When to seek derogation, and the best approach

Andrew Poplett, an Authorising Engineer (Water & Ventilation), who has over 30 years' experience of healthcare estates management, with specific and specialist knowledge of water and critical ventilation systems, takes a look at when it may be appropriate for NHS Trusts and other health service-providers to seek derogations from official guidance and advice, the optimal approach, and how to avoid the potential pitfalls.

The question of derogations has been a complex, and, at times, highly contentious, issue for many years. It can often start with a debate over the legal status of NHS-specific guidance, and include a range of challenges. This article offers an individual opinion on the various issues, and highlights the long-term consequences and repercussions which NHS service-providers should consider when considering how to manage derogations, and, simultaneously, retain the ability to demonstrate compliance assurance to all stakeholders.

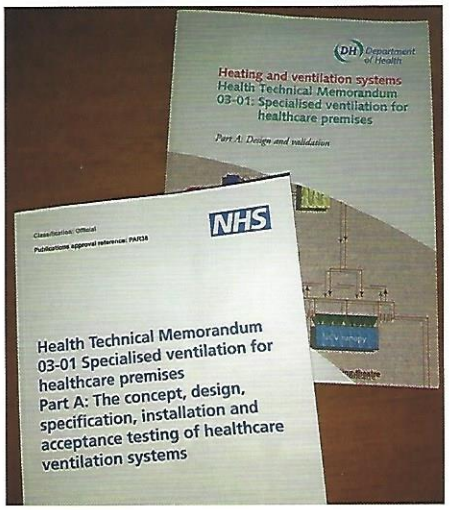
NHS standards

Over the years the NHS has developed a comprehensive range of documents to provide guidance and advice for those involved in the design, construction, and operation, of healthcare facilities. These include Health Building Notes (HBNs), Health Technical Memoranda (HTMs), Health Guidance Notes (HGNs), Health Facilities Notes (HFNs), and Fire Practice Notes (FPNs), to name just a few, with some of these standards now archived or superseded. It must also be noted that within the devolved administrations there are a number of documents which contain subtly differing guidance, although the manner in which these should be managed can be universally applied.

Debate over the status of all of these documents can be highly contentious, and generally is not definitively defined. However, in my opinion, the following elements need to be considered:

Legal

Anecdotal evidence is that any failures to follow the practice or advice set out in these documents has been used in court proceedings to find against hospital Trusts. These are most likely to be in connection with Health & Safety Executive prosecutions, or possibly civil or medical malpractice cases. The various Devolved Administrations agree that the documents produced are guidance documents. They become legal requirements when they form part of a contract, but the guidance documents are generally considered as an Approved Code of Practice, or – at the very least – good practice.



Over the years the NHS has developed a comprehensive range of documents to provide guidance and advice for those involved in the design, construction, and operation, of healthcare facilities. These include Health Building Notes, Health Technical Memoranda (shown), Health Guidance Notes, Health Facilities Notes, and Fire Practice Notes.

Department of Health & Social Care guidance is relevant, and is generally taken to be authoritative by the relevant authorities and the courts, but is not conclusive. However, if the guidance isn't followed, the Trust would be expected to justify why, and to demonstrate what measures they took to satisfy the requirement of 'taking all reasonably practicable steps' to protect people affected.

In addition, the Health and Social Care Act (2012), Health and Social Care Act (Regulated Activities) Regulations 2014, and the Care Quality Commission (Registration) Regulations 2009, are all used as the basis for CQC registration and certification. As such, these regulations are used as the reference by the CQC for all healthcare providers (including the NHS).

Key criteria outlined

Regulation 15 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 outlines 20 key criteria under which all healthcare providers must operate. The intention of this regulation is to make sure that the premises where care and treatment are delivered are clean, suitable for the intended purpose, maintained, and, where required, appropriately located, and that the equipment that is used to deliver care and treatment is clean, suitable for the intended purpose, maintained, stored securely, and used properly. Providers retain legal responsibility under these regulations when they delegate responsibility through contracts or legal agreements to a third party, independent suppliers, professionals, supply chains, or contractors. They must therefore make sure that they meet the regulation, as responsibility for any shortfall rests with the provider.

Regulation 15(1)(c) stipulates that healthcare promises must be 'suitable for the purpose for which they are being used,' i.e. that they must be fit for purpose in line with statutory requirements, and should take account of national best practice. Any alterations to the premises or the equipment that is used to deliver care and treatment must be made in line with current legislation and guidance. Where the guidance cannot be met, 'the provider should have appropriate contingency plans and arrangements to mitigate the risks to people using the service'.

While the NHS guidance documents are not mandatory (unless specifically stated), they do, however, state that any departures / derogations – including the measures implemented – should provide a degree of safety not less than that achieved by following the guidance set out in the various documents.

