Statement of

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Experience and Expertise:

1. My name is Edward McLaughlan and my address is - c/o NHS National Services Scotland, 5 Cadogan Street, Glasgow. My date of birth is [redacted] and I am 59 years old. As of 19 April 2022 I have been seconded to NHS Lanarkshire to work on the project to replace Monklands hospital and my role will be to help the project team to provide assurance of compliance with all appropriate standards and guidance in scope for NHS Scotland Assure. Prior to this date I was an Assistant Director of Health Facilities Scotland, having held that post since 2006. Health Facilities Scotland provides support to the health service in Scotland in matters that relate to the design, operation, maintenance, and disposal of its buildings. It is part of NHS National Services Scotland ("NSS") which is a National Health Board providing support to the NHS in a diverse range of topics. NSS is part of the health service. Since the creation of NHS Scotland Assure in 2020, Health Facilities Scotland is now part of NHS Scotland Assure, which in turn is part of NSS. I led a team of approximately 40 national leads and advisors to deliver a diverse range of services including developing national strategies and change programmes to deliver safe, effective healthcare facilities. I was accountable for various services including estates elements of infection prevention in the built environment, research, statutory compliance, critical engineering services (water systems, ventilation etc), medical device safety and sustainability. To provide perspective on the level of resource available to support NHS boards during the period the Inquiry is considering, i.e. 2009 to the present, the resource available in engineering has been one member of staff across all health boards. I fulfilled a similar role to this during the 1990s, but not during the period the Inquiry is considering, i.e. 2009 to the present. At this time it was mainly filled by Ian Stewart and then Ian Storrar. Ian Stewart was a temporary member

of staff who fulfilled the role between two permanent members of staff; Lex Campbell, who left the role in 2011, and Ian Storrar who came into the role in 2015.

2. I was a member of the directorate management team for NHS Scotland Assure and have played a part in the development of that service from its inception. NHS Scotland Assure was formed to ensure that the buildings NHS Scotland builds and operates are compliant with appropriate standards and guidance. It was launched in shadow form in late 2019 and full form in Summer 2021. When NHS Scotland Assure launched, Health Facilities Scotland was encompassed in it and therefore my role with Health Facilities Scotland and with NHS Scotland Assure were one and the same thing.

3. Prior to my assistant director role I was a director of NHS Scotland Property & Environment Forum Executive from 2002 to 2006. This is the organisation that became Health Facilities Scotland. Before this, the same service was called the Healthcare Engineering & Environment Unit, where I was Principal Engineer, providing the Health Service with technical advice on engineering and environment issues. I came to the Health Service from Winton Caledonian, a ventilation and water hygiene consultancy, where I was a Principal Engineer from 1993 to 1995. Prior to that I held posts in the Property Services Agency, which managed the non-health government property portfolio, and in the British Merchant Navy, serving as an engineering officer. I have the following academic qualifications and membership:

   MBA - Master of Business Administration (1996)
   BEng (hons) - Bachelor of Engineering with Honours (1991)
   CEng - Chartered Engineer (1993)
   MIHEEM – Member of the Institute of Healthcare Engineering and Estate Management (1996)

4. I have a Bachelor's degree in Environmental Engineering. Environmental in this case refers to the built environment and thus the degree is in building services such as heating, lighting and ventilation. Therefore, I have qualifications relevant to ventilation but I would not class myself as an expert in healthcare ventilation as I have not spent the majority of my career working on this topic.

General Principals of Hospital Ventilation:

5. Scottish Health Technical Memorandum ("SHTM") 2025 (superseded by SHTM 03-01), SHTM 00 and SHTM 03-01 are engineering guidance notes. The SHTMs are the Scottish version of UK guidance relating to healthcare engineering. They are there to support the people who provide these services. I understand that in both the projects under consideration by the inquiry, they were used as part of the briefing process for the design. They are issued to the health boards as guidance, but if they are specified in a contract then they become contractual requirements. It appears to me from early interactions relating to the Inquiry, that those not close to the issue might assume they are an instruction manual handed out by government. This is not the case; they are the health service's interpretation of the responsibilities it has under the applicable legislation, regulations, codes of practice and government policy. These obligations include those enabled under the Health and Safety at Work act and other instruments such as the Building (Scotland) regulations. The 03-01 series follows on from the 2025 series, which was guidance originally published in the early 1990s, which in turn built on earlier guidance. The elements and typical functions of a hospital ventilation system are set out in SHTM 03-01 (Bundle 1, document 9, page 618) at Paragraphs 1.40 to 1.56. I consider my view on what is meant by ventilation and why it is important to be in line with this as the guidance was issued to NHS Scotland under my remit.

6. I have been asked what features of a ventilation system are relevant to patient safety and care. The role of the ventilation system is set out in SHTM 03-01 Part A (Bundle 1, document 9, page 618) at paragraphs 1.1 to 1.56. The ventilation system, taken as a whole, is relevant to patient safety and care. It is best to approach it in that way, rather than trying to break down components of it as being relevant individually to patient safety and care. The ventilation system has implications for the safety of staff and visitors as well as patients. These implications are situation specific. Some examples include; if the filtration in the ventilation system was fitted wrongly it could allow particulate contamination into the space. If the air change rates in a space are not

sufficient then the contaminants in the air won't be diluted sufficiently. If the temperature in a space is wrong, the windows might be open when they are supposed to be closed or vice versa. Another example is if the humidity is wrong, it can promote mould growth in some circumstances. It should be noted here that ventilation is only one aspect of the protection of patients from harm.

