitary charge.

199. The deal structure meant that the transfer of risk from the public sector to the private sector was more theoretical that real. This calls into question the suitability of the revenue funded model. If the revenue funded model is to be used on future healthcare projects, it is critical that the brief is clearly set out and a mechanism is found for more streamlined changes to be made.

4. The decision-making and governance structure for the project in the period after financial close

Particular emphasis will be placed on the decision making and governance concerning SA1, the instruction of IOM Limited, the consideration of the reports produced by IOM Limited and the escalation to Scottish Government

4.1 The decision making and governance processes NHSL had in place to oversee the project and whether they were adequately and effectively implemented.

200. In the period after financial close, there were no changes made to the decision making and governance structures up until July 2019. The detail of the governance structure is set out in PPP 9 (Bundle 11, page 255). Changes were made after problems were identified by IOM Ltd. An incident management team was established (later renamed the executive steering group). Further changes were made when NHSL was

escalated to level 3 and then level 4. This is addressed at question 4.10 (paragraph 218 below).

4.2 Whether the operational management and governance provided by NHSL was adequate and effective for the scale of the project.

201. The operational management and governance was in line with standard procedures in place at the time. The Chair is invited to find that the operational management and governance structures were not key factors resulting in the problems with the hospital.

4.3 The extent to which decision makers sought and facilitated input from clinical leadership teams, IPC, Estates, technical experts and other relevant parties when making key decisions to ensure that the built environment made proper provision for the delivery of clinical care.

202. Decision makers did facilitate input from clinical leadership teams, IPC, estates and technical experts. However, all relevant disciplines were not involved at all the key stages.

203. There were some key failings in decision making that arose from not ensuring all relevant disciplines were consulted in advance of decisions being made. By way of example, IPC were not involved in the decision making around SA1. They were not aware of the terms of the technical solution set out in SA1 and were not aware that the Stage 4 HAI-SCRIBE would not be completed before the hospital was handed over (Bundle 5, pages 30-31). As a result, the hospital was accepted by NHSL in circumstances where it could not be satisfied that the hospital was safe.

4.4 The steps taken by NHSL's IPC team, in particular the lead infection control doctor for NHSL, to ensure that a validation report that complied with SHTM 03-01 was obtained.

204. SHTM 03-01 (2014) outlined the requirements for commissioning and validation (Bundle 1, pages 1035, 1148). These involved a range of tests to demonstrate that the system was working as required. At the end of the validation process, a validation report was to be produced. This was addressed at paragraphs 8.64 and 8.65:

"Ventilation system commissioning/validation report

8.64 Following commissioning and/or validation a full report detailing the findings should be produced. The system will only be acceptable to the client if at the time of validation it is considered fit for purpose and will only require routine maintenance in order to remain so for its projected life.

8.65 The report shall conclude with a clear statement as to whether the ventilation system achieved or did not achieve the required standard. A copy of the report should be lodged with the following groups:

- *the user department;*
- *infection control (where required);*
- *estates and facilities."*

205. There is a degree of ambiguity in the guidance as to what the "required standard" is. Is it the standards set out in the guidance or the contractual standard (which may involve a derogation from the guidance)?

206. There was a degree of confusion on the part of NHSL as to the level of inspection and testing that required to be conducted before the hospital could open. Mr Henderson (Estates) explained in his evidence that complications arose due to the NPD model. NHSL had responsibility for providing healthcare at the hospital. However, it did not own the building. The building was owned by IHSL. Mr Henderson was

therefore unclear as to what reports should have been instructed/ obtained by NHSL as opposed to IHSL.

207. Dr Inverarity raised the need for validation for theatres to be carried out on 24 August 2018. Dr Inverarity highlighted the need to do this *"...given the recent experiences by my microbiology colleagues in Glasgow with their new children's hospital"* (Bundle 7, vol 1, pages 218-219). Dr Inverarity's point was raised again, including by email on 4 January 2019 (Bundle 4, page 4). Dr Inverarity had flagged the requirement for formal validation reports rather than "*a collection of documents*". This was raised with the project management team before SA1 was formally signed.

208. A variety of documentation was provided by IHSL to NHSL to demonstrate that the system was working to the required standard. This was in the form of raw data as opposed to a formal report. Mr Henderson of NHSL was initially content with the documentation provided by IHSL in relation to commissioning and validation (Bundle 4, page 6). However, the IPC team, including Dr Inverarity and Ms Guthrie, were not content with the available information. The IPC team were not able to readily interpret the raw data and wished to see a report that complied with the guidance set out in SHTM 03-01. In particular, they wished to see a clear statement that there was performance to the required standard and that only routine maintenance would be required. The project team agreed to additional testing as they wished IPC to be wholly satisfied with the technical performance of the ventilation system (Bundle 6, page 11).

4.5 Contact between NHSL and individuals involved in the Queen Elizabeth University Hospital and whether this had any role in the key decisions made in the period after financial close, including the decision to instruct IOM Limited.

209. Ronnie Henderson sought advice from an estates department colleague at the QEUH on the pressure parameter for multi-bed rooms (email exchanges, July 2017: PPP 8, paragraph 9.7.26, Bundle 11, page 210). Consistently with the way in which NHSL approached that issue, the exchange did not appear to involve consideration of the possibility that different parameters would apply if the rooms were in a critical care department.

210. Dr Inverarity was aware of emerging problems at the QEUH in the summer of 2018. As highlighted at paragraph 207 above, on 24 August 2018, Dr Inverarity raised the need to obtain a formal validation report given the experiences of his colleagues at QEUH. Dr Inverarity described this as "*absolutely an issue we need to get right*" given the experiences of his microbiology colleagues at the QEUH. The importance of an independent validation report does not appear to have been appreciated by the key decision makers in the project team despite the potential problems at the QEUH having been drawn to their attention by Dr Inverarity.

211. A discussion Dr Inverarity had with infection control consultants at the QEUH in March 2019 drew to his attention that ventilation systems in the QEUH isolation rooms had to be refitted because their original design had not provided appropriate pressures and air flows. This prompted him to ask a colleague to ensure that NHSL's ICT were given appropriate information about air flows and pressure in the RHCYP isolation rooms (PPP 8, paragraph 9.13.9, Bundle 11, page 246; Dr Inverarity, Transcript, page 77).

4.6 The reasons for the instruction of IOM Limited by NHSL to conduct testing of the ventilation system.

212. IOM Ltd were instructed to seek to ensure that the ventilation system fully complied with the requirements of SHTM 03-01 (2014). The reason for the instruction was the fact that Dr Inverarity and his colleagues in IPC had not accepted the raw data provided to them as complying with the validation requirements set out in SHTM 03-01. Without a formal validation report that addressed the issues set out in SHTM 03-01, they did not consider that they could complete the Stage 4 HAI-SCRIBE procedure and confirm that the hospital was safe for patients.

4.7 The commissioning and testing carried out by IOM Limited and the consideration of the results by decision makers, and governance bodies, within NHSL.

213. IOM Ltd was instructed to test the ventilation system against the requirements set out in SHTM 03-01.

214. The testing conducted by IOM Ltd identified that for certain spaces in the hospital the pressure regime and air changes did not conform to the guidance set out in SHTM 03-01 (Bundle 6, pp202, 205, 209, 213, 216, 220, 221, 227, 234, 235, 238, 241, 245, 254, 256).

215. Mr Currie was aware of the emerging issue on 24 June 2019. Senior management at NHSL were aware of the issue on or around 28 June 2019 (Bundle 6, page 252). Mr Davison of NHSL was aware of the issue on or around 1 July 2019. The issue was escalated to the Scottish Government on 2 July 2019.

4.8 When concerns regarding the ventilation system at the RHCYP/DCN were escalated by NHSL to Scottish Government.

216. The issue was escalated to the Scottish Government on 2 July 2019.

4.9 Whether there was any deliberate suppression of concerns regarding the ventilation system by any party involved in the project.

217. There is no evidence of any deliberate suppression of concerns regarding the ventilation system by any party involved in the project.

4.10 The escalation of NHSL to Level 3 and subsequently to level 4 of the NHS Board Performance Escalation Framework.

218. There was a framework for escalation of health boards set out in the "NHS Board Performance Escalation Framework". NHSL was escalated to level 3 and then level 4 of the framework during the project.

219. NHSL was escalated to level 3 on 12 July 2019 (Bundle 7, vol 1, page 339). An Oversight Board was appointed. The Oversight Board was created to provide advice to the Scottish Government on the readiness of the facility to open (Bundle 3, pages 9, 11). The Oversight Board started work in August 2019. Clinicians and IPC were fully involved in the work being carried out (Bundle 3, page 13).

220. The Oversight Board contained a range of skills. It was tasked with reporting to the Scottish Government on when the hospital could open.

221. NHSL was escalated to level 4 of the framework on 13 September 2019 (Bundle 7, vol 3, page 564). When NHSL was escalated to level 4, a senior programme director (Mary Morgan) was appointed. The evidence indicates that she assisted with resolving the problems with the project. The governance structure after the appointment of the Oversight Board and the appointment of Mary Morgan is set out in Bundle 3, page 335.

4.11 Changes made to the decision making and governance structure including: (i) the appointment of a Senior Programme Director; and (ii) the creation of the Oversight Board.

222. This is addressed in the answer to topic 4.10.

4.12 Whether the organisational culture within NHSL encouraged staff to raise concerns and highlight issues in relation to the projects at appropriate times.

223. NHSL had appropriate policies in place which would allow concerns to be highlighted. There is no evidence indicating that any issue regarding organisational culture prevented relevant issues being raised. See answer 2.10 above.

4.13 Whether there were failures in the operation of systems and, if so, whether that was a result of failures on the part of individuals or organisations tasked with specific functions.

224. There was a failure to fully comply with the requirements of SHFN 30. In particular, the stage 4 HAI-SCRIBE was not completed before the hospital was handed over. This was a decision that was taken by NHSL for commercial reasons. IPC had no knowledge of, or input into, this decision.

4.14 Whether national oversight and support was adequate and effective.

225. National governance is addressed in chapter 32 of PPP 9.

226. When the Scottish Government was asked to provide additional funding, it did not seek any specific technical assurances. For example, it did not instruct a review by HFS. On one view, this indicates that national oversight and support was not adequate and effective. However, for the reasons set out at paragraphs 182 and 185 above it is not clear that this was the forum for such issues to be identified. The Chair will require to consider the level of oversight that it is appropriate for national government to have over technical issues in projects being run by health boards.

4.15 Whether there was effective communication between relevant organisations (including NHSL, Scottish Government, and NHS NSS).

227. The available evidence indicates that there was, in general, effective communication between relevant organisations.

228. There may have been a failure to ensure NHSL's chief executive, Mr Davison, knew of the Cabinet Secretary's decision to postpone the opening of the hospital before that decision was announced to the public. Any such failure would be regrettable, given the importance and the urgency of the matter to NHSL. The delay may only have been a matter of minutes, but there was obvious risk of embarrassment to NHSL and to Mr Davison personally (Wright, Transcript, page 71; Davison, Transcript, page 220; Freeman, Transcript, page 63; Connaghan, Transcript, pages 122, 148).

229. The Cabinet Secretary's requirement that communications be approved by the Scottish Government may have unduly inhibited NHSL's ability to communicate effectively (Davison, Transcript, page 118; cf. Freeman, Transcript, page 65). However, we have not identified any specific issues that are material to the TOR.

5. The decision making, and governance, around the decision not to open the hospital in 2019

230. Mr Currie was aware of the problems emerging from the testing conducted by IOM Ltd on 24 June 2019. The senior management team at NHSL were aware of the issue by 28 June 2019. Mr Davison was made aware on or around 1 July 2019. The issue was escalated to the Scottish Government on 2 July 2019. On 4 July 2019, the Cabinet Secretary, Ms Freeman, took the decision that the hospital would not open as planned. Ms Freeman took responsibility for the matter and determined that the hospital should not open until she was sure that the Hospital complied with extant published guidance, including SHTM 03-01. This was on the basis she wanted to be sure that the

hospital was safe for patients. Ms Freeman equated compliance with SHTM 03-01 with patient safety.