Minimum standard or best practice

Often the minimum standard or best practice are defined by the parties on either side of a debate around derogation. In the author's opinion the answer is

actually that both need to be met; the guidance sets safe minimum standards which should not be relaxed where they impact on patient safety or operational resilience, including lifespan. However, there isn't an alternative guidance document which could be described as best practice or 'compliance plus' standards, as the NHS guidance is generally considered by many as 'world-leading'. It is thus not unreasonable to describe it as best practice, or even as an Approved Code of Practice, at least in some circumstances.

Definition of a derogation

In the simplest of forms (the dictionary definition), a derogation is an exemption from, or relaxation of, a rule or law or standard. As it applies to NHS guidance, this exemption must be appropriately recorded, with all implications understood and accepted by all parties, and approved at a suitable level, and, where appropriate, alternative and equivalent mitigation must be agreed for the risks or implications of the derogation.

The need to demonstrate a robust process for agreeing any derogation from technical guidance is a core component of the assurance process, and, as such, must provide a clear, auditable trail.

Derogations to guidance will potentially increase risks to the organisation, and potentially clinical activity or patient safety – and should thus only be considered in exceptional circumstances. A schedule of derogations will be required for any project. This schedule is not a simple list of derogations which can be stored in a project file and forgotten about; it needs to be comprehensive, stored where it can be easily referenced by all stakeholders, and kept under regular review and monitored to ensure that it remains safe and appropriate. To this end it is understood that the Devolved Administrations are considering a formalised derogations process, which it is hoped will be issued in the near future.

Risk assessment

While it is recognised that derogation is required in some cases, this must be risk-assessed, agreed, and documented, in order that it may be considered within the appraisal and approval process. Derogations must be properly authorised by the project's senior responsible owner, and informed and supported by appropriate technical, Infection Prevention & Control (IPC), and clinical advice (irrespective of a project's internal or external approval processes).

Reasons or drivers to consider derogating

Typically there are many reasons cited to derogate from elements of, or even entire, HTMs or HBNs, including, but not limited to:

- Refurbishment of existing buildings, facilities, or services (including the limitations associated with existing footprints etc).
- Room allocation and sizes.
- Cost or budget allowance, (however, cost should never be the sole consideration, as the budget should be set to reflect full compliance).
- The scope of the project.
- The omission of a compliance issue at business case/design/construction stage, or
- 'We haven't done it before, or had it agreed on a previous scheme'.

Table 1: The minimum information needed for a full and detailed schedule for all proposed derogations or clarifications considered during a project or scheme.

Reference Number of Standard	For example, HBN / HTM reference
Specific Clause reference	
Derogation/Clarification	Details of what is being proposed for derogation, including a detailed reason/ explanation of why, the extent/impact, and details of any proposed alternative design solutions.
Derogation proposed by	Name of individual or company proposing/ requesting the derogation.
Date	
Comments by Project team lead	Name of individual with details/commentary to evidence initial design review, and a recommendation to approve or reject the proposed derogation.
Date	
Comments by Authorised Person (AP)	Name of individual with details/commentary to evidence any recommendation to approve or reject proposed derogation.
Date	
Working Safety Group (if applicable) comments/ risk assessment	Details/commentary to evidence any recommendation to approve or reject the proposed derogation.
Date	
Comments by Authorising Engineer (AE)	Name of individual with details/commentary to evidence any recommendation to approve or reject the proposed derogation.
Date	
Executive Board Level Designated Person assessment	Sign-off by the DP or similar level Board member to accept or reject derogation.
Date	
Status	Approved or rejected (including a time limit if appropriate).

Considering the full implications

At times a derogation is a sensible and safe option to consider; however, the full implications of any such consideration must be carefully balanced, and a full and detailed record made of the impact, risks, cost consequences, practical limitations of a scheme or site, and a formal review and approval process. This process may also identify other forms of mitigation or control measures, and should also include a post-project 'in use' assessment to ensure that the decision was justified with the benefit of operational hindsight.

What cannot be derogated

In HTMs and HBNs, modal verbs such as 'must', 'should', and 'may', are used to convey notions of obligation, recommendation, or permission. The choice of modal verb will reflect the level of obligation needed to be compliant.

The following describes the implications and use of these modal verbs in HTMs/HBNs:

- 'Must' is used when indicating compliance with the law. These cannot be the subject of derogation.
- 'Should' is used to indicate a recommendation (not mandatory/ obligatory), i.e. among several possibilities or methods, one is recommended as being particularly suitable – without excluding other possibilities or methods. These are elements which, in extreme or specific circumstances, could be considered for an area of derogation. However, the

organisation must be able to clearly demonstrate the circumstances/ reasons for the derogation, and, if required, provide evidence of what measures it took to satisfy the requirement of 'taking all reasonably practicable steps' to protect people affected.