7. The safety implications of the "parameters" that can be controlled are also situation specific. The way in which the guidance and the work arising from it affects a burns patient for instance will be different from the safety requirements relating to an infectious patient.

8. SHTM 03 01 Part A (2014) Paragraph 7.6 says "The supply of air to a room has four main functions: to dilute airborne contamination; to control air movement within such that the transfer of airborne contaminants from less clean to cleaner areas is minimized; to control the temperature and if necessary the humidity of the space; to assist the removal of and dilute waste gases where used."

9. It goes on to explain at 7.8 "There are four routes whereby airborne contaminants may appear in a room:- through the supply air; shed directly by the room occupants; arising as a result of the work activities; transferred from adjacent spaces."

10. Differential pressure will prevent contamination between areas when doors are closed. Information on air leakage through closed doors and hatches for a range of differential pressures is given in Table A3 of SHTM 03 01.

11. Whilst patients, staff and visitors can contract infections in any part of a hospital, as they can outwith a hospital, those at particular risk, because of immunocompromise or open wounds, are accommodated in specialised facilities as described in SHTM 03 01 Part a, section 7 "Specialised Ventilation Systems".

12. The parameters ventilation systems are intended to control are set out in section 1 of SHTM 03 01 Part a. These include comfort conditions, such as temperature, air movement, fresh air requirements, air cleanliness, odour dilution and in the case of air

conditioning, humidity. More specialised systems are intended to fulfil specific safety requirements including dilution or removal of harmful substances including microorganisms and gases, prevention of contamination to/from adjacent spaces, or the prevention of the introduction of contaminants through specialised filtration.

13. There are always conflicting requirements when designing, building, and operating a real hospital. It is important to say at this point that I have no direct experience in designing or building a hospital. The inputs that go into making a new healthcare facility are very numerous and each piece of guidance must be considered in 'the round'. Things like availability of staffing, location of the facility, height of building are all inputs that have to be considered. They all interface with each other in such a way that they can have impacts on each other, and decisions have to be taken with that in mind. In trying to deliver the best possible patient care, those responsible have to take in to account things other than ventilation, such as staff and costs. In this way, over engineering the building would detract from the balance of the best possible overall package of care. Some compromises might be required in the design and build involving for instance requirements of energy efficiency and space.

14. Compliance with the principles set out in SHTM 03-01 should, in my view, be achievable in most circumstances. Where a decision is made not to comply with guidance, those designing the facility should develop an appropriately safe design for agreement with those responsible for the facility. The guidance sets out a good approach to dealing with issues, which is peer reviewed. It may set out at times, more than one approach, and even within the guidance a choice between options may be available. Following a different approach that is not set out in the guidance is not necessarily wrong. If the Health and Safety Executive (HSE), for example, are considering a health and safety matter, they will likely look to see whether an approach taken outwith the guidance has been properly considered and assessed by the professionals responsible. I would not expect the SHTM guidance to be HSE's starting point. From my understanding, HSE will go in if there is a safety issue to investigate, they will look at legal requirements and the regulations enabled under legal requirements. If the specifics are not contained in those two levels, I would expect them to look for best practice guidance. I am not aware of better guidance than that issued by HFS and its UK

equivalents.

15. It may be that compliance with named guidance is specified in a contract. Where that is the case, a process is required to manage choices which have to be made within the guidance and to ensure that any derogation is controlled and agreed.

Technical Guidance:

16. The following is a list of the main categories of technical guidance, relevant to Scottish hospitals, produced for use by the NHS in Scotland:

a) Scottish Health Technical Memoranda – SHTM

These give comprehensive advice and guidance on the design, installation and operation of specialised building and engineering technology used in the delivery of healthcare (for example medical gas pipeline systems, and ventilation systems). They are applicable to new and existing sites, and are for use at various stages during the inception, design, construction, refurbishment and maintenance of a building.

b) Scottish Health Facilities Notes – SHFN

These give comprehensive guidance on the operation of healthcare facilities. The topics within the group of guidance includes infection prevention and control, cleaning services frameworks, security, and health and safety.

c) Scottish Health Planning Notes – SHPN

These give comprehensive guidance on the operation of healthcare facilities. The topics within the group of guidance includes planning for in-patient facilities for both adults and children, accident and emergency facilities, and isolation facilities.

d) Scottish Health Technical Notes – SHTN

These provide comprehensive guidance on a range of healthcare specific standards, policies and current best practice.

e) Health Building Notes – HBN

Health Building Notes should be read in conjunction with the relevant parts of the Health Technical Memorandum series. Health Building Notes give best practice guidance on the design and planning of new healthcare buildings and on the adaptation or extension of existing facilities.

17. All of the above guidance, with the exception of Health Building Notes, is produced and maintained by HFS in collaboration with the NHS Scotland Health Boards. HBNs are produced by NHS Improvement in England, but may be approved by HFS for use in Scotland. Health building notes only apply in Scotland when they have been reviewed and approved for use, rather than producing a separate Scottish document.