231. The decision was taken by Ms Freeman. However, NHSL (and Mr Davison, in particular) were in full agreement with the decision. At that time, all parties considered that there was insufficient evidence to show that the hospital would be safe for patients (Bundle 7, vol 1, page 51).

232. There was significant national oversight from 2 July 2019. This was in the form of the Cabinet Secretary taking control of the key decision making. Regular reports were provided to the Cabinet Secretary. She was only prepared to allow the hospital to open when she received assurances that it fully complied with the relevant published guidance (Bundle 7, vol 1, page 79). Regular briefings were provided to the Cabinet Secretary on the progress being made in rectifying the issues with the ventilation system (e.g. Bundle 13, volume 4, page 465).

233. There was also additional national oversight through use of the "NHS Board Performance Escalation Framework". NHSL was escalated to level 3 and then level 4 of the framework during the project.

234. When NHSL was escalated to level 3, an Oversight Board was appointed (Bundle 7, vol 1, page 339). The Oversight Board was created to provide advice to the Scottish Government on the readiness of the facility to open (Bundle 3, pages 9, 11). The Oversight Board started work in August 2019. Clinicians and IPC were fully involved in the work being carried out (Bundle 3, page 13).

235. The Oversight Board contained a range of skills. It was tasked with reporting to the Scottish Government on when the hospital could open.

236. NHSL was escalated to level 4 of the framework on 13 September 2019 (Bundle 7, vol 3, page 564). When NHSL was escalated to level 4, a senior programme director (Mary Morgan) was appointed. The evidence indicates that she assisted with resolving the problems with the project. The governance structure after the appointment of the Oversight Board and Mary Morgan is set out in Bundle 3, page 335.

237. HVC Notice 107 was issued, and Settlement Agreement 2 was entered into, by NHSL. HVC Notice 107 specifies the technical requirements for changes to the ventilation system for critical care in terms of the pressure regime and required air changes per hour to ensure compliance with SHTM 03-01.

238. Hoare Lea and Imtech were engaged by IHSL to design and build a ventilation system to comply with the requirements set out in HVC Notice 107.

239. IOM Ltd then carried out validation testing to demonstrate compliance of the system with SHTM 03-01. They confirmed that the system complied with SHTM 03-01.

240. Ms Freeman was only prepared to agree to allow the hospital to open (first the DCN, then the RHCYP for out-patients, then the entire RHCYP) when she was satisfied that it complied with published guidance.

241. The system was tested by IOM Ltd and was found to comply with the requirements of SMTM 03-01. Mr Maddocks has produced a report indicating that the revised system complies with published guidance.

242. Ms Freeman did not seek any advice on whether the hospital was "*unsafe*" with the original specification (as per SA1). Mr McKechnie (Wallace Whittle) contends the specification complied with SHTM 03-01. This view was not communicated to the Scottish Government. No substantial consideration was given to Mr McKechnie's views, or to the risk assessments completed in 2017 and 2018, when the decisions were made not to open, and then to open, the hospital. There was an assumption made that compliance with SHTM 03-01 is the means to ensure a critical care department is safe.

5.1 When the Scottish Government became aware of a potential issue with ventilation at the RHCYP/DCN.

243. The Scottish Government became aware of this issue on or around 2 July 2019. The issue was escalated to the Cabinet Secretary who took personal responsibility for the matter.

5.2 Whether perceived issues with the QEUH impacted on the decision making. This will include consideration of contact from whistle-blowers at the QEUH with the Scottish Government and its relevance (if any) to decisions taken in relation to the RHCYP/DCN.

244. Ms Freeman was aware of emerging issues in relation to QUEH when she took her decision not to open the RHCYP/DCN. In particular, she was aware of concerns that had been raised by Dr Inkster who worked there.

245. The emerging issues at the QUEH were part of the relevant background to the decision. In particular, Ms Freeman was aware of the difficulties in seeking to rectify problems once a hospital had opened to patients. However, the key reason for the decision was that the hospital did not comply with SHTM 03-01. Ms Freeman considered that non-compliance with the published guidance created an unreasonable risk to the safety of patients. She was also concerned as to whether the identified issues were the only issues with the hospital, or an indication that there might be others.

5.3 The basis for the Cabinet Secretary's decision not to open the hospital, including the material available to her.

246. The Cabinet Secretary was aware that there was non-compliance with published guidance. She considered that the non-compliance resulted in a risk to patient safety. She was concerned as to whether the non-compliance with SHTM 03-01 was the only issue with the hospital.

247. No evidence was available to Ms Freeman indicating that the hospital was safe for patients.

248. No risk assessment was undertaken prior to the decision being taken not to open the hospital. Ms Freeman determined that the new hospital had to comply with SHTM 03-01. Therefore, no risk assessment was subsequently undertaken in relation to the safety of the hospital as built under SA1. No consideration was given after that point to whether additional measures could be implemented to allow the hospital to open without significant remedial works being undertaken.

5.4 Communications with patients and families. This issue was covered at the Inquiry's first set of hearings in relation to patients and families. The intention is for relevant individuals within NHSL and Scottish Government to have an opportunity to address the issue from their perspective.

249. The physical, emotional and other effects on patients and families were addressed at the first set of hearings held by the Inquiry. The evidence indicates that patients and families were shocked and extremely concerned by the decision to cancel the opening of the hospital. In relation to the RHCYP, children required to be treated in a sub-optimal Victorian building. In relation to the DCN, there was a known risk of harm to patients due to the problems with the water system which NHSL required to manage to seek to reduce the risk of harm to patients.

250. A large number of patients, and appointments, were impacted by the decision not to open the new hospital. Approximately 2255 appointments required to be rescheduled immediately from July 2019 alone. Of these, 1586 were paediatric appointments and 669 were for DCN patients (Bundle 7, vol 1, page 303).

251. No formal complaints were received by NHSL or the Scottish Government in relation to the decision not to open the hospital or in relation to the rescheduling of appointments so they could take place in other hospitals (Bundle 7, vol 2, pages 113 and 117).

252. There are several aspects to the communication with patients and their families. The evidence indicates that NHSL informed all patients of the fact that appointments would not be taking place at the RHCYP/DCN as planned. A strategy was put in place to seek to ensure that patients and families knew where to attend for treatment. No evidence was led of any adverse issues surrounding that communication.

253. Patients and families were not provided with a written explanation, for the reasons for the RHCYP/DCN not opening as planned, by either NHSL or the Scottish Government. Two letters were sent to staff by the Cabinet Secretary providing an explanation of the situation. However, no similar letters were sent to patients and families. Mr Davison and Ms Freeman agreed that the communication to patients and families was sub-optimal in this regard. Ms Freeman acknowledged that if a similar problem was to arise in the future, a letter should be sent to patients and families.

254. Ms Freeman attended the old Sick Kids and DCN in August and October 2019 to seek to explain to staff and patients the reasons for the decisions that had been taken and to understand what steps could be taken to facilitate treatment being provided at the hospitals in the period until the new hospital could open.

255. The Scottish Government took overall responsibility for communication. This meant that NHSL could not have direct contact with patients or staff without prior approval from Scottish Government. Mr Davison indicated that this prevented NHSL being open and transparent with patients. Ms Freeman's position was that this decision was taken to ensure that there was clear and consistent messaging and to avoid confusing the public. We have not identified any specific issues that are material to the TOR.

6. The changes to the ventilation system required by HVC Notice 107 and made prior to the opening of the hospital

256. There were significant changes made to the ventilation system as a result of HVC 107 and Settlement Agreement 2. These resulted in the critical care rooms

(specified as balanced/ negative pressure and 4 air changes per hour) being changed to positive pressure and 10 air changes per hour. This required extensive remedial works. The ductwork and air handling units required to be replaced. The works were carried out by Imtech and Hoare Lea. They are addressed in the witness statement of Mr Winning. The revised system was tested by IOM Ltd and found to fully comply with SHTM 03-01 (Bundle 1, p2995, 3000 to 3002, 3008, 3014 and 3233). This was confirmed by Mr Maddocks in his report and in his oral evidence to the Inquiry.

6.1 Why the brief, and agreed strategy, for the ventilation system for critical care rooms and isolation rooms (as at the point of SA1) was deemed no longer to be adequate or appropriate.

257. NHSL had always wished the ventilation system to fully comply with SHTM 03-01 unless it agreed to a formal derogation. It did not knowingly agree to any such derogation for critical care rooms. Therefore, changes were made to seek to ensure that the ventilation system in critical care rooms fully complies with SHTM 03-01.

258. NHSL's overall requirement was to safely cohort infectious patients, for example, patients with respiratory syncytial virus (RSV). This requirement did not change throughout the project. However, the brief and strategy to achieve this objective changed significantly during the project. As at SA1, the technical solution was balanced or negative pressure. By HVC 107 and Settlement Agreement 2 this had changed to positive pressure.

259. Clinicians considered that the objective of safely cohorting infectious patients should be achieved by way of balanced or negative pressure. The evidence available to the Inquiry indicates that this is an acceptable strategy to cohort patients. However, this strategy would be in conflict with the published guidance set out in SHTM 03-01. This was not recognised by NHSL at the point SA1 was entered into.

260. NHSL produced a risk assessment in 2017 (which was refreshed in 2018) outlining the need to cohort patients. The risk assessments were not formally signed off by anyone in IPC. There does appear to have been some involvement from IPC,

potentially Janette Richards (or Rae). However, there is no clear evidence that she was aware that some of the relevant spaces were in critical care. She is not a signatory to the Risk Assessments. There is no communication available to the Inquiry indicating that anyone in IPC was shown the Risk Assessments.

261. At no point was any specific consideration given to air changes by clinicians or estates. There is reference to 4 air changes in various communications. However, these were merely outlining what had been specified in the environmental matrix. There was no appreciation that this was lower than the specification in SHTM 03-01.

262. In the period after the IOM Ltd reports were available, there were intensive discussions about whether it would be safe to change the ventilation system from balanced/ negative pressure to positive pressure. The consensus view was that this would be a safe environment. This view was also endorsed informally by Peter Hoffman (Public Health England) and Malcolm Thomas (one of the authors of HTM 03-01).

263. The key change was to air changes per hour. Ultimately, either pressure regime (balanced/ negative or positive) was likely to be adequate and safe. The change to positive pressure and 10 air changes per hour was made because Ms Freeman considered that the new build hospital must comply with the requirements of SHTM 03-01. No party – either from NHSL or Scottish Government – gave any consideration to a permanent solution that did not fully comply with SHTM 03-01.

264. No risk assessment was undertaken to assess whether 4 air changes per hour would have been safe either itself or with additional protective measures. The evidence of Dr Inverarity is that research conducted after the Covid-19 pandemic indicates that any air changes of less that 6 would likely have caused unacceptable risk to staff members treating infectious patients. This is consistent with the evidence of Professor Humphreys.

265. Given that the available evidence indicates that patients could be safely cohorted using either balanced/ negative pressure or positive pressure, the key issue was that the system was not providing 10 air changes per hour.

266. The evidence of the NHSL witnesses was that the intention was always for full compliance with SHTM 03-01. There was an error in the specification of the air change rates that was not spotted by clinicians or technical advisors. MML contend that although they drafted the technical schedule to SA1, they had no responsibility for the content of the document. It is no part of the remit of the Inquiry to determine whether MML has any legal liability for the technical schedule it drafted.

6.2 Whether lessons were learned from QEUH in relation to the ventilation system.

267. There were lessons learned from the QEUH. For example, a letter was circulated seeking confirmation about various controls, prompted by emerging issues at the QEUH (Bundle 13, vol 1, page 762).

268. Dr Inverarity was aware of potential problems with the ventilation system in summer 2018. He raised this with the project team to seek to ensure that an appropriate validation report was obtained. This is an example of lessons being learned by some individuals involved in the project. However, these learning points were not immediately apparent to all members of the project team.

269. While Dr Inverarity had discussed general concerns regarding the ventilation system with colleagues working at the QEUH in 2018, the evidence indicates that it was only in July 2019 that he was aware that there were potential issues with air changes and pressure rates at the QEUH (Bundle 13, vol 8, page 2226). By this time, the ventilation system had been installed at the RHCYP/DCN and SA1 had been concluded.

