Andrew Poplett Enterprises Ltd

Template Derogation Protocol

For the

Identification, Justification, Recording, & Management

Of NHS standards & guidance including All HTM's/HBN's

Project & Operational

Derogations

Derogation Protocol - Template

Introduction

The Issue of derogation or managing compliance to NHS guidance and standards is often a complex and potentially contentious issue with very long term implications. It can often involve legal issues, and the legal status of NHS specific guidance, and include a range of challenges.

This protocol outlines a process for all aspects to be considered and stages to follow when assessing and managing any potential derogation and is intended for use on all technical disciplines. It should be noted that a derogation in one area may have implications to other areas and all aspects need to be adequately identified, assessed, and documented when determining if a derogation is appropriate.

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 an agreed appropriate level, and where applicable alternative and equivalent mitigation 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 only be considered in exceptional circumstances. A schedule of derogations will be required for any/all project(s). This schedule is not a simple list of derogations which can be stored in a project file. It is required to be comprehensive and stored where it can be easily referenced by all stakeholders and kept under regular review and monitored to ensure it remains safe and appropriate.

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).

NHS Standards (mandatory, guidance, minimum standards, or simply best 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 (HBN's), Health Technical Memorandum (HTM's), Health Guidance Notes (HGN's), Health Facilities Notes (HFN's) and Fire Practice Notes (FPN's), 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 to 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 the following elements need to be considered;

Legal - Anecdotal evidence is that any failures to follow these documents has been used in court proceedings to find against hospital Trusts. These are most likely to be in connection with Health and 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, however the guidance documents are generally considered as an Approved Code of Practice or at the very least good practice. This is summarised below from a general legal assessment of the status and use of these guidance standards;

'DoH guidance is relevant and is generally taken to be authoritative by the relevant authorities and the court, but this 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.

Also 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).

Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 15 These Regulations outline 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.

15(1)(c) suitable for the purpose for which they are being used, Premises 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.'

Whilst 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 this is defined by the parties on either side of a debate around derogation. In practice the answer can be both, the guidance sets safe minimum standards which should not be relaxed where they impact 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 are generally considered by many as world leading, it is not unreasonable to describe them as best practice or even an Approved Code of Practice, at least in some circumstances.

Reasons or drivers to consider derogating

Typically there are many reasons cited to derogate from elements of even entire HTM's or HBN's, 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),
- Scope of project,
- Omission of compliance issue at business case/design/construction stage, or
- We haven't done it before or had it agreed on a previous scheme.