18. Production of guidance is through peer support; it is not hierarchical. By this I mean it is not an instruction manual handed down by government for health boards to comply with. The health service works together to develop appropriate guidance for people who may be working on various aspects within a project, in order that they get a good comprehensive overview of a specific topic. When it comes to producing guidance, we recruit the best expertise both within and outwith the UK. When the guidance is produced the people who do the drafting tend to be authorising engineers, however, other disciplines are involved both in the drafting of the guidance and the production of source materials, such as research papers, clinical experts and construction experts. Authorising engineers are part of the external advice structure that sits within the engineering governance structure set out in SHTM 00. These are people who tend to spend the majority of their working time on one topic have a degree of expertise which makes them well suited to the production of guidance. Contributors also include educators, manufacturers, non-engineering roles such as infection control experts,

clinicians, and professional bodies. Consultation on the guidance is wide and multi layered. HFS works with the territorial health boards to facilitate production of the guidance. This approach goes back to before the time HFS was part of NSS, and follows the devolution of responsibility for all aspects of managing property from government to the NHS in the 1990s. The Healthcare Engineering and Environment Unit, which sat within West Lothian NHS Trust, was set up by the NHS Scotland Estates Environment Forum, a group of estates leads from each of the NHS Trusts in Scotland. In the mid 1990s, the Estates Environment Forum was chaired by the Chief Executive of West Lothian NHS Trust and concentrated on Environmental and engineering issues at that time. It subsequently moved, with the chair role of the forum, to Borders NHS Trust and over time its remit expanded to include property, fire, facilities management, decontamination and other topics.

19. Estates and Facilities guidance in NHS Scotland is developed jointly between NSS and the health boards. I have mentioned NSS specifically here because although the majority of the work is done by HFS, there are other parts of NSS that are relevant such as procurement and infection control. The sign off process for guidance is through stakeholder groups, representing the best expertise NHS Scotland has on each topic. The process is that a draft goes to stakeholder group of those who will use it from the service and is modified as necessary, before being put out to wider consultation. A finalised version is then put to the stakeholder group for their agreement.

20. These stakeholder groups do not need to contain one representative from each board. Rather it is a group whose representatives are nominated by the engineering lead for each board, through the Scottish Engineering Technology Advisory Group, to best represent the expertise in the service in that topic. The Scottish Engineering Technology Advisory Group is one of three advisory groups that are involved in the operation of HFS. The other two are in relation to property and capital planning, and facilities management. There could also be some non-health board people on the group if their expertise is seen as advantageous. The groups are at liberty to recruit anyone that they see fit. For example, the ventilation group currently has a seat for an external authorising engineer and an infection control representative. During the period in question there was not a specific seat for infection control on the national advisory

groups and collaboration was directly between HFS and Health Protection Scotland (HPS) Antimicrobial Resistance and Healthcare Associated Infection (ARHAI) as most of what is discussed at these engineering meetings is not relevant to infection control.

21. There are currently four stakeholder groups: Heating and Ventilation; Water; Electrical; and Medical Gases. There have always been groups established for specific subjects such as those listed. From my memory these four advisory groups have been place for the majority of the time under consideration. Each reports to the Scottish Engineering Technology Advisory Group, which reports in turn to the Strategic Facilities Group. The Strategic Facilities Group is made up of Directors of Facilities from each of the health boards and is traditionally chaired by the director of HFS. This is the only group that is normally chaired by the HFS director, as the culture we promote is for the health boards to 'own' the groups. HFS are present at all the groups, but not normally chairing, as HFS' role is to support rather than direct the service.

22. The creation of NHS Scotland Assure will not change that relationship. NHS Scotland Assure's role is to support the territorial boards to provide assurance to government and others.

23. Most HFS guidance originates from HTMs, produced for the Department of Health in England. Four nations input is part of the process in the drafting of the HTMs. It is important to have a common approach to the thrust of the guidance across the UK, as patients should expect to be treated in facilities of a consistent standard and the engineering principles do not change depending where in the UK the building is. The contractors in the NHS supply chain also typically operate throughout the UK, so consistency of guidance reduces the risk of errors. In the process of developing SHTMs the drafting is primarily concerned with putting the HTM guidance into a Scottish context, referring to the relevant Scottish organisations, legislation and regulation. Where a need is identified in Scotland, HFS may take the lead in production and guidance produced in this way is then available to feed the production processes in England, Wales and Northern Ireland. There are several documents in the water guidance, SHTM 04 series, produced this way.

24. In the 1990s and earlier, guidance was produced UK wide, and a cover letter went out from Scottish Office, to deal with how it was to be adopted in Scotland. Northern Ireland and Wales take a similar approach, although each administration has taken variations on adopting or developing guidance at different times. For pragmatic reasons, we do not always adapt UK wide guidance for the Scottish context. We will sometimes advise boards to use a UK document as it is. This is more common with Health Building Notes than HTMs. My colleague Susan Grant can advise on examples if required.