270. The QEUH was being built around the same time as the RHCYP/DCN. There were clearly emerging issues at the QUEH in late 2018 and early 2019. These issues had not been fully investigated. Therefore, there was limited opportunity to learn lessons. Moreover, the QEUH had a different specification for the ventilation system. Given the fact that the systems were not identical, there were no clear opportunities for lessons to be learned.

271. However, there was a lack of formal procedures to allow knowledge from the QEUH to be shared in relation to the RHCYP/DCN. Contact was largely on an informal colleague to colleague basis. There were no formal structures for information and knowledge to be exchanged between health boards.

272. Dr Inkster (QEUH) had discussions with Dr Inverarity. However, there was no evidence of any structured meetings between GGCHB and NHSL to discuss emerging issues at the QEUH. The Chair will need to consider whether this should be addressed for the future.

273. There are also gaps in the ability for other health boards to learn lessons from the RHCYP/DCN. NHSL commissioned a report from Grant Thornton. It accepted the conclusions of the report and the need for changes to be made to systems. These learnings have not been shared more widely within the NHS. This gives rise to a real risk of similar mistakes being made on future projects by other health boards.

6.3 The input (if any) from clinical leadership teams, IPC teams, estates teams, technical experts and other relevant parties prior to HVC Notice 107 being issued and Settlement Agreement No 2 being concluded.

274. There was significant input from clinicians, IPC, estates and technical advisors prior to HVC Notice 107 and Settlement Agreement 2 being concluded.

275. Dr Inverarity was involved in discussions with stakeholders on whether the proposed solution would be safe. The consensus view was that the new solution would be safe.

276. Dr Inverarity and Ms Guthrie were involved in risk assessing every clinical space in the hospital. This included a line by line review of the proposed technical solutions (Bundle 13, vol 7, page 152; Guthrie, Transcript, pages 127 to 131).

277. HFS were content with the proposed solution (Bundle 3, page 797; 944) albeit HFS were not taking design responsibility itself.

278. MML confirmed that they had identified no "*red flags*" in relation to the proposed solution albeit no design assurance was provided (Bundle 3, page 972).

279. MML maintained throughout the remedial works process that they could not confirm that any design solution was appropriate without undertaking design responsibility. MML could not be designer and client advisor (Bundle 3, page 943). The qualified statements are consistent with this approach.

280. There was some evidence given at the hearings that gave the impression that MML had approved the final solution set out in Settlement Agreement 2 and had signed the "AHU Remedials Cover Sheet" (Transcript for Mr Maddocks, pages 66-67). Mr Maddocks was asked to consider the AHU Remedials Cover Sheet (Bundle 1, page 3233) which was signed by a number of individuals. The document available to Mr Maddocks at the hearing contains redactions hiding the signing blocks. The redactions suggest that all listed individuals may have signed the document. However, that is not the case. The unredacted document was not signed by any individual from MML. The only assurance provided by MML was that it has identified no "*red flags*" with the design (Bundle 3, page 972).

6.4 The reasons for NHSL issuing HVC Notice 107 and entering into Settlement Agreement No 2.

281. NHSL issued HVC Notice 107 and entered into Settlement Agreement 2 to ensure that the new hospital fully complied with the guidance set out in SHTM 03-01.

6.5 The changes made to the design for the ventilation system for critical care rooms and isolation rooms.

282. Significant changes were made to the design. In particular, the pressure regime was changed to positive pressure. The air changes were changed to 10 air changes per hour.

6.6 Remedial works undertaken to the ventilation system in relation to critical care and isolation rooms.

283. The remedial works were extensive. The ventilation system, concerning the critical care where the dispute arose, was effectively replaced. By way of example, the ductwork and Air Handling Units were replaced.

6.7 Whether the remedial works have been adequate and effective. In particular, whether the ventilation system in critical care and isolation rooms is designed, and commissioned, in compliance with published guidance and best practice.

284. The remedial works have been adequate and effective. The ventilation system in critical care and isolation rooms is designed, and commissioned, in compliance with published guidance and best practice.

285. This is evidenced by the testing carried out by IOM Ltd (Bundle 1, p2995, 3000, 3002, 3008, 3014, 3233). It is addressed in the report by Mr Maddocks and in his oral evidence. There is no evidence before the Inquiry indicating any residual safety concerns arising from the ventilation system.

7. The decision making, and governance, around the decision to open the hospital

7.1 The basis for the Cabinet Secretary determining that the hospital should open.

286. Governance is dealt with in detail in PPP 9.

287. The Cabinet Secretary was only prepared to agree to allow the hospital to open when she was satisfied that the ventilation system complied with published guidance.

288. The air changes and pressure in critical care was a standing item on the agenda of the Oversight Board. (The minutes of the Oversight Board are included in Bundle 3). By 8 March 2021, Ms Morgan, the Senior Programme Director, was satisfied that the hospital was safe to open. By this time, the IOM Ltd reports had been obtained showing that the hospital complied with SHTM 03-01, IOM Ltd confirmed that the ventilation system was fit for purpose and would only require routine maintenance to remain so. Gordon James, HFS, had reported no outstanding issues from HFS' perspective. HAI Scribe 4 had been completed by Lindsay Guthrie (Bundle 8, page 240).

8. Whether the hospital provides a suitable environment for the delivery of safe, effective person-centred care

8.1 The material demonstrating that the ventilation system in critical care and isolation rooms provides a suitable environment for the delivery of safe, effective person-centred care.

289. IOM Ltd carried out testing that demonstrates that the ventilation system complies with SHTM 03-01 (Bundle 1, p2995, 3000, 3002, 3008, 3014, 3233). IOM Ltd confirmed that the ventilation system was fit for purpose and would only require routine maintenance to remain so.

290. NHSL also received assurances from various parties including Dr Inverarity. Ms Guthrie completed the stage 4 HAI-SCRIBE.

291. HFS and the Authorising Engineer confirmed that they were content with the revised specification. MML provided confirmation that no issues had been identified by them albeit they were not taking design responsibility.

292. The hospital provides a suitable environment for the delivery of safe, effective person-centred care.

9. Changes in Policies, Procedures, Protocols and Governance Arrangements after the project

9.1 Whether NHSL, and the wider NHS, have implemented recommendations from previous reports (including the Grant Thornton report) and whether these are now embedded in the wider NHS.

293. Grant Thornton reported to NHSL on the governance and internal controls for the RHCYP/DCN project (Bundle 10, page 4). Their report included recommendations for NHSL to strengthen its internal controls for major capital projects, and NHSL's response to those recommendations (ibid., page 39).

294. NHSL accepted the recommendations made by Grant Thornton, having been involved with discussions about them before they were made, and have sought to implement them. This work has been complex, and delayed both by the Covid pandemic and by NHSL's desire to take account of the establishment of Assure ("Assure").

295. NHSL wish to test the measures they have developed in real projects. Whilst this initiative has been started it has not been possible yet to complete it because of a pause on capital expenditure.

296. NHSL has supplied to the Inquiry a bundle containing its draft assurance framework documentation (Bundle 13, volume 11, pages 4 to 88) and internal committee papers relating to it (ibid. pages 89 to 143).

297. The Grant Thornton report was shared with the Scottish Government but, because it was commissioned by NHSL for their own use, it has not been shared more widely within the NHS. NHSL have, however, circulated their framework to the Scottish Government and it is available to other health boards via NHSL's website.

298. The following witnesses dealt with the issue:

- Susan Goldsmith, Transcript, 125 to 137
- John Connaghan, Transcript, 159 to 162
- Alan Morrison, Statement, paragraphs 74 to 77

9.2 Whether there are systemic knowledge transfer arrangements in place to learn lessons from healthcare construction projects and whether they are adequate and effective

299. Prior to the creation of Assure, there were no formal knowledge transfer arrangements in place. While there was scope for the Scottish Government and/ or NHS bodies to communicate with health boards, there was no structured mechanism to ensure that lessons were learned from previous projects.

300. Assure has introduced procedures to seek to ensure that lessons are learned from previous projects. On 13 December 2022, it published a paper on its website identifying lessons learned by HFS and ARHAI from significant healthcare construction projects (Assure Lessons Learned: Overview for the Interim Review Service; https://www.nss.nhs.scot/publications/nhs-scotland-assure-lessons-learned/). The lessons learned informed Assure's Key Stage Assurance Review Workbooks (ibid., page 3), and included:

- The need to establish a clear brief which is understood and agreed by all stakeholders at a sufficiently early stage (page 4)

- The need to audit design, with input from chartered engineers and infection control specialists (page 4)

- The need for risk assessment in accordance with guidance (page 6)

- The need for rigorous scrutiny of derogations by all stakeholders (page 6)

- The need to assess the competence and experience of contractors for the work (page 8)

- Particular examples of lessons learned in relation to key building engineering systems (fire, ventilation, electrics, medical gases, and water) (page 10).

301. Assure has replaced their Initial Agreement KSAR with a briefing for health boards on lessons learned, which takes place at the early stages of a project (Rodger, Transcript, page 123).

302. As for infection control incidents arising from engineering issues, infection control protocols are outlined in the National Infection Prevention and Control Manual. Assure's engineers support ARHAI staff in that context (Rodger, Transcript, 219).

9.3 Whether NHSL and the Scottish Government had an opportunity to learn lessons from the experience of issues relating to ventilation at the QEUH and whether they took advantage of that opportunity.

303. Informal communications amongst infection control doctors about the functioning of PPVL isolation rooms took place in 2016 (Dr Inverarity, Statement, paragraph 95). Dr Inverarity raised the need for validation for theatres to be carried out on 24 August 2018. He highlighted the need to do this *"...given the recent experiences by my microbiology colleagues in Glasgow with their new children's hospital"*, and emphasised the need to do so prior to handover: "*Glasgow have identified many issues since accepting their building that they are in the process of retrospectively addressing and we should avoid finding ourselves in that position*" (Bundle 7, vol 1, pages 218-

219). Dr Inverarity's point was raised again, including by email on 4 January 2019 (Bundle 4, page 4). He had flagged the requirement for formal validation reports rather than "*a collection of documents*". This was raised with the project management team before SA1 was formally signed, but this did not result in the Stage 4 HAI-SCRIBE being completed before the hospital was handed over. Whilst Dr Inverarity appeared to have learned the lesson from the QEUH, NHSL as an institution failed to act upon it.

304. Dr Inverarity was made aware in March 2019 through discussions with infection control consultants at the QEUH about air flow and pressure issues in their isolation rooms, and on that basis asked his colleague to ensure that similar details were properly assessed in the context of NHSL's HAI SCRIBE review (Inverarity, Transcript, page 77; Bundle 13, volume 3, page 462).

305. Otherwise, information sharing about the QEUH ventilation appears to have been minimal until late 2018 into early 2019 (Donald Inverarity, Transcript, page 71; Janice MacKenzie, Transcript, page 70). The ventilation systems at the RHCYP/DCN were, in their original form, completed by late 2018.

306. Sufficient concern about ventilation at the QEUH had arisen within the Scottish Government by early 2019 to prompt a meeting of the Strategic Facilities Group on 23 January 2019. Paul Gray, the then Director of Health and Social Care, wrote to all Scottish health boards on 25 January 2019 seeking confirmation that certain controls were in place and working effectively. The letter sought confirmation that all critical ventilation systems were being inspected and maintained in line with SHTM 03-01 (Bundle 13, volume 1, page 762). The focus at that stage was on inspection and maintenance, rather than design and installation.

307. The underlying cause(s) of the issues arising at the QEUH may not, however, have been known at that time (Wright, Transcript, page 31).

308. The Inquiry has correspondence between QEUH whistle-blowers and the Scottish Government from 2019 onwards (Bundle 13, volume 10; Jeane Freeman Supplementary Statement, paragraph 8). The Inquiry has, however, yet to hear detailed evidence about the issues relating to ventilation at the QEUH. From the evidence which

the Inquiry has heard in relation to the RHCYP/DCN, very little information was available to NHSL and the Scottish Government about lessons to be learned from the ventilation systems at the QEUH prior to completion of the RHCYP/DCN critical care ventilation in 2018.