- 'May' is used for permission, i.e. to indicate a course of action permissible within the limits of the HTM/HBN. Again, these elements could be considered for an area of derogation, but the organisation must be able to clearly demonstrate the circumstances/reasons for the derogation, and, if required, to provide evidence of what measures it took to satisfy the requirement of 'taking all reasonably practicable steps' to protect people affected.

The process of derogation

When considering a derogation, the initial question needs to be clearly established as to who has the authority to agree a derogation, and who ultimately holds the responsibility for the decision. Once a derogation has been identified as potentially being required or desired, the issue needs to be very clearly defined by the requester as to the exact nature and extent of the potential derogation. This should include full details of the clause or area of derogation, the reason(s) for the inability to conform to the relevant standard, the predictable consequences of the derogation, and what, if any, mitigation is being proposed to minimise or remove the residual risk of non-conformance.

Following the request, the project team should log it, and undertake a review to assess the request, with input from the appropriate working safety group and Authorised Person(s) for the discipline(s) involved. If considered necessary, the opinion of / comment from the Authorising Engineer for the specific discipline should also be sought, to ensure that all aspects have been suitably identified and considered. For the avoidance of doubt, the review must be comprehensive, and should include representation for all stakeholders, including clinicians, IPC, Operational Estates & Facilities, and the Project team. It must not be undertaken in isolation by the Project Team.

Essential considerations

The review process must consider a wide range of potential implications and consequences, including, but not limited to:

- Patient, staff, or visitor safety.
- Patient, staff, or visitor comfort.
- Maintainability.
- Changes in guidance / best practice since publication of an HTM or HBN.
- Advances in technology since publication of an HTM or HBN.
- Clinical activity and clinical process/development or 'creep'.
- Timescales (both in terms of project programme, and the lifespan of the development).
- Practical limitations (e.g. space and existing building restrictions).
- Lifespan and whole-life costings.
- Energy consumption and running costs.
- Cost (reduced capital costs must not be put ahead of whole-life or revenue costs).

A full understanding

Once all of these elements have been considered, and the scope of the impact of the potential derogation agreed, a risk-based assessment should be completed to enable the ultimate decision to be made by the Designated Person for the respective system/service, with a full understanding of the consequences of the approval or rejection decision.

Records

A full and detailed schedule must be developed and retained for all proposed derogations or clarifications considered during a project or scheme. This schedule should be comprehensive, and should include, as a minimum, the information (per derogation) shown in Table 1.

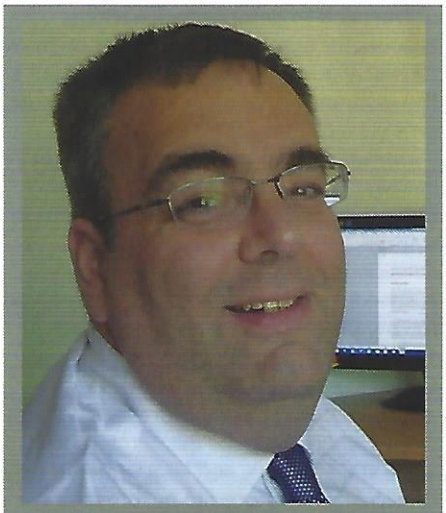
This schedule would form the basis of a live document register, which should be accessible to all stakeholders for review purposes and information. Where considered necessary, the schedule or register of derogations may also lead to inclusion onto the organisation's risk register, to ensure that approved derogations do not get overlooked or forgotten.

Ongoing management and review

While the majority of derogations tend to be considered in connection with capital investment projects, there are also circumstances when operational derogations are required. These can relate to a relaxation of testing or inspection, or resource shortages or other operational considerations, such as access or external circumstances (such as a global pandemic). Under these circumstances operational decisions are taken, but it is rare to find these incidents recorded as derogations – whether temporary or permanent.

All derogations need to be kept under constant and ongoing review to ensure that operational changes, clinical activity, or condition surveys and investment planning, are undertaken with the full knowledge that areas of the estate may not be fully compliant. An example might include an area converted to manage emergency admissions due to the pandemic becoming a more long-standing or permanent facility even after immediate pressures have passed. A non-compliant heat recovery unit (which doesn't conform the HTM 03-01 standards for AHUs) intended as a short-term fix (say for an 18-month period) becomes a semi-permanent ventilation solution to the area. Equally, the use of temporary, 'tent-style' isolation facilities become a permanent solution, when a more substantial permanent provision could be developed and installed to provide a safer, and more robust, solution. In emergency situations people can make sub-optimal decisions, and these issues should be kept under review to ensure that they remain appropriate, or, with the benefit of hindsight, that lessons are learned to avoid repetition.

One option for this review process could be to incorporate the review into the standing agenda of the relevant working safety group. This would provide a forum for the majority, if not all, of the agreed derogations, which would be held on a central register. **hej**



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Andrew Poplett has a national client base, and currently provides advice, support, awareness training, and independent auditing services, to over 30 NHS Trusts and private healthcare providers in his role as an Authorised Engineer.