25. The Inquiry are aware of all the guidance issued by the NHS that is relevant to ventilation systems in hospitals. Additional relevant guidance may be produced by organisations outwith the NHS such as the clinical associations. The Scottish Building Standards Agency issues Technical Standards that govern the air tightness of buildings. General guidance on ventilation systems, not specific to the NHS, will be found elsewhere, examples include the guides issued by The Chartered Institution of Building Services Engineers, the Building Services Research and Information Association, Building Research Establishment, Heating and Ventilating Contractors Association, Institute of Healthcare Engineering and Estate Management. Where NHS specific guidance does not cover an issue, the professionals involved will use their professional judgement and possibly refer to other guidance in resolving the issue.

26. To the best of my recollection, there has been no specific direction from SG in relation to any HFS guidance, other than mandating compliance with decontamination guidance in the wake of the BSE crisis in the early 2000s.

SHTM 00 Best Practice Guidance for Healthcare Engineering – Policies and Principals:

27. As assistant Director for the Engineering, Environment and Decontamination section of HFS, I was responsible for the department that published this guidance. The current version was published in February 2013. I am not sure of the date of first publication of this document in its original form. A search of our records has been undertaken but a copy of the original guidance from before February 2013 has not been found. The search was undertaken by two of my colleagues, our principal architect Susan Grant and

our research manager Geraldine O'Brien. Although NHS NSS has a document retention policy requiring documents disposed of to be recorded, we do not appear to have a record of when, or by whom, those documents were disposed of. In recognition of that, as part of Assure, we have created a computer based quality management system based records system.

28. I would not have been personally involved in the drafting of SHTM 00. That would have been undertaken by Ian Stewart (now unfortunately deceased). Ian Stewart was the principal engineer at the time. I would have read and discussed parts of the document with Ian. I was familiar with the document upon which it was based (HTM 00). The document would have been signed off by a stakeholder group and authorised for publication by myself. A specific Stakeholder Group may have been convened at the time and would have reported to the Scottish Engineering Technology Advisory Group.

29. The purpose of SHTM is explained in the executive summary of the document and in section 1 "scope". SHTM 00 states, on page 4, that it seeks to provide "*general guidance*".

30. SHTM 00 (and HTM 00 on which it is based) was introduced at the time the SHTM (and HTM) suite moved from the old four digit (e.g. 2025) numbering system to the new two and two digit format (e.g. 03 01), taking the numbering of ventilation documents as an example. It was recognised that, as the older documents had been developed at different times by different people, there were differences in how they each expressed the overarching management requirements, which could lead to confusion. SHTM 00 brought together and standardised the terminology and structures applicable to all SHTMs.

31. In the Executive Summary, SHTM 00 states that "The aim of Scottish Health Technical Memorandum 00 is to ensure that everyone concerned with the management, design, procurement and use of the healthcare facility understands the requirements of the specialist, critical building and engineering technology involved."

32. The document is provided as guidance for suitably qualified and experienced colleagues. It is general in as much as it cannot possibly cover every circumstance in which it might be used and comprehensive in that it covers all the key issues within its scope.

    SHTM 00 states, at page 8, that:

    a. *"Regardless of procurement route, whether by traditional means or through a Public Private Partnership (PPP), it is essential that, as part of the briefing process, those involved in the provision of the facility are advised that all relevant guidance published by Health Facilities Scotland (HFS) is available electronically for purchase from HFS. In selecting technical advisers and preferred bidders, it is strongly recommended that their healthcare experience or credentials are thoroughly verified by the NHS Board. References should be obtained and followed up.*

    b. *Only by having a knowledge of these requirements can the healthcare organisation's Board and senior managers understand their duty of care to provide safe, efficient, effective and reliable systems which are critical in supporting direct patient care. When this understanding is achieved, it is expected that (in line with integrated governance proposals) appropriate governance arrangements would be put in place, supported by access to suitably qualified staff to provide this 'informed client' role, which reflect these responsibilities."*

33. I am asked by the Inquiry team to explain why this statement was included in SHTM 00. We have no record of why those involved in the production of SHTM 00 chose to include this text, which is a modification of that found in the HTM. That said, the duty of care to protect the health safety and welfare of patients, staff and visitors is enshrined in the Health and Safety at Work Act and its regulations. I think it was relevant and appropriate for this statement to be included. The guidance was produced under my remit and, although I didn't write it, I will have read it before it went out and I share that view. My understanding is that the text is consistent to the legal requirements we

were working under and, in my view it is also good practice. HFS guidance documents have been provided free of charge, rather than being available for purchase, since shortly after the publication of this document. They have always been free to the NHS.

34. The legislative requirements listed on page 21 of SHTM 00 are the main legislative requirements, as they relate to engineering systems and activities. Paragraphs 3.5 and 3.6 state this.

35. SHTM 00 and 03-01 carries a disclaimer that *"the contents of this document are provided by way of general guidance only*. Etc" This disclaimer was originally introduced when the Healthcare Engineering Environment unit, which preceded HFS, was set up as an arms-length division of West Lothian NHS Trust, having been devolved from the Scottish Office. The purpose was to recognise that the guidance could be used in a number of ways, including commercial contracts, where any error might result in a claim against the NHS.