309. After IOM Limited had reported to NHSL in June/July 2019 that the ventilation in the RHCYP critical care department delivered air changes below the recommended level, Dr Inverarity corresponded with Dr Theresa Inkster, his microbiologist colleague at NHS Greater Glasgow & Clyde. That helped inform his thinking but there were differences in the ventilation systems between the two hospitals (Donald Inverarity, Statement, paragraphs 136, 142, 152, 190; Transcript, pages 77, 124, 128, 135).

310. Jeane Freeman's decision-making about the RHCYP/DCN from July 2019 was influenced by her knowledge of events at the QEUH (Supplementary Statement, paragraphs 16 to 20) including the difficulties of making changes to key building systems after a hospital has opened and patients are being treated in it.

9.4 The changes in relation to new hospital projects arising from the creation of Assure.

311. Assure ("Assure") is a division of NHS NSS. It provides the services formerly supplied by Health Facilities Scotland (HFS) and Antimicrobial Resistance and Healthcare Associated Infection Scotland (ARHAI) together with the new Key Stage Assurance Review process (Bundle 9).

312. Assure was set up to seek to prevent a recurrence of what happened at the RHCYP/DCN, being the late discovery that the performance of a key building engineering system (the ventilation in the critical care department) fell below the parameters recommended in SHTM guidance.

313. Plans for Assure's creation began to form a matter of days after IOM Limited had reported on that non-compliance (Alan Morrison, Transcript, 118; Malcolm

Wright, Transcript, 76). These plans were prompted by Jeane Freeman's desire that the Cabinet Secretary for Health, who is ultimately accountable to Parliament for the health service, be given robust assurance about healthcare construction projects (Morrison, Assure Statement, paragraph 9).

314. Assure was launched on 1 June 2021. From that date, all projects requiring approval from the Scottish Government Capital Investment Group ("CIG") have been required to undertake Assure's Key Stage Assurance Reviews ("KSARs"). The key stages of project approval at which KSARs are to take place are Outline Business Case, Full Business Case, Construction, Commissioning and Handover. CIG approval will require satisfactory completion of the relevant KSAR (DL (2021) 14, Bundle 9, page 70). The Scottish Government may also commission Assure to undertake reviews on other projects where it considers that appropriate (Morrison, Assure Statement, paragraph 29). Since 6 February 2023, no building project undergoing Assure's KSARs may open to the public until it has received "supported status" from Assure (DL (2023) 03 Bundle 9, page 75).

315. In practical terms, therefore, Assure has significant influence over the funding and progress of healthcare building projects in Scotland and whether or not they open to patients. An important limitation on Assure's role, however, is that it does not certify that design solutions are adequate or safe. It does not, for example, provide confirmation that the projects have complied with all applicable guidance. Responsibility and accountability for that compliance remains with the NHS board which is running the project, and any contractors or consultants which the board engages for that purpose.

316. Assure is neither an inspector, not a regulator.

317. Assure has published workbooks for each of the KSARs, which explain the process and set out a framework of questions to be addressed in each review (Bundle 9, pages 107 to 266).

318. Assure describes its KSARs as delivering "*an independent peer review*" and "*a challenge to the robustness of the Health Board's brief, plans and processes*" (e.g.,

Bundle 9, page 124). They provide an opportunity to identify, and allow health boards to address, potential shortcomings in project governance in particular around compliance with guidance applicable to building engineering systems (water, plumbing and drainage; ventilation; electrics; medical gases), and infection prevention and control in the built environment.

319. The KSARs aim to gain assurance that the boards have suitable expertise and procedures in place to ensure proper decision-making about their requirements in relation to these matters, and that they maintain appropriate records about those decisions. Assure's Head of Engineering emphasised the importance of a "*golden thread*" by which key project decisions are documented for future reference (Rodger, Transcript, page 131). In the particular context of ventilation design, the KSARs require (for example) evidence that the ventilation requirements for particular rooms have been signed off by various stakeholders (Bundle 9, page 138), and that the board's authorising engineer has been involved and reviewed the design proposals (ibid., page 139).

320. In Mr. Rodger's words, the Key Stage Assurance process "*aims to ensure that the Health Board's project governance and procedures are such that the risk of inadvertent non-compliance with guidance is reduced*". The key term is "*reduced*": the KSAR process is not a guarantee that such risk will be eradicated (Transcript, page 118). He explained that Assure does not check all project details for compliance with guidance, but carries out sample reviews to a degree necessary to gain confidence in the project's management. The degree of scrutiny required to gain that confidence may vary from project to project (Transcript, 165, 175). The process therefore requires sound judgment by the Assure staff who carry it out.

321. Mr Rodger emphasised the centrality to the KSAR process of a comprehensive understanding of the needs of the patients using the facility (Transcript, page 140).

322. The chair may wish to consider the adequacy of these arrangements. In our submission, they represent a robust challenge to help improve boards' governance and compliance with guidance, both on the project undergoing review and for future projects, and provide assurance to government (and indirectly to boards and the public)

about these matters. Whilst they do not involve Assure certifying compliance, or inspecting buildings to check for compliance, that may represent a reasonable compromise on grounds of cost and practicality. It may also help maintain the division of responsibility between government and health boards on which the NHS in Scotland is currently based. It may be that, over time, and as a result of undergoing KSARs, health boards' understanding of guidance, and their project governance practices will improve, reducing the future burden of the KSARs (Rodger, Transcript, 202, 208). It may also be that Assure's own expertise and experience will develop through their engagement with health boards and their projects, helping them to refine and improve the KSARs and the guidance.

323. The Chair will also wish to carefully consider Ms Freeman's evidence on these issues. Ms Freeman's vision was for a centre of excellence to undertake a role akin to a clerk of works. She wanted to ensure that there was physical testing of key building systems. Assure does not undertake that role. Ms Freeman also outlined that, in her view, Assure is not a complete answer to the challenges that arise in healthcare building projects. She considered that more consideration may need to be given to whether the Government should have a greater role in such projects due to the fact that the Cabinet Secretary ultimately has responsibility for the public being treated in safe hospitals (Transcript 34, 78, 114 to end). This was not favoured by other witnesses, who generally preferred leaving accountability with health boards (Wright, Transcript, page 92, 100; Morrison, Transcript, page 173; Morgan, Transcript, page 264; McQueen, Transcript, page 221; Connaghan, Transcript, page 157).

324. Key witness evidence on Assure is set out in the following documents:

- Jeane Freeman, Statement, paragraphs 150 to 157; Transcript, 34, 78 to 80, 114 to 137
- Alan Morrison, Statement on Assure; Transcript, 161 to 180
- Julie Critchley, Statement and Transcript
- Thomas Rodger, Statement and Transcript

- Malcolm Wright, Transcript, 90 to 102
- Steve Maddocks, Report paragraph 6.1
- Lindsay Guthrie, Statement, paragraph 268 onwards
- Tracey Gillies, Transcript, page 67 onwards
- Alex McMahon, Transcript, page 63 onwards
- Professor Connaghan, Transcript, page 154 onwards
- Mary Morgan, Transcript, page 264 onwards
- Lindsay Guthrie, Transcript, page 153 onwards
- Graeme Greer, Transcript, page 193 onwards
- Ronnie Henderson, Transcript, page 181
- Stewart McKechnie, Transcript, page 142
- Sarah Jane Sutherland, Transcript, page 196
- Dr Donald Inverarity, Transcript, page 173

325. Points which the chair may wish to consider include:

- Whether Assure unnecessarily duplicates work which others are already engaged to deal with: designers, technical advisers, etc
- The KSARs are mandated only for projects requiring CIG approval; for other projects, it is a matter for the health boards whether or not they choose to follow them (Rodger, Transcript, 138).

- The need to refine, and streamline, the various processes which aim to ensure compliance with guidance, such as NDAPs and KSARs (Rodger, Transcript, page 142).

- The benefits in efficiency and consistency to be derived through the same Assure team carrying out each KSAR stage on any given project (Rodger, Transcript, 210).

- Concerns that Assure has gone too far in emphasising that boards must themselves take responsibility for compliance with guidance, tending to avoid providing the assistance that boards need (Rodger, Transcript, 211).

- The need to work with resource limitations which affect health boards, and to ensure the KSAR process does not put pressure on staff (in particular IPC professionals) to work beyond their competence.

- Related to the above, ensuring that clinicians and IPC staff are involved only where their expertise is genuinely needed.

- The recognition by various witnesses that Assure is new and will require time to bed down.

- The KSAR workbooks may require to be updated to reflect the most recent SHTM guidance (Rodger, Transcript, 179).

326. Witnesses were generally positive about the Assure KSAR process, although few had direct experience of it and no project has yet gone through the full process.

9.5 Changes introduced by the most recent version of SHTM 03-01, including the creation of the Ventilation Safety Group.

327. A new version of SHTM 03-01 was issued in February 2022 (Bundle 1, page 2263). It is substantially revised from the previous version (2014 version: Bundle 1, page 1035). Important provisions of the revised guidance include:

- The recommendation to treat it "*as the standard to be achieved*", and for new build facilities to comply with it unless the Ventilation Safety Group has agreed a derogation (pages 2268, 2289).

- The introduction of the Ventilation Safety Group ("VSG"), the remit of which is to assess all aspects of ventilation safety and resilience required for the safe development and operation of healthcare premises.

  Its remit explicitly applies to the design, commissioning and validation of new systems. It is to report to a designated person at board level. Derogations from SHTM guidance are to be subject to the scrutiny, and agreement in writing, of the VSG; and derogations are to be supported by a body of evidence that the proposal will provide a degree of safety no less than if the SHTM guidance had been followed (pages 2269, 2286).

- Definitions are provided for clinical areas and critical systems (the latter of which includes critical care areas) (page 2288).

- Clarification of the areas where natural ventilation is appropriate (e.g., paragraph 5.6, page 2298)

- Improved clarification of recommendations for particular areas, including recommended air change rates.

  Critical care areas are now defined as being those in which level 2 or 3 care is provided (paragraph 5.41, page 2304; chapter 8, page 2314; pages 2340, 2341; Appendix 2, page 2431; Appendix 12 (defining care levels), page 2487).

- Guidance on validation, including a requirement for all new and refurbished ventilation systems to be independently validated prior to acceptance by the client.

  This validation is to be carried out by the health board's authorising engineer or someone of similar standing, who is completely independent of those who designed, supplied, installed, commissioned, or are to operate and maintain, the system. It is now essential for the validating engineer to have been involved in the initial brief and design specification, and for any derogations to be clearly defined, agreed and documented during those earlier stages. This should prevent issues of non-compliance arising from inadequate design being detected unexpectedly only at the stage of final validation. The validating engineer is to provide a full report of the validation findings, which concludes with a clear statement on whether or not the system achieved the standard set out in the agreed design specification (chapter 12, page 2402 onwards).

328. Further comment on these issues is available in the following:

- Henderson, Transcript, page 186
- MacKenzie, Transcript, page 83
- Greer, Transcript, page 200
- Pike, Transcript, page 94
- McKechnie, Transcript, page 132
- Sutherland, Transcript, page 142
- Inverarity, Transcript, pages 21, 178
- Maddocks, Transcript, page 70
- Greer, Transcript, pages 136, 200
- Pike, Transcript, page 96
- Hall, Transcript, page 184

329. The Chair may wish to consider whether the issue with non-compliant ventilation in the RHCYP/DCN critical care department would have arisen had the updated version of SHTM 03-01 been in place at the time. In our submission, had the

foregoing changes been in place, and implemented, it is much more likely that the RHCYP/DCN ventilation would have been designed and installed to meet the SHTM recommendations first time, and that the cost and disruption of remedial works would have been avoided.

330. The Chair may also wish to consider whether, in the particular context of ventilation at least, the changes to SHTM 03-01 would be a sufficient and proportionate way to address the type of issue which arose on the RHCYP/DCN project without the need for Assure's KSAR process. That is particularly so given the cost and time which compliance with the KSARs is likely to involve, and the fact that Assure neither certifies compliance nor purports to eradicate issues of non-compliance.