36. I have been referred specifically to regulation 9 of the Building (Scotland) Regulations 2004, and to paragraph 3.14 of schedule 5 to those regulations which, I am told, provides that "Every building must be designed and constructed in such 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. I have no input into the content of building standards, nor do I have any particular expertise in that field, other than knowing that the building regulations are amongst the requirements that apply to the provision of ventilation in buildings. The obligation to comply with relevant legislation lies with those managing the construction project, although SHTM 03-01 may be seen as an appropriate means of compliance.

37. Compliance with SHTMs is not mandatory. SHTMs are peer produced guidance and are there to support, rather than replace appropriate management and engineering expertise. As it is not mandated by government, there is no sanction from government for non-compliance. There may of course be sanctions for non-compliance where compliance with guidance is specified in a contract. It is also recognised that written

guidance cannot apply to all circumstances, and as long as sound management and appropriate expertise is applied, there is no reason why safety should be compromised.

SHTM 03-01 General Overview:

38. The following is the inquiry team's understanding of HFS ventilation guidance put to me for agreement, which I have slightly modified in paragraph 36

SHTM 03-01: General Overview

The Inquiry Team advised me that they understand that that this guidance replaced SHTM 2025 and is:

a) primarily intended to ensure that those responsible for developing and operating hospitals (such as health boards) meet their various legal obligations relating to ventilation;

b) that those legal obligations derive from various sources, some of which are specific about particular requirements for ventilation, and some of which take the form of more general (and less defined) duties of care (such as those arising at common law and from sources such as the Health and Safety at Work etc Act 1974);

c) that in attempting to define those duties and what should be done to fulfil them, the authors have drawn upon a variety of sources, including: statutes and statutory instruments; building standards; British standards; government publications; NHS publications, including Health Planning Notes and Health Technical Memoranda; industry publications by bodies such as CIBSE (Chartered Institution of Building Services Engineers) and HVCA (Heating & Ventilating Contractors' Association); the Health and Safety Executive; DIN (Deutsches Institut Fur Normung); and scientific research;

d) that the guidance is the outcome of collaboration by professionals from diverse technical backgrounds;

e) that it will have been intended to be consistent, so far as possible, with related guidance dealing with other aspects of hospital design, construction and operation;

f) that, whilst its primary function is to ensure that those developing and operating hospitals meet their obligations, it will in practice function as a source for health boards to define what they expect to be delivered by others whom they engage to design, construct and operate hospitals (and in that context may be used as, or at least to inform, a contractual specification); and as a source for those who have been engaged to design, construct and operate hospitals as evidence that their work reaches an objectively acceptable standard and is therefore likely to be compliant with the applicable legal obligations;

g) that, whilst some aspects of the guidance may reflect an underlying legal obligation which cannot be departed from without breaking the law, the guidance is not itself the source of those legal obligations and does not have any inherent legal status;

h) that in many other respects the guidance makes only recommendations, albeit ones which are informed by a wide range of appropriate technical knowledge and which represent a cross-disciplinary consensus, about ways in which legal obligations and duties might be met; but could not realistically, and does not in fact, seek to provide definitive rules to apply in all circumstances;

i) that it follows that appropriate professional judgment will still be required when designing, installing and operating ventilation in hospitals, and it should not therefore be assumed that slavishly following the letter of the guidance will be sufficient in all circumstances to produce an acceptable ventilation installation which is compliant with the law; and that, in any event, such judgment will be needed when ventilation is needed in circumstances for which the guidance does not provide;

j) that departures from the recommendations in the guidance may be justified in some circumstances, but this would have to be a matter of professional judgment

based on the prevailing circumstances, and be acceptable to whoever bore ultimate responsibility for the hospital.

39. I have been asked to comment on the inquiry's understanding of the guidance SHTM 03-01 that replaced SHTM 2025 above. Whilst I broadly agree with this understanding, there are some points I would add. In paragraph (a) I would say that it is important to note that that the guidance is the outcome of collaboration by professionals from diverse technical and clinical backgrounds. At paragraph (f) I would also add that the guidance will, in practice, function at times as a source for health boards to define what they expect to be delivered by others, who have been engaged to design, construct and operate hospitals, as partial evidence that their work reaches an objectively acceptable standard. Furthermore, where the inquiry's understanding states that the recommendations in the guidance are "informed by a wide range of appropriate technical knowledge", I would suggest this also includes clinical knowledge. Similarly, I would say that the guidance follows appropriate professional and clinical judgment (h). Finally, where the inquiry's understanding states "that departures from the recommendations in the guidance may be justified in some circumstances, but this would have to be a matter of professional judgment". I would add that this would also be a matter of clinical judgement in some circumstances. (i).

40. Unfortunately, a search of HFS records reveals that HFS has no record of when SHTM 03-01 was first published. That version was based on a document labelled SHTM 2025, which was published in 2001. This in turn was based on a document called HTM 2025. There is some doubt about when SHTM 03-01 came in to being. NSS cannot find records of the dates so these dates are largely from memory. HTM 03-01 was published in England prior to 2011. Part B of SHTM 03-01 was published in 2011 (Bundle 1, document 6, page 287) and Part A of SHTM 03-01 was published in 2013 (Bundle 1, document 8, page 433) then later reissued in 2014 (Bundle 1, document 9, page 618). I don't recall why it was reissued so soon after first being published. Part A and Part B refer to design and operation sections of the document. Part A is the most relevant part for construction contracts and Part B is relevant for the operation post construction.

41. As Assistant Director for HFS, my department contained a number of services, one of which is Engineering. HFS published this document in Scotland, having managed its development through a stakeholder group, representing the NHS Scotland Boards, named the National Heating and Ventilation Advisory Group.

42. The underlying HTM guidance was originally drafted under contract by Department of Health (of the UK Government) to a lead author with a large group of individuals in support. There would have been four nations input at that time. HTM guidance is currently published by NHS Improvement (and formerly by NHS Estates,) an agency of the Department of Health.

43. It was adapted for Scotland by HFS through the National Heating and Ventilation Advisory Group. The principle adopted is that any changes should be as limited as reasonably practicable, as the engineering aspects are generally as applicable in Scotland as elsewhere in the UK. What does change is the context, for instance references to Scottish Government and health boards, rather than trusts. There are also some areas where practice is different in Scotland. The majority of the document is consistent with the HTM.

44. SHTM 03 01 was developed from the HTM by HFS, in collaboration with the National Heating and Ventilation Advisory Group, which is a stakeholder group of senior engineers representing the NHS Scotland Boards, who are the principal users of the guidance. All members of the Advisory Group are practicing healthcare engineers with extensive operational experience of healthcare ventilation systems. They are however, likely to have less specialised expertise than those involved in the UK drafting process, many of whom would be Authorising Engineers, who spend most of their working time on healthcare ventilation. Decisions were made by discussion and agreement, and all involved agreed to publication of the final draft. I have no records, but I believe infection control colleagues would have been consulted. The Scottish stage follows on from the UK stage where there would also have been consultation with infection control, clinicians and professional bodies.

45. The document is intended to be used by health board staff and contractors as appropriate to each project. Its intended users are described in the introduction to the document, and in particular, paragraph 1.2, which says "This edition of Scottish Health Technical Memorandum 03 'Ventilation in healthcare premises' is published in two sections. It is equally applicable to both new and existing sites. It gives comprehensive advice and guidance to healthcare management, design engineers, estate managers and operations managers on the legal requirements, design implications, maintenance and operation of general and specialised ventilation in all types of healthcare premises"

46. The guidance is general in that it applies to a broad range of circumstances and needs to be interpreted in light of these. It is comprehensive in that it covers all the main specific healthcare aspects of the subject.

47. There have been various approaches to creating HTMs and SHTM's over the years. Most common is an England led agreement process for what the priorities for guidance are. NHS Improvement will produce around 10 document revisions a year over the whole sphere of facilities, which includes maybe one or two engineering documents. HFS has input to that process. When the English document is published, Scotland, Wales and Northern Ireland take that document and adapt it for their area. We normally look to change as little as possible, as the engineering doesn't change, but what changes for each country is terminology, bodies and sometimes clinical practice. Sometimes circumstances in Scotland dictate that we develop specific guidance for Scotland, different from other parts of UK. The review for Scotland is normally led by the HFS Principal Engineer for engineering guidance. Typically the document will have a number of rounds of consultation before it is published.

48. I am asked to what extent is it acceptable to depart from the terms of SHTM03-01 and to what extent does it leave room for professional judgment? The intention when developing guidance is that it is to support suitably qualified and experienced staff in both the health board and supply chain, to deliver their duties effectively. It is not a specification. The client chooses which guidance it wants used in its projects. It is my view that all applicable guidance should be applied to any project

unless circumstances dictate otherwise, and where guidance is not followed, those responsible should provide an appropriately safe alternative, but the decision is the responsibility of the health board. This view is based on an interpretation of HSE's approach to investigating health and safety incidents. Health boards often cite compliance with guidance in their contracts, which makes compliance a contractual requirement and, as guidance often contains choices, a process for managing derogations from the guidance is necessary.

49. The risks of not following the guidance will depend on the application, but might include things like infection of immunosuppressed patients through inadequate filtration, failure to adequately dilute contaminants in the ventilated space or failure to maintain pressure differentials allowing contaminants to pass from one space to another. The risks differ between areas of the hospital, for example, in an operating theatre the air is intended to be changed very frequently, around 25 changes per hour to be able to dilute particles. The relationship between air change rates and dilution of contaminants is not linear, i.e. 12.5 air changes per hour doesn't give half the dilution of 25 air changes per hour. Each increase in air change rates contributes less to dilution than the one before. It may be helpful to consider the areas of a hospital in two broad categories; general areas and specialised areas. For general wards, the patient might not be well, but they are not unusually susceptible to increased infection risk. Other than the legislative requirements under the Health and Safety at work act, through the Control of Substances Hazardous to Health Regulations, ventilation is also provided for comfort. The risks are higher in relation to specialised ventilation systems, such as those found in table 1A. In these areas the ventilation system is an integral part of controls for patient safety. An example would be isolation rooms to protect the patient from the surroundings or the surroundings from patient. In a critical care or intensive care area there is a barrier provided by ventilation that creates cascading air flows from cleaner areas to less clean areas.

50. I am asked what review/audit processes (if any) ought to be in place to check the compliance of a ventilation system with the guidance? The checks and tests for ventilation systems are set out in detail in section 8, validation of specialised

ventilation systems.