9.6 Lessons learned to ensure past mistakes are not repeated

331. We address this matter in section 5 below, on potential recommendations.

4. The questions posed in Terms of Reference 1 - 12

Remit

332. The overarching aim of the part of the Inquiry dealing with the RHCYP/DCN is to consider the planning, design, construction, commissioning and, where appropriate, maintenance of that hospital. Planning and initial design were considered at the earlier hearing diet. The remaining issues were dealt within at the most recent hearings diet. No relevant issues concerning maintenance have been identified. The focus of the hearings was on the pressure and air changes in critical care. Other relevant issues, that had the potential to adversely impact on patient safety and care, are addressed in PPP 7 and the accompanying Note.

333. The ventilation system for critical care at the RHCYP/DCN, as originally installed and commissioned, was not adequate and had the potential to adversely impact on patient safety and care.

334. The evidence before the Inquiry indicates that safety is not a binary issue. Rather, there is a sliding scale of risk from safe to unsafe, which can be influenced by many factors. SHTM 03-01 sets out recommended parameters reflecting a consensus about what is appropriate to create an appropriate level of patient safety. These are consistent with parameters set in other countries. Any departure from such recommendations, taken in isolation, is liable to increase risk. However, the evidence indicates that other factors could be introduced to make a space that did not have ventilation compliant with SHTM 03-01 sufficiently safe such that patients could be treated there. For example, the old Sick Kids hospital at Sciennes did not have any mechanical ventilation but the other control measures ensured that a safe environment was created in which to treat patients.

335. The available evidence indicates that achieving 4 air changes per hour when 10 are recommended creates an unacceptable level of risk to the safety of patients unless other sufficient control measures are introduced. This was the evidence of Professor Humphreys at the earlier diet of hearings. His view was that achieving less than 50% of the air changes specified in guidance would create an unacceptable risk to patient safety. Dr Inverarity gave evidence indicating that achieving less that 6 air changes per

hour gave rise to a real risk to the safety of staff, based on the additional knowledge those working in the field have gained following the Covid-19 pandemic.

336. The shortcomings in the ventilation system at the RHCYP/DCN were only identified a matter of days before the hospital was due to open. Those shortcomings could have been prevented if a clear brief had been agreed before financial close. They could have been identified earlier than they were if the standard HAI-SCRIBE procedures had been followed prior to handover.

337. The decision not to open the hospital as planned had a significant impact on patients and families. Patients and families were shocked and scared. They had limited information as to why the hospital was not opening as planned.

338. In relation to the RHCYP, care required to continue in the sub-optimal, Victorian Sick Kids hospital building at Sciennes. However, safe care could be provided there. There is no indication of adverse clinical outcomes for patients, in the period up to the RHCYP opening, arising from the built environment. The issues were more acute for the DCN. It had problems with the water system, including pseudomonas. Patients had contracted brain infections. There was a reduction in capacity for operations. There were therefore risks associated with its continued use.

339. Significant remedial works were carried out to the ventilation system at the RHCYP/DCN to remedy non-compliance with SHTM 03-01. This involved extensive works to replace the ventilation system for the relevant areas.

340. The independent testing, and expert evidence, indicates that the remedial works have been successful. The ventilation system in the hospital fully complies with published guidance, including SHTM 03-01. The hospital environment is suitable for the delivery of safe, effective person-centred care. No evidence is available to the Inquiry indicating any contrary position.

TOR 1

341. The Chair is invited to find that a key building system at the hospital was defective in the sense used in the TORs. The specification for the ventilation system for the RHCYP/DCN – in the period from financial close until the remedial works were completed – did not clearly conform to relevant guidance. This is not a finding that the ventilation system was in breach of the Project Agreement, but that it did not fully comply with SHTM 03-01 as NHSL had intended that it should.

342. The key deficiency was with air changes per hour. The ventilation system in critical care provided fewer than half the recommended air changes per hour in certain rooms. Pressure did not conform to the guidance in SHTM 03-01 but this had been risk assessed and found to be preferable for the proposed clinical functions.

343. The ventilation system was replaced. The ventilation system is now adequate. It is capable of the function for which it was intended. It conforms to applicable recommendations, guidance and good practice. In particular, it fully complies with the guidance in SHTM 03-01.

344. In a report published by NHS NSS on 9 September 2019, the following comments were made on the state of the evidence base:

"From an infection prevention and control perspective, there is low-quality to no evidence from outbreak reports and current guidance, respectively, to support minimum ventilation requirements. Therefore, it is not possible to make conclusive statements regarding the individual minimum ventilation parameters for inpatient care areas. A rapid review of the literature found limited clinical evidence to directly implicate air change rates alone in having a direct impact on the development of an outbreak or incidence of infection. Therefore, it is reasonable that, in the absence of evidence, healthcare design teams should continue to adhere to current national guidance. In the event of a deviation from the current recommended ventilation parameters, design teams should ensure that air changes per hour are maintained as close as possible to the recommended air changes per hour without compromising other aspects of the ventilation system requirements. In addition a full assessment of the services and patient

population should be carried out and mechanisms for monitoring established. Caution is advised in relying on air change rates alone to provide adequate protection from infection; this is only one part of a multifactorial process involved in creating the appropriate airflow patterns with appropriate mixing and dilution of contaminants. Nationally, further research is required to look beyond air change rates to examine the effects that other factors such as supply and exhaust location, door position and motion, spatial orientation, surface composition, temperature, humidity, and air distribution patterns have on particle migration in clinical areas." (Bundle 3, p119, paragraph 4.2.6).

345. The issue of "risk" to patients from non-compliance with parameters set out in published guidance is an area the Chair may consider should be the subject of recommendations. In particular, the Chair may consider that there is a need for more research into the link between air change rates and risk to patients.

346. Professor Humphreys gave evidence indicating that there needs to be a wholesale review of hospital ventilation including consideration being given to new technologies. The Inquiry heard evidence from Mr Maddocks that the science and technology in this area is developing. The concept of "equivalent air changes" per hour has been introduced as a result of technological advances including the use of air scrubbers/ portable HEPA filters and ultra violet light technology. The Chair may consider that this is an area where suitable recommendations should be made.

347. Issues concerning the ventilation system (other than pressure and air changes) are set out in the Note to PPP 7. Non-ventilation issues are addressed in PPP 7.

TOR 2

348. The contractual structure and financing are addressed in detail in PPP 10 and our previous submissions.

349. The contractual structure did not directly contribute to the defects that arose. If a clear brief had been set out at financial close, it is unlikely that problems would have arisen on the project.

350. NHSL's decision to depart from the original project requirements (including the requirement for a full set of room data sheets at financial close) resulted in a situation where the brief for the ventilation system was not clear or finalised at financial close.

351. The Chair will require to consider whether the NPD model contributed to mistakes that were made at later stages of the project.

352. For example, the Inquiry has heard evidence that IHSL was in financial difficulties at the point of SA1. It had significant liabilities but no income stream. NHSL departed from standard procedures, including completing HAI-SCRIBE stage 4 prior to handover, because of the need to accept the hospital and trigger the payments to IHSL. Had the standard procedures, including HAI-SCRIBE Stage 4, been followed, the issues with the ventilation system would have been detected sooner than they were, albeit still after they had been built in.

353. NPD contracts aim to transfer full design risk to the project company, except in relation to operational functionality. However, the health board still has responsibility for the delivery of safe healthcare. The project demonstrates that it can be difficult to make changes to technical specifications after financial close in a revenue funded project. It can be particularly difficult for a health board to obtain clear advice on perceived problems with a specification for a technical building system at the later stages of a project because advisors do not wish to risk taking overall design responsibility for a proposed design. When issues of non-compliance with SHTM 03-01 were identified, MML were resistant to advising on the adequacy of the solution as they did not consider they could take on the design risk for the ventilation system.

TOR 3

354. NHSL put in place governance procedures to oversee the project. These were in line with the procedures set out in the Scottish Capital Investment Manual. The governance structures are set out in detail in PPP 9.

355. The project was overseen at key milestones. However, the Chair will wish to consider whether the governance procedures at key stages, particularly for the approvals of SA1, were adequate and effective.

356. The project team determined that the proposed technical solutions set out in SA1 were acceptable to NHSL. The governance bodies were told the technical solutions were appropriate. However, there was no vouching provided by the project team to support this view. In particular, no report from IPC, engineers or technical advisers was provided. IPC had not been involved in the discussions leading up to the agreement. The technical advisors had declined to sign off on the appropriateness of the solution as they were not designers and did not wish to take on design responsibility. These difficulties do not appear to have been reported to the governance bodies, including the Finance and Resources Committee and the Board of NHSL.

357. However, unless the governance bodies had insisted on an independent technical review being undertaken, it is difficult to see how the problems with the project could have been avoided.

358. Input was provided by clinicians, IPC, estates officers and technical experts. One key problem was that not all relevant disciplines were involved at the correct times. In particular, IPC were not involved in the decision to accept the technical solution set out in SA1 or in the decision to accept the hospital without the standard stage 4 HAI-SCRIBE procedure being completed. Another problem was that NHSL staff with the requisite knowledge did not combine it to reach the correct conclusion: NHSL's project clinical director and commissioning manager between them knew enough about the clinical context, the proposed technical solution, and the SHTM guidance to identify the departure from that guidance, but did not identify that departure because each lacked

information the other had. These issues resulted in decisions being taken which resulted in a built environment that was not safe for patients.

359. There is no evidence indicating that there were issues with organisational culture that discouraged staff from raising concerns. There were formal policies in place in relation to raising concerns and whistleblowing in particular. This is addressed in greater detail in PPP 9.

360. Staff did raise concerns during the project. By way of example, Dr Inverarity raised concerns in relation to the lack of a suitable validation report. This led to a suitable report being instructed and the detection of the ventilation problems before patients were transferred to the hospital.

TOR 4

361. There is no evidence indicating any deliberate concealment or failure to disclose wrongdoing.

362. NHSL had whistleblowing policies in place during the project and there were a variety of channels through which concerns could be raised. These are addressed in PPP 9, chapter 36 (Bundle 11, page 619).

363. From September 2005, NHSL had in place a "Freedom of Speech Policy and Procedure". This policy was for staff to raise concerns at work and where the NHSL grievance procedure and wider polices such as race equality and equal opportunities would not be appropriate.

364. In 2016, this was replaced with the 'Whistleblowing Policy and Procedure'. The purpose of this policy "*is to ensure employees have a proper and widely publicised procedure for voicing whistleblowing concerns*."

365. Prior to 2013, human resources policies were publicised to members of staff through an 'Employment Policies Manual'. This was first produced in 2005 and distributed to all NHS workplaces with regular updates issued. This manual was withdrawn in 2013 with the development of the HR Online website which sat within the NHSL intranet. Thereafter, staff were directed to HR Online to ensure they were accessing the most up to date version of the policies and guidance.

366. NHSL communicated polices to members of staff in a variety of ways namely using a bulletin to all staff entitled 'Team Brief', intranet content and information cascaded to staff through the management structure.

367. In 2019, NHSL introduced "Speak Up", an initiative designed to encourage staff to feel safe and supported in raising concerns. This was introduced so that staff who had a concern could discuss this confidentially and receive advice and guidance on what to do next to address the issue.

368. NHSL had in place Incident/Adverse Event Management Policies throughout the period of the project which provided another avenue through which concerns could be raised.

TOR 5

369. The Scottish Government, and Cabinet Secretary in particular, had ultimate responsibility for the NHS and healthcare delivery in Scotland. However, the responsibility for delivering the project sat with NHSL.

370. The Scottish Government had an oversight role. However, once the funding had been put in place, the national oversight was relatively limited. The Scottish Government would only have further involvement if the project experienced problems.

371. A degree of national oversight was provided in relation to SA1. The Chair will require to consider whether the national oversight was adequate and effective.

372. Statements made to the Scottish Government on the suitability of the technical solutions set out in SA1 were taken at face value without any supporting material. For example, no view was sought from HFS and no report from a qualified expert was provided to confirm that the works were necessary and appropriate. On one view, this was a missed opportunity to identify the problems at an earlier stage.