51. The guidance takes into account the key pieces of relevant legislation applicable at the time of drafting. Whilst it does not absolve users of the need to comply with legislation, it provides a partial means to compliance with legislative requirements. It is produced by, and consulted with, appropriate technical and clinical subject matter experts, and can thus be taken as good practice guidance. The guidance identifies the most relevant pieces of legislation to the primary functions of healthcare ventilation systems, however, it is not practical to list all legislation that might apply in all circumstances.

52. The Preface to SHTM 03-01 notes that it was not intended to repeat unnecessarily international and European standards, industry standards or UK legislation; but that, where appropriate, those would be referenced. Other pieces of legislation are likely to apply to issues which I believe would be outwith the scope of the inquiry, such as electrical wiring regulations, moving and handling or working at heights regulations.

53. Paragraph 2.60 of SHTM 03-01 (Bundle 1, document 9, page 618) refers to Activity Database A-Sheets as including specific requirements for individual spaces and departments. This is not my area of expertise, however, my understanding is that for the purposes of the RHCYP project, this function was performed by the environmental matrix. The environmental matrix specifies the client's requirement for the conditions to be maintained in each room.

54. Within HFS I would defer to my colleague Susan Grant, an Architect, in respect of questions with regard to the Environmental Matrix, Activity Data Base sheets, SHPNs that the inquiry is interested in and A Sheets. I would be straying outwith my competence if I was to provide detailed answers to the Inquiry' queries on such matters.

55. No one piece of guidance takes precedence over any other. The ultimate decision in the case of conflict rests with the health board team managing the project.

56. I have been asked to comment on paragraph 1.37 of SHTM 03-01 (Bundle 1, document 9, page 618) "In assessing the need for more specialised ventilation and the standards desired for patient care, managers will need to be guided by their medical colleagues and by information published by Health Facilities Scotland". I believe those who manage healthcare facilities have a duty of care to understand the risks that they are managing. Part of that is understanding the circumstances of the risks and that's why the guidance is relevant. It is important to note that the facility is only part of the risk management required, another major part is clinical care. For example, if a specialised unit has effective ventilation, there might still be a risk if the clinical care is not right, so the intention is that the decisions on what is provided and how it is provided are broadly based and all key stakeholders views should be considered.

Part A of SHTM03-01 Table A1

57. Whilst a definitive answer would require reference to the original authors, my understanding of the purpose of table A1 is to provide recommended performance parameters for specific applications.

58. Appendix 1 (Bundle 1, document 9, page 756) is headed up "Recommended air-change rates", without reference to the other parameters which Table A1 contains. I don't believe that is significant. It does not indicate air changes are more important than the other parameters. As with other aspects of the guidance there is a need for suitably qualified and experienced professionals to interpret it. Each parameter within table A1 has an impact on patient safety and care, and each has different implications.

59. Air change rates are specified, amongst other factors, for the ability to dilute contaminants. Pressure differentials are intended to control the direction of air flow to reduce the risk of contaminants being introduced to, or emitted from a space, depending on whether patients are susceptible or infectious. Temperatures are

intended to provide a suitable environment for treatment and recovery. Filtration is intended to reduce contaminants entering the space through the supply air.

60. These parameters were selected through the experience of experts in the field over many years, adapted over time to reflect changes in knowledge and practice.

61. The parameters, to the best of my knowledge, are based on a scientific consensus and on judgment. The isolation room and pressure differential models for example, are based on full scale models and computer simulations at the Building Services Research and Information Association (BSRIA). Operating theatre standards are based on tests carried out when each new model theatre was introduced, and modelling work has also been carried out at the University of Leeds. These origins are, however, irrelevant in my view, when compliance is a contractual requirement. The issue then becomes that these are the specified performance criteria required by the board and the contractor has a contractual obligation to deliver them.

62. The question of the extent to which the parameters can be departed from, without adversely impacting on patient safety and care is unanswerable in a general sense and will depend on the circumstances. This is why there is a need for appropriately skilled and qualified professionals to interpret the guidance in light of the circumstances.

63. It is understood that departures from the specified parameters might result from the design process. If the client specifies compliance with the guidance in the contract, any deviation becomes a change to the contract requirements (a derogation) and should be controlled and agreed in line with the requirements of the contract.

64. HFS does not have a record of how the different entries on the "applications" column on the table were selected. It is likely that these were through discussion amongst those involved in creating the HTM on which the SHTM is based. In some cases, I believe the information has been incorporated from other sources such as clinical bodies but the authors of the HTM would be better placed to advise.

65. UK practice is the practice described in UK guidance, i.e. the SHTM and HTM. UK and US guidance are used in many parts of the world, with many countries using these either direct, or as a basis for their own guidance. They take cognisance of each other and many parts of the world use one or the other.

66. The pressures reflect the application being served and the need to be able to maintain conditions in the space, whilst still being able to perform activities like keeping doors closed or being able to open them against the pressure.

67. The nomenclature in the filtration column is in common use in the ventilation industry and specifies the type and efficiency of filter required. The detail of filter grading is beyond my expertise, however, higher numbers generally relate to greater ability to arrest particles. These are described paragraph 4.116 onwards and in tables 4, 5 and 6.

68. The letters in the ventilation column signify whether the air is supplied to the space, extracted from it or natural, and will have implications for whether the room is at positive or negative pressure, relative to adjacent spaces. i.e. supplied air will exfiltrate from a space, whereas the extract of air will cause infiltration from adjacent spaces. This relates to whether the potential contaminant under consideration exists within the space (extract) or in the adjacent spaces (supply). Because natural ventilation is dependent on external factors such as wind pressure, it can positively or negatively pressurise the space, and as such is only applicable to spaces where pressures are not critical.

69. The types of accommodation listed in the table are in general use, however, different names may be used in different places to relate to the same, or similar applications. The decision about the types of patient to be accommodated and the performance requirements that patient group requires should be decided by the health board team at the time of specifying their requirements. The recommended performance parameters are set out in section 7 and Table 1a.

70. The guidance is intended to be followed where the application is directly relevant and, where there is a need to design for an area where there is no direct fit with an application described in the guidance, the judgement of appropriately qualified and experienced professionals should be relied upon, with the ultimate decision resting with the client, i.e. the health board. For the example cited by the inquiry team of how the guidance would be applied in particular contexts, such as multi bed rooms in general wards, would be expected to be treated like general wards in table 1a, unless there was a specific reason not to.

71. Any ambiguity/uncertainty should be resolved by appropriately qualified and experienced professionals and all relevant stakeholders, with the ultimate responsibility for accepting any solution lying with the health board.

72. Although I wasn't involved, I believe table 1a was added to the guidance to bring together ventilation requirements from a number of different sources. Some existed in previous iterations of the guidance and some were specific to the clinical application. The naming conventions in the table are typical, although other names might be used for the same, or similar applications. Clinical staff would decide the required level of protection for the patient group. Since Scottish specific guidance was first published in the 1990s this has been accepted by the NHS in Scotland as the applicable guidance for Scotland. That said, it is guidance, and those in charge of a project have the autonomy to choose to follow whatever guidance they judge best, and it is for them to justify their approach.

Table A2 "Hierarchy of cleanliness"

73. The hierarchy of cleanliness relates to operating theatre suites, where the essential principle is that clean air is supplied to the operating room and then passes to progressively less clean areas where less critical activities are carried out. Further information on operating suites can be provided as required, however detailed analysis will require specialist input.

Updates to the Guidance:

74. The version of SHTM 03 01 that I refer to throughout this statement was published in February 2014. It has recently been superseded by interim guidance published in February 2022. My colleague Ian Storrar is better placed than me to describe the process by which the new interim guidance was produced. It has been developed from the English guidance. It is issued in interim form because some of the staff resources necessary to complete it have been diverted to other national priorities, such as Covid and responding to public inquiry requests.

75. I am asked whether there have there been changes to the various sources on which the guidance is based. There may have been changes to guidance in other countries, legislation and Health and Safety Executive codes of practice amongst others, which may have been consulted during the drafting process of the HTM. HFS does not currently actively track changes to sources between updates to its guidance.

Children & Young People:

76. Ventilation requirements do not differ for children and young people.

Scottish Health Planning Note 04

77. SHPN 04 is relevant to inpatient accommodation. Within that guidance is isolation rooms, which is set out in supplement 1. SHPN 04 supplement 1 is guidance on the positive pressure ventilated lobby (PPVL) arrangement, which is a general purpose isolation room intended for source, or protective isolation (infectious or immunosuppressed patients) where a higher standard of isolation is not required. That supplement is specifically the publication of work done with the Building Services Research and Information Association (BSRIA). It was produced as UK guidance by NHS estates and was then adapted for Scotland.

Documentation for Tenderers

78. I am asked what technical guidance I would expect to be provided to tenderers involved in a procurement exercise for a new hospital in Scotland. The intention when developing guidance is that it is to support suitably qualified and experienced staff, in both the health board and supply chain, to deliver their duties effectively. It is not a specification, unless deemed so in a contract. The health board chooses which guidance it wants used in its projects. It is my view that all applicable guidance should be applied to any project, unless specific circumstances dictate otherwise, and where guidance is not followed, a suitably safe approach should be taken. Any decision not to follow guidance should be the responsibility of the health board, rather than their advisors, and should involve all relevant stakeholders. This view is based on an interpretation of the Health and Safety Executive's approach to investigating health and safety incidents, where I would expect them to use industry guidance as the standard to be met, and look for evidence that any deviation was properly managed in light of the circumstances. Health boards often cite compliance with guidance in their contracts, which makes compliance a contractual obligation.

As guidance may contain choices, a process for managing derogations from the guidance is necessary. The guidance is developed using a wide range of expertise from the UK and elsewhere and in that respect can be considered best practice guidance. It is not possible to produce guidance that is applicable to every circumstance; for example, the same guidance has to apply to a major acute hospital but also a health centre. It has to be processed through the judgement of appropriately skilled and qualified people. However, it is not a standard because there is no legislation that requires it to be complied with.

I believe that the facts stated in this statement are true. I confirm that I am willing for this statement to form part of the evidence before the Inquiry and to be published on the Scottish Hospital's Inquiry Website.

Edward McLaughlan
20 April 2022

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