373. However, it is not clear that any potential problems with this aspect of governance made any material contribution to the shortcomings in the ventilation system. IHSL had confirmed that the ventilation system fully complied with published guidance (Bundle 4, page 9). Mr McKechnie still maintains that position. If he had been asked for confirmation at the time, he would presumably have given it. Greater scrutiny of those involved in the project would have been unlikely to detect the problem.

374. Unless a full audit of the proposed technical solution had been instructed, it is difficult to see how the issues could have been detected by the governance bodies. The Chair will require to consider whether the instruction of such a review would have been realistic or proportionate.

375. Further assurance would now be provided within the health board through the Ventilation Safety Group, with additional oversight external to the health board from Assure. Therefore, even if the Chair concludes that there were problems with national governance and oversight, significant and substantial steps have been taken to address them.

376. There was very substantial national oversight from 2 July 2019. This was in the form of the Cabinet Secretary taking control of the key decision making. She was only prepared to allow the hospital to open when she received assurances that it fully complied with the relevant published guidance (Bundle 7, vol 1, page 79). Regular briefings were provided to the Cabinet Secretary on the progress being made in rectifying the issues with the ventilation system (e.g. Bundle 13, vol 4, page 465).

377. There was also additional national oversight through use of the "NHS Board Performance Escalation Framework". NHSL was escalated to level 3 and then level 4 of the framework during the project.

378. National oversight and support for the project also came from SFT. This involved assistance for NHSL in preparing the project for procurement under an NPD structure and in carrying out Key Stage Reviews at important stages in the procurement process. SFT's focus, consistently with the nature of its expertise, was on the commercial and financial aspects of the project. This included an interest in design and the terms of the Project Agreement but only insofar as they impacted upon those aspects. It was never part of SFT's role to consider compliance with technical guidance such as SHTMs, never mind to detect errors at the level of detailed parameters in an environmental matrix of which the Board and its advisers were unaware.

379. The available evidence indicates that there were effective communications between NHSL and Scottish Government in the period to 4 July 2019. Updates were provided to the Scottish Government on the progress of the project. For example, when there was the potential for litigation, NHSL regularly briefed the Scottish Government.

TOR 6

380. SHTM 03-01 (2014) outlined the requirements for commissioning and validation (Bundle 1, pages 1035, 1148). These involved a range of tests to demonstrate that the system is working as required. At the end of the validation process, a validation report was to be produced. This was addressed at paragraphs 8.64 and 8.65:

"Ventilation system commissioning/validation report

8.64 Following commissioning and/or validation a full report detailing the findings should be produced. The system will only be acceptable to the client if at the time of validation it is considered fit for purpose and will only require routine maintenance in order to remain so for its projected life.

8.65 The report shall conclude with a clear statement as to whether the ventilation system achieved or did not achieve the required standard. A copy of the report should be lodged with the following groups:

- *the user department;*
- *infection control (where required);*
- *estates and facilities."*

381. There is a degree of ambiguity in the guidance as to what the "required standard" is. Is it the standards set out in the guidance or the contractual standard (which may involve a derogation from the guidance)?

382. There was a degree of confusion on the part of NHSL as to the level of inspection and testing that required to be conducted before the hospital could open. Mr Henderson (NHSL's commissioning manager) explained in his evidence that complications arose due to the NPD model. NHSL had responsibility for providing healthcare at the hospital. However, it did not own the building. The building was owned by IHSL. Mr Henderson was therefore unclear as to what reports should have been instructed/ obtained by NHSL as opposed to IHSL.

383. A variety of documentation was provided by IHSL to NHSL to demonstrate that the system was working to the required standard. This was in the form of raw data as opposed to a formal report. Mr Henderson of NHSL was initially content with the documentation provided by IHSL in relation to commissioning and validation (Bundle 4, page 6). However, the IPC team, including Dr Inverarity and Ms Guthrie, were not content with the available information. The IPC team were not able to readily interpret the raw data and wished to see a report that complied with the guidance set out in SHTM 03-01. In particular, they wished to see a clear statement that there was performance to the required standard and that only routine maintenance would be required. The project team agreed to additional testing as they wished IPC to be wholly satisfied with the technical performance of the ventilation system (Bundle 6, page 11).

384. The Board of NHSL was not involved in the original decision to instruct testing by IOM Ltd. This was instructed by the project team as a result of the position adopted

by IPC. But for the position of IPC, there is a real risk that the hospital would have opened without all required testing having been carried out. The project team were content with the original raw data provided by IHSL. There is no indication that the Board itself would have insisted on any further testing being carried out or the production of a report that complied with SHTM 03-01 to be produced.

385. The original testing of the system was conducted in line with an interpretation of the contractual requirements. The system was not tested against the requirements of SHTM 03-01.

386. It is important to highlight that, at this stage, NHSL considered that the system had been designed to fully comply with SHTM 03-01 with the exception of known derogations for the neutropenic ward, and from 6 to 4 air changes. Otherwise, NHSL did not understand there to be any difference between the contractual requirements and the requirements set out in the published guidance.

387. The testing conducted by IOM Ltd identified that for certain spaces in the hospital the pressure regime and air changes did not conform to the guidance set out in SHTM 03-01 (Bundle 6, pages 202, 205, 209, 213, 216, 220, 221, 227, 234, 235, 238, 241, 245, 254, 256).

388. Mr Currie was aware of the emerging issue on 24 June 2019. Senior management at NHSL were aware of the issue on or around 28 June 2019 (Bundle 6, page 252). The issue was escalated to the Scottish Government on 2 June 2019.

389. When the non-conformance was identified, remedial works were carried out and further testing was conducted by IOM Ltd. This demonstrated that the system was functioning in conformance with SHTM 03-01.

390. The additional testing by IOM Ltd was against the standards set out in SHTM 03-01. It provided assurance to the Board of NHSL that the ventilation system functioned in accordance with the final contractual specification, guidance and good practice.

391. No relevant issues have been identified in terms of the information and training provided on the operation and maintenance of key building systems.

TOR 7

392. To remedy the defects, the critical care ventilation system was effectively replaced. Imtech and Hoare Lea were engaged to design and install a ventilation system that provided positive pressure and 10 air changes per hour.

393. The revised specification for the ventilation system is set out in HVC 107 (Bundle 3, page 1146) and Settlement Agreement 2 (Bundle 3, page 1204). These documents set out that NHSL wanted to amend the critical care ventilation system from 4 air changes to 10 air changes per hour with an associated change to the pressure regime (all as described in HVC 107).

394. In accordance with Clause 33 of the Project Agreement and Schedule Part 16 of the Project Agreement, NHSL issued IHSL with a Board Change Notice in respect of the required works. The works were carried out and testing was then carried out by IOM Ltd.

395. IOM Ltd confirmed that the ventilation system met the requirements of SHTM 03-01. Mr Maddocks has provided an expert report confirming that the system is designed, and operating, in conformity with SHTM 03-01.

396. HFS was fully involved in relation to reviewing NHSL's proposed permanent solution for the ventilation and the *"…contracting, design, installation, commissioning and setting to work processes as well as assurance around the appropriate advice on infection control."* (Bundle 3, pages 16, 17). All topics were to be reviewed from Estates and IPC perspectives and an assessment made against the published guidance.

397. Air changes and pressure were regular items on the agenda of the Oversight Board. On 8 August 2019, the Oversight Board agreed in principle that:

"…if a technical solution was designed that would allow 10 air changes per hour in the required rooms in the critical care area, which complied with the relevant SHTM standard, and was properly implemented, then the critical care area would be fit for use." (Bundle 3, pages 43, 44).

398. Mr Henderson (NHSL commissioning manager), Mr Jameson of IOM Ltd and Mr Rayner (Authorising Engineer) were content that air handling units were acceptable to the client because, at the time of validation, they were considered fit for purpose and would only require routine maintenance in order to remain so for their projected life (Bundle 1, page 3233).

399. John Rayner, authorising engineer, issued a design assurance statement on 17 May 2020. He stated that, following a review of the design, he was satisfied that it met NHSL's performance requirements (Bundle 3, page 974).

400. HFS were content with the proposed solution (Bundle 3, page 797; 944) albeit HFS were not taking design responsibility itself.

401. MML confirmed that they had identified no "*red flags*" in relation to the proposed solution albeit no design assurance was provided (Bundle 3, page 972).

402. MML maintained throughout the remedial works process that they could not confirm that any design solution was appropriate without undertaking design responsibility. MML could not be designer and client advisor (Bundle 3, page 943). The qualified statements are consistent with this approach.

403. All of the evidence before the Inquiry indicates that the remedial works were adequate and effective. No witness has expressed any concerns about the safety of any key building system at the RHCYP/DCN since the hospital opened.

TOR 8

404. The physical, emotional and other effects on patients and families were addressed at the first set of hearings held by the Inquiry. The evidence indicates that patients and families were shocked and extremely concerned by the decision to cancel the opening of the hospital. In relation to the RHCYP, children required to be treated in a sub-optimal Victorian building. In relation to the DCN, there was a known risk of harm to patients due to the problems with the water system which NHSL required to manage to seek to reduce the risk of harm to patients.

405. A large number of patients, and appointments, were impacted by the decision not to open the new hospital. Approximately 2255 appointments required to be rescheduled immediately. Of these, 1586 related to paediatric patients and 669 to DCN patients (Bundle 7, vol 1, page 303).

406. No formal complaints were received by NHSL or the Scottish Government in relation to the decision not to open the hospital (Bundle 7, vol 2, pages 113, 117).

407. There are several aspects to the communication with patients and their families. The evidence indicates that NHSL informed all patients of the fact that appointments would not be taking place at the RHCYP/DCN as planned. A strategy was put in place to seek to ensure that patients and families knew where to attend for treatment. No evidence was led of any adverse issues surrounding that communication.

408. Patients and families were not provided with a direct explanation, for the reasons for the RHCYP/DCN not opening as planned, by either NHSL or the Scottish Government. Two letters were sent to staff by the Cabinet Secretary providing an explanation of the situation. However, no similar letters were sent to patients and families. Mr Davison and Ms Freeman agreed that the communication to patients and families was sub-optimal in this regard. Ms Freeman acknowledged that if a similar problem was to arise in the future, a letter should be sent to patients and families.

TOR 9

409. This is not applicable to the RHCYP/DCN

TOR 10

410. This is addressed in the previous closing submissions.

TOR 11

411. There were no systematic knowledge transfer arrangements in place to learn lessons from healthcare construction projects in the period prior to the creation of Assure.

412. The Scottish Government did write to health boards in relation to certain discrete issues that arose on the QEUH. However, the evidence before the Inquiry indicates that there was no centralised system for capturing and recording learnings from healthcare construction projects. Therefore, any board faced with a new build hospital project would not have been able to readily access learnings from previous projects.

413. The landscape for projects has undoubtedly changed with the creation of Assure. It is a specialist body which is intended to gather knowledge and experience about healthcare building projects, and make it available to boards undertaking new projects. If done properly, this should allow lessons to be learned on an ongoing basis. The procedures are addressed in more detail in answer to topic 9 in the list of topics.

TOR 12

414. NHSL had opportunities to learn lessons from the experience of issues in relation to ventilation and water at the QEUH.

415. The Scottish Government wrote to all health boards in relation to the risk of cryptococcus following issues emerging at the QEUH (Bundle 4, page 8). This prompted NHSL to seek assurances in relation to the design of the hospital. An assurance was provided by IHSL that there was full compliance with SHTM 03-01.

416. There were wider opportunities to learn from experiences at the QEUH. There was contact between Dr Inverarity and Dr Inkster in relation to emerging issues at the QEUH.

417. Dr Inverarity knew, in 2018, that issues had arisen with the ventilation system at the QEUH that needed significant remedial works to be carried out. He sought to avoid similar issues occurring at the QEUH. However, Dr Inverarity was not involved in key decisions, including the decision to not complete the standard stage 4 HAI-SCRIBE procedure before the hospital was handed over to NHSL.

418. The more difficult issue is whether there were truly opportunities to learn from the experiences at the QEUH and avoid similar issues at the RHCYP/DCN. The key dispute in relation to the RHCYP/DCN came to a head in 2018. Agreement was reached and the works to the ventilation system were carried out in 2018, albeit the agreement was not formally approved and documented until February 2019. Over this period of time, there was little concrete evidence available to NHSL about the problems with the QEUH ventilation system. Therefore, learning opportunities were limited. The Chair may wish to keep this term of reference under review when further hearings take place in relation to the QEUH.

5. Potential Recommendations

419. In this section, we discuss potential recommendations. Some of these the Chair could make now. Others may be better deferred until the Chair has heard evidence on the QEUH, although he may nonetheless welcome Core Participants' comments on them now.

420. Appendix 2 of our previous written submission records witnesses' suggestions for improving the procurement and building process for new hospitals. These remain valid for consideration and we do not repeat them here.

421. We repeat the suggestion we have previously made for a symposium or round table meeting to discuss potential recommendations with stakeholders. This may best be done after the Chair has heard the evidence in relation to the QEUH. The Chair may wish to consider circulating a paper to interested parties in advance of the symposium, setting out proposals for discussion.

422. It is important to note that there have been significant reforms since the hospital opened. These have gone a long way to addressing key problems. SHTM 03-01 was updated in 2022 and a further version is expected in 2024. The introduction of the VSG is, in our submission, perhaps the single most important improvement for avoiding in the future the type of issues which arose on the RHCYP/DCN project. It provides a forum for all relevant disciplines to meet, consider and approve ventilation decisions. It should ensure that the "partnership" model (as set out in guidance such as SHFN 30) is fully achieved.

423. The revised guidance also improves clarity around recommended parameters, for example linking them to definitions of the level of care being provided in a space. Such changes should reduce the risk of misunderstandings, particularly on the part of engineers, on future projects.

424. The establishment of Assure is also a positive step. Assure conducts key stage assurance reviews on projects to seek to ensure that similar problems to those that arose on the RHCYP/DCN do not arise in the future. There is an issue as to whether the

current model for Assure – which is neither an inspector nor a regulator – is the correct one. We address this further below.

Potential Recommendations – Suitable for an Interim Report

Risk assessment if funding route changes

425. The RCHYP/DCN project demonstrates that risks can arise if design or specification-related material generated in the context of one funding model is then used, without proper assessment of the risks of doing so, after the funding model is changed. The risks of using the environmental matrix from the capital-funded phase for the revenue-funded phase were inadequately assessed or mitigated. It was provided to tenderers with insufficient assessment as to whether it would be useful. NHSL intended that it was a document that could not be relied on by tenderers. That is not how IHSL interpreted the document. In our submission, the lack of a suitable risk assessment is the genesis of many of the problems that arose on the project. As Mr Maddocks explained in his report, and in his evidence, there is little point in providing a "draft" environmental matrix that could not be relied on. Its inclusion was likely to cause confusion to tenderers but this was not appreciated at the time.

426. In situations where the funding model or procurement route changes mid-project, a risk assessment should be conducted to assess whether work done on the project to that point is suitable for the revised project. The rationale for decisions taken in this regard should be formally recorded.

Clarity in brief

427. It is critical that the health board's brief for key building systems is clear, unambiguous and finalised before a contract is signed and financial close is achieved. While development of the design can be carried over to the reviewable design development phase, clarification of the health board's brief should not.

428. In determining whether or not the health board's brief is sufficiently clear and unambiguous, appropriate consideration must be given to the element of judgment and

interpretation of guidance which may be necessary for the building systems to meet the clinical needs of the board. The board is best placed to identify which output parameters of key building systems are essential for the particular clinical uses it has in mind for the hospital. Those should be specified by the board as part of its brief and not left to the judgment of the project company and its subcontractors during the design phase.

Derogations – Requirement for a Standard Form

429. SHTM guidance now requires the VSG to be involved in any decision to depart from guidance. However, there is no standard form for a derogation from guidance. The requirement is simply that there should be a body of evidence justifying a decision. Different health boards could therefore adopt different procedures for recording a derogation.

430. The evidence before the Inquiry from the public sector (including NHSL), and industry, indicated that a standard form derogation for use throughout the NHS would be beneficial. This would ensure that derogations are captured and recorded in a uniform way. This would result in consistent and uniform practices. It would also bring clarity to how a derogation is agreed and ensure that the approval of all parties is recorded in an appropriate and familiar way.

Duplication of Procedures

431. A range of procedures now exists to help ensure health board projects meet appropriate standards. One is the NHS Scotland Design Assessment Process ("NDAP"). There is also a Sustainable Design and Construction Procedure ("SDAC"). In addition, there is the Assure KSAR procedure. These can be time consuming and demanding to complete. There is a risk they become unduly bureaucratic and focused on process rather than substance. It is important that they be streamlined, and potentially merged, to ensure they are thorough and robust whilst avoiding duplication and unnecessary delay and cost. They must be genuinely helpful to boards and cognisant of the commercial and other pressures likely to affect projects.

432. Consideration should also be given to how complimentary procedures – such as aspects of HAI-SCRIBE – can potentially be streamlined to avoid duplication with other procedures.

Information about common errors

433. SHFN 30 (2007) stated that common errors on projects included incorrect air turnover and airflow patterns (Bundle 13, vol 3, pages 554, 557). This was removed from the most recent version of SHFN (2014), but the RHCYP/DCN project demonstrates that the risk persists.

434. It is important that common project errors are not repeated. One helpful step is to ensure health boards undertaking projects have ready and early access to useful information about such errors so that they are aware of them and thereby better equipped to avoid them. The information should be updated as new, significant errors are identified. It should be drafted to be genuinely useful, so should focus on material errors which, if repeated, would have a material impact, and for which there are identified solutions which are capable of being readily implemented. Information which is not prepared with rigour is unlikely to be helpful and may be counterproductive.

435. Consideration should be given to whether the "*lessons learned*" process introduced by Assure adequately addresses this issue. It may be helpful for the Chair to request NHS NSS to address this issue in its closing submissions.

Commissioning and Validation for Revenue Funded Projects

436. The evidence indicated some uncertainty about which entity should be responsible for commissioning and validation of engineering systems on revenue funded projects: the health board which is to be responsible for health services in the building, or the project company which owns and maintains it.

437. In a standard capital funded project, the facility would be owned by the health board. It would therefore be for the health board to instruct the commissioning and validation. The answer is less clear for a revenue funded model and this should be

clarified. However, the end result should be the same. A short report should be generated confirming whether there is full compliance with published guidance.

Role Specifications

438. There are two aspects to this issue: (1) role specifications within the NHS; and (2) the role of advisors.

439. Within the NHS, there is a lack of clarity about the role to be played by particular disciplines in new build hospital projects. There is clear guidance that there should be a partnership approach, with all relevant disciplines involved. However, there is a lack of clarity about the tasks each should undertake and the extent of their involvement at various stages. This risks undermining the partnership model as there is scope for different disciplines to consider that a specific issue/ decision is not within their sphere of knowledge and/ or it is not for them to be actively involved. There is also a risk that disciplines are involved at some stages where this is not necessary or beneficial. This potentially risks wasting limited resources: for example, clinicians and IPC personnel being involved in highly technical meetings about engineering issues that they have no experience in and can contribute nothing to; or about engineering issues where well-established guidance is to be applied without giving rise to any clinical or infection control issues on which their expertise is needed.

440. This issue is most acute in relation to IPC. Dr Inverarity, Ms Guthrie and Ms Sutherland highlighted the demands placed on IPC professionals. Ms Guthrie and Ms Sutherland highlighted that under the new system, IPC professionals believe they are being forced into the role of "quality control" officers. They consider that IPC professionals are being put under pressure to "sign off" technical aspects of design for key building systems for which they have no relevant expertise.

441. It is important that there is clarity as to what is expected from individual disciplines at various stages of a project. That is particularly so given that the VSG now mandates multi-disciplinary decision making.

442. The evidence before the Inquiry indicates that a job/ role specification for various disciplines, particularly IPC, would be beneficial.

443. The Inquiry heard evidence that NHS National Education Scotland is working on a knowledge and skills framework for the built environment. Professor McMahon outlined that there is also a proposal to produce a role specification for IPC. He indicated that this should be completed before he retired in Easter 2024. The Chair may wish to have an update on the progress made in relation to these initiatives from relevant parties in their closing submissions.

444. Consideration should also be given to whether there are sufficient IPC professionals to resource the current system. Several witnesses raised concern about there being insufficient IPC staff to implement the procedures introduced by Assure. If there are insufficient personnel to resource the system, it will not work effectively.

445. Similar issues arise in relation to advisors. The evidence before the Inquiry indicates that there was a lack of clarity in relation to role of technical advisors, particularly MML, after financial close.

446. MML was appointed to provide a project management role and to provide "*ad hoc*" advice on a range of technical matters. It was often unclear when and if NHSL were instructing, and when and if MML were providing, formal advice on technical matters which NHSL were entitled to rely upon.

447. This created a situation whereby there was a lack of clarity in relation to what advice and assurance (if any) MML were providing. NHSL considered that specific input and assurance was being provided on technical solutions. For example, Mr Henderson and Ms MacKenzie outlined that they considered that MML were providing a very wide range of technical advice and assistance including advising on the suitability of the technical matters in SA1. Mr Greer of MML considered that MML had a more limited role and had specifically not agreed to have any responsibility for the technical solution set out in SA1.

448. Purported assurances from technical advisors on the suitability of technical solutions formed the basis of some decision making at Board level. Communications were also provided to Scottish Government on certain technical solutions being appropriate because there had been input and assurance from advisors.

449. There is an absence of contemporaneous documentation demonstrating when technical advice was sought and when technical advice was provided.

450. The lack of clarity in relation to technical advice can be contrasted with the role of the solicitors. When legal advice was sought, there tended to be a very clear instruction with a very clear statement of the advice provided in response.

451. In our submission, a similar procedure should be considered when technical advisors (particularly engineers) are providing specific technical advice. There should be a clear record of the advice requested and the advice tendered. This should ensure that there is clarity around what input advisors are providing. This is particularly important where, as on the RHCYP/DCN project, the technical advisors work closely day-to-day with the health board's project team. Such arrangements can lead to informality and a lack of clarity about the scope and role of the advice, and the reliance which can be placed upon it. Following our recommended approach should generate a body of evidence to support and document relevant decisions. This should contribute to more robust governance and oversight of decision making.

452. This issue was highlighted in the Grant Thornton report. NHSL has taken steps to address the issue. However, it is not clear form the available evidence that any such changes have taken place more widely within the NHS. In our view, a uniform policy or procedure for boards undertaking new build hospital projects in relation to obtaining, and recording, technical advice on key issues would be beneficial.

Training

453. Good decision-making about building engineering systems and their role in infection control depends upon contributions from a number of distinct professional disciplines, in particular engineers, IPC professionals and clinicians. Their decisions

are likely to be improved if each has a basic understanding of the way in which the various disciplines overlap in ensuring patient safety and care.

454. Healthcare engineering does not feature in the mandatory training for microbiologists or IPC professionals. The evidence indicates that there is the potential for individuals with little or no training, or practical experience of the key building system in a hospital (e.g. water and ventilation), to be asked to undertake key roles on projects.

455. In our submission, it would be helpful for IPC professionals to receive some basic training on the recommendations made by the NHS's own guidance for engineering systems, insofar as they are made in the interests of patient safety and care, before working on large scale hospital projects.

456. The evidence also indicates that engineers would benefit from basic training on infection control principles and clinical requirements before embarking on new build hospital projects.

457. Clinicians involved in projects would benefit from basic training in the recommended output parameters of building engineering systems which have a direct bearing on the safety and care of patients in their departments. For example, it would be helpful for clinicians working in departments for which specialist output parameters are recommended, such as the particular pressure gradients or air change rates recommended for critical care departments, to have basic knowledge of what those recommendations are.

Risk assessment of the implications of non-compliance with guidance

458. When the decision was taken not to open the RHCYP/DCN, no risk assessment was undertaken to determine if the ventilation system (as installed) was unsafe. The decision, instead, was that the hospital should not open until there was full compliance with SHTM 03-01. The evidence indicates that the system as installed would have had unacceptable risk. Therefore, the decision was justifiable. However, mere non-compliance with recommendations/guidance will not always, automatically, equate to an unsafe environment. In future, an individual risk assessment should be undertaken

to ensure that appropriate decisions are taken, and that expensive remedial work is not instructed unnecessarily.

Potential Recommendations – For Consideration after the Evidence about the QEUH

459. There are a range of other potential recommendations that the Chair may wish to consider. At this stage, we do not consider that there is sufficient material for the Chair to reach a definitive decision on these matters. We consider that evidence in relation to the QEUH would assist the Chair in determining whether any are necessary or appropriate. Therefore, while we set out a range of options below, we are not advocating that any recommendations are made in relation to these issues at this stage.

A Review of Hospital Ventilation

460. The evidence before the Inquiry indicates that there is a lack of clear, research-based evidence in relation to the healthcare built environment, including the link between specific air changes per hour and infection risk (Bundle 3, page 199).

461. Professor Humphreys gave evidence indicating that there should be a review of hospital ventilation. Professor Humphreys stated that:

"There is a need for a review of ventilation quality in healthcare facilities, particularly for vulnerable patients even if risks are complex and there are a number of factors, which affect the development of infection."

"I think that over the last 10 or 15 years, the complexity of care has increased in hospitals and particularly in in critical care areas, and we're now seeing a much greater, I think, number of vulnerable patients who are immunocompromised and a more heterogeneous group of patients, some of which may not be recognised as vulnerable…"

"…in the context of the COVID-19 pandemic, we have realised that…our hospitals were under huge pressure because of the transmissibility of COVID and because we

had very, very defined and, in many instances, very limited facilities in which to care for these patients because most of our areas within hospital were naturally ventilated and we had no control over where the airflows were going. So we often had to come up with innovative ideas in terms of, for example, putting fans on windows to extract the air from a core area where there might be COVID patients to make sure the air from those COVID patients was not going back into the rest of the ward."

"…we need to review and I think probably either increase the number of air control ventilated facilities or avail of alternative technologies such as portable HEPA filtration systems, or there are various air purification systems that are marketed out there commercially that may be worth looking at."

"I think we need to look at the categories of patients we now have in hospital compared to 10 or 15 years ago because most of the facilities that many of us work in are not only 10 or 15 years old, but would be older, much older than that, and we need to look at the proportion of those patients that are low risk, medium risk, high risk, and maybe very high risk, such as our neutropenic patients. We need to look at what current facilities we have for those patients and whether we believe that those are adequate or not. Then I think we need to incorporate into that some sort of future planning not only for increased numbers of some of those patients that I talked about, but perhaps a bit more flexibility such that if we have another pandemic, we can perhaps react better. So those would be, in very broad general terms, the kind of things I'm talking about."

"…[the review] would need to…involve, obviously, management and healthcare planners, it would need to involve infection prevention and control and infection specialists, it would need to involve clinicians looking after these patients, engineers, architects and probably health economists as well amongst others…"

(Humphreys, Transcript, page 67).

462. The Chair may consider that further research requires to be conducted to ensure that national guidance is adequate, appropriate and has a robust scientific underpinning.

463. The Chair may consider that any such research should address emerging areas including "equivalent air changes per hour" and new technologies (such as ultra violet light) for which there is no national guidance in Scotland (cf. England: Bundle 13, vol 10, page 297).

464. Assure has a research engineering department. It is involved with Napier University in research into the healthcare built environment. It may be helpful for the Chair to receive submissions on the nature of this research to determine whether Assure should be left to progress with the matter of whether a wider review is required. It may be helpful to the Chair if the nature of the research being conducted was addressed further in the closing submissions on behalf of NHS NSS.

Legislative Intervention

465. When the new centre of excellence was under consideration, one of the issues identified by research was that the published guidance required "*more teeth*" (Bundle 9, page 60). No specific steps appear to have been taken in this regard beyond requiring projects to have approved status under the KSARs (which include a degree of technical assessment) before funding is provided.

466. The Chair will require to consider whether this is sufficient or whether further steps require to be taken to seek to ensure that hospitals provide a safe environment for patients, families and staff.

467. Several witnesses considered that key parameters for critical building systems (particularly ventilation and water) should not be mere guidance. The Chair may wish to consider whether the parameters for key building systems should be enshrined in law. That may depend on the view the Chair reaches on whether further research is required in this area.

468. The Scottish Government equated compliance with SHTM 03-01 with patient safety. Non-compliance was considered to be an unacceptable risk to patient safety. If that is the prevailing view, then it is hard to understand why the parameters would be mere "guidance" rather than a legal standard that must be complied with.

469. If the Chair considers that recommendations should be made on this issue, changes could made to the Building (Scotland) Regulations 2004 and/ or the Technical Handbook.

470. The Building (Scotland) Regulations 2004 set standards for buildings in Scotland. Building Standard 3.14 concerns Ventilation. It states that:

> *"Every building must be designed and constructed in a way that ventilation is provided so that the air quality inside the building is not a threat to the building or the health of the occupants".*

471. Section 3.14.5 of the Mechanical Ventilation, Environment (Non-domestic buildings) Technical Handbook provides that at least 8 litres/second of fresh air per occupant should be provided. There is no further specification as to the air quality for a building such as a hospital.

472. The Buildings Standards Technical Handbook does not contain any references to published guidance or associated standards. That is in contrast to the regime in England. There, the Building Regulations 2010 introduce the concept of "Approved Documents". These set out what, in ordinary circumstances, may be accepted as one way to comply with the Building Regulations. Approved Document Part F "Ventilation requirements vol 2" contains specific reference to published guidance such as Health Technical Memorandums as a method of complying with the building regulations.

473. The Cabinet Secretary gave clear evidence that she equated compliance with the guidance with ensuring an adequate level of patient safety. Until the hospital complied with the parameters set out in SHTM 03-01, it was not in her view sufficiently safe for patients to occupy the building.

474. If the Chair accepts this analysis, it is difficult justify setting out the requirements in non-binding "guidance". The Chair may consider that compliance with the parameters should be a legal requirement unless there is a justification for non-compliance with a suitable derogation.

475. However, an overriding theme of the evidence was that it was difficult to take guidance – that is open to interpretation, and requires judgment to apply – and to make compliance with it a contractual requirement. Those same issues would arise for a legislative requirement. Therefore, thought may need to be given to whether specific parameters for key building systems could be set out clearly and comprehensively in the Technical Handbook and/ or legislation.

476. Any such provision should also allow for a derogation if the clinical need arises. A process for documenting a derogation would need to be included in any legislative provision.

477. In our submission, any such provision should be for new build hospitals at the point of construction. There should not be an ongoing requirement to comply with any updated standards at a later point in time to avoid the need for existing facilities to constantly be updated to the most modern of requirements. In our submission, that is likely to be practically unworkable, prohibitively expensive and disproportionate.

The role of NHS Assure

478. The Inquiry heard two competing views on the role the centre for excellence should have.

479. Certain witnesses considered that the centre for excellence should have an inspection role and formally "sign off" that a building complies with published guidance. This approach was favoured by individuals that had worked for NHSL on the project (including Mr Henderson and Ms McKenzie). Other witnesses did not think that Assure should have any such role. Responsibility for the project should sit with the health board.

480. The Chair will require to consider whether any changes are necessary in this regard.

A review of NHS Assure

481. The majority of the evidence available to the Inquiry indicates that Assure has made a positive contribution in seeking to minimise the risk of key building systems having inappropriate specifications. However, it has created a significant burden, particularly for IPC professionals. A review of Assure's role may be appropriate to ensure that it builds on the positive work it has done to date.

The briefing of Projects

482. The critical issue with the project was the lack of clarity in the brief. Assure has produced a template environmental matrix. The template is not mandatory and there is no absolute requirement for it to replace room data sheets.

483. The evidence from Mr Maddocks was that there should be "one source of truth" (i.e. one document that sets out the specific technical requirements). The Chair may consider that the brief should be defined either by room data sheets or by an environmental matrix, but not both. Having both risks confusion and contradiction. An alternative is to ensure any environmental matrix (which the evidence indicates to be a helpful document welcomed by those who work on projects) is derived directly from the room data sheets with appropriate document control to ensure no divergence between them. In this regard, the Chair may recall Mr Maddocks' evidence that an environmental matrix can be derived directly from the ADB database.

484. If the environmental matrix option is to be adopted, the Chair may wish to consider whether the notion of "room function" (included in the template environmental matrix) is helpful. It was the incorrect application of generalised "room function" data to rooms in departments subject to different recommendations that resulted in the problems in the environmental matrix for the project.

Standardisation

485. The Inquiry has heard evidence about the benefits of standardisation. Assure is working on "*repeatable rooms*". To date, 7 have been produced. The Chair may wish to consider whether this work should be expanded.

486. Hospitals require to provide a similar level of care throughout the country. It may be that problems could be reduced if there was a standard layout and technical specification for specific spaces. These would be uniform throughout the NHS. That would avoid a situation where clinical output specifications, bespoke environmental matrices, etc have to be created for individual projects. Projects may be able to be conducted with less risk, and at lower design cost, if that work was carried out in advance. This would, however, come at the cost of flexibility.

487. One option the Chair may wish to consider is whether a fully populated template environmental matrix, that is maintained and updated by the NHS, would be beneficial for health boards. This might include room entries which reflect standardised rooms or the recommendations made by guidance.

488. Mr Stevenson, of MML, highlighted the potential benefits of an Environmental Matrix maintained by the NHS. Such a system would avoid the need to create a bespoke environmental matrix for each project (Transcript, page 41):

> *"…it would be good if we had, say, an NHS- provided Environmental Matrix for the industry to use. That would certainly get rid of a lot of conflicts and discussions over variations…If we had something produced by the NHS, give a definitive list from the schedule of accommodations and the provisions, the industry could feed back into that as things develop and change – because they always change, technologies change, procedures change, rooms change – the industry could then be bringing that back to the NHS, HFS, etc. and saying, "Look, we've got a new room type here. Can we agree on this as a criteria?" for that criteria to then be embedded into the master matrix, say. So, again, that would be the industry giving active feedback back into a centrally held NHS document. I think that would be a worthwhile exercise."*

489. The Chair will wish to consider whether there is further standardisation work that could contribute to reducing errors. For example, it may be worth considering preparation of an NHS standard set of Board Construction Requirements which set at least a starting point for hospital building projects. In preparing these, consideration could be given to how best to avoid problems which can arise from unfocused requirements to comply with NHS guidance which, in itself, is neither mandatory nor definitive in all circumstances.

Procurement

490. The Target Operating Model outlined that current procurement processes were "*not fit for purpose*" (Bundle 9, page 59). Witnesses were unable to assist the Inquiry with what specific aspects of procurement were considered to be not fit for purpose. The Inquiry has thus far only considered the procurement of the NPD model. However, we have been unable to identify any specific aspect of the procurement procedure itself that was not fit for purpose, as opposed to its implementation in the particular circumstances of the RHCYP/DCN project. The Chair may wish to revisit this issue after hearing evidence on the QEUH.

The Funding of Projects

491. A number of witnesses questioned whether revenue funding was appropriate for healthcare projects. Mr Greer outlined that while, theoretically, the risk is transferred that is not always the reality. Fundamentally, the requirement to provide safe healthcare facilities rests with the health board. The evidence before the Inquiry indicates that making changes after a contract is signed, particularly changes to technical specifications, is very difficult on a revenue funded project. Any such decisions can lead to delays in the delivery of projects and significant increases in cost. There is also no clear route to obtain quick technical advice on changes, as the entire ethos of the model is to push design risk to the private sector partner and advisors will be reluctant to take on any design assurance role if changes need to be made mid-way through a project.

492. The Chair may wish to review this issue once he has heard further evidence on the QEUH which proceeded by way of capital funding.

Alternative Models

493. Mr Maddocks outlined that one issue with current healthcare projects is that they can be adversarial. He gave evidence on partnering models whereby there is project insurance rather than various parties holding their own insurance. He outlined the potential benefits of this model in fostering a more collaborative approach to projects.

494. When the Chair has evidence of the capital funded model, the Chair may wish to give consideration to whether this model would be appropriate for hospital projects.

John MacGregor KC (Senior Counsel to the Inquiry)

and

Ross McClelland, advocate (Junior Counsel to the Inquiry)

7 May 2024