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

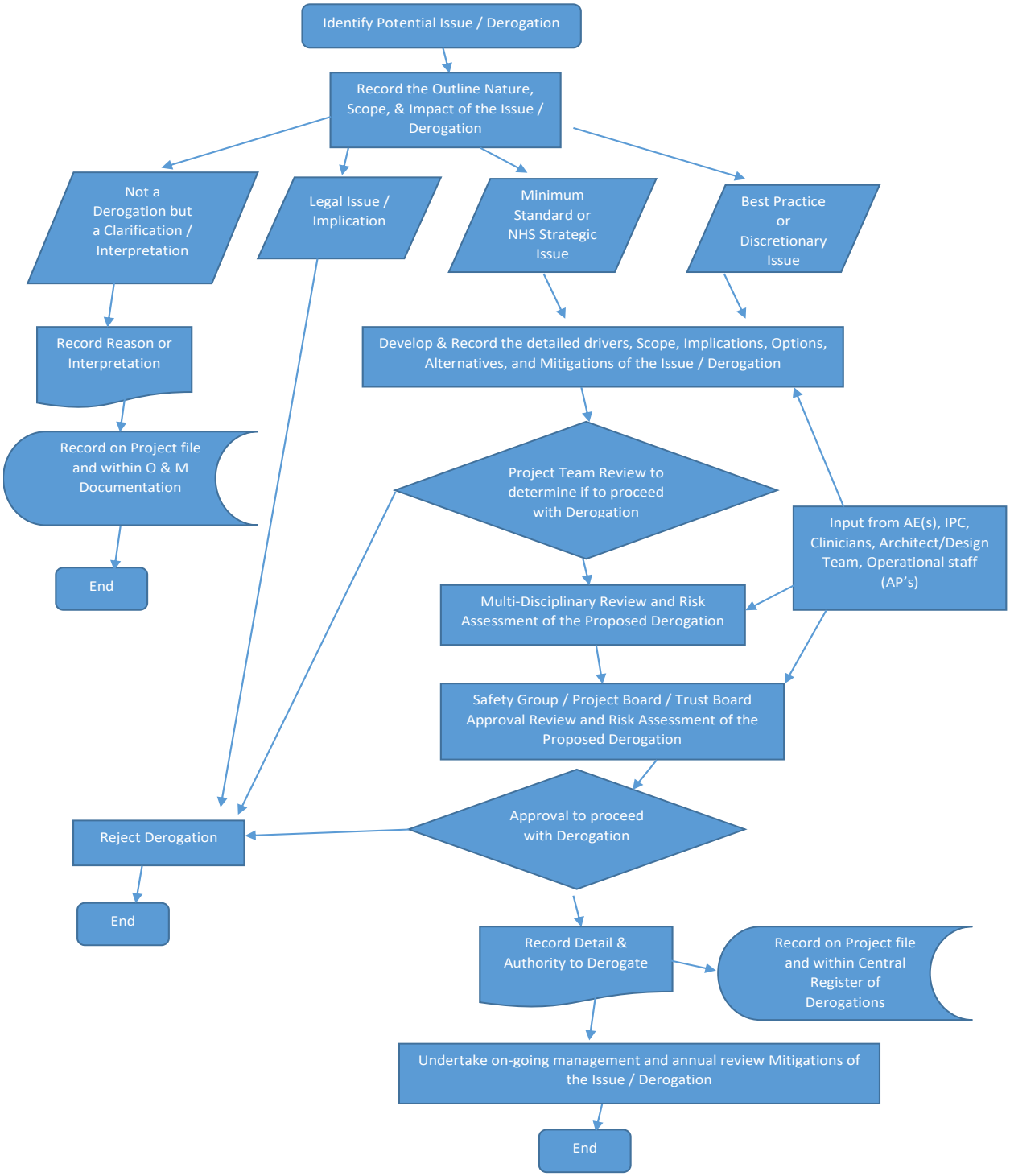
The process of derogation

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 the request 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/comment from the Authorising Engineer for the specific discipline should also be sought to ensure all aspects have been suitably identified and considered. For the avoidance of doubt the review must be comprehensive and include representation for all stakeholders including clinicians, IPC, Operational Estates & Facilities and the Project team, it must not be done in isolation by the project team.

Derogation Flow Diagram



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 lifespan of the development)
- Practical limitations (e.g. space and existing building restrictions)
- Life span and whole life costings
- Energy consumptions and running costs
- Cost (reduced capital costs must not be put ahead of whole life or revenue costs)

Risk Assessment

Once all of these elements have been considered and the scope of the impact of the potential derogation agreed and 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 include as a minimum the following information (per derogation);

Reference No of Standard	*For example HBN/HTM reference*
Specific Clause Reference	
Derogation/Clarification	*Details of what is being proposed for derogation including the exact extent and scope of the derogation requirement.*
Derogation Reason/Driver	*Details of the reason/explanation of why, 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 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	
Comments by Authorising Engineer (AE)	*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 proposed derogation.*
Date	
Risk Assessment / Details of potential consequences	*Details of any risks or potential consequences as a result of the proposed derogation*
Mitigation / Control measures to address identified risk elements.	*Details of any mitigation or supplementary control or management issues which could be used to reduce or address identified risks*
Comments/Review Recommendations for Board Level Designated Person consideration	*Consensus assessment of all stakeholders to the proposed derogation with if practical a recommendation to accept or reject.*
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).*

For the avoidance of doubt the Duty Holder or Designated Person MUST make the final decision to accept or reject a request for derogation even where that decision is informed by advise from either external advisors or working multidisciplinary safety groups.

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 the inclusion onto the organisations risk register to ensure approved derogations do not get overlooked or forgotten.

Recording file structure

All approved derogations must be kept in such a manner as to enable regular (at least annual) review to ensure the decisions taken remain appropriate for any potential usage changes. As such it is recommended that a filing structure or database system is developed to centrally record and manage derogations. One approach is to allocate a referencing system to any agreed derogation which incorporates the following details as a minimum;

- Site reference
- Building reference,
- Level or floor reference (thins could be all floors if it applies to an entire building)
- Guidance reference (HTM or HBN reference)
- Date

This file structure or referencing system should enable specific elements for example any ventilation derogations (HTM 03-01) to be filtered or chosen as a condensed schedule to enable the respective working group to undertake an annual review exercise. The specific clause and derogation detail and reasoning would be stored under this searchable file structure.

On-Going Management & Review of Agreed Derogations

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

All derogations need to be kept under constant and on-going review to ensure that operational changes, clinical activity or condition surveys and investment planning is undertaken with the full knowledge that areas of the estate may not be fully compliant. An example of this could 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 AHU's) intended as a short-term fix (say 18-month period) becomes a semi-permanent ventilation solution to the area. Or 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 situation people can make sub-optimal decisions and these issues should be kept under review to ensure they remain appropriate or with the benefit of hindsight 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. It may also be appropriate to ensure that any agreed derogation is recorded on the Trust or divisional/Departmental risk register as an accepted risk to ensure both operational and management staff are aware of the status and accepted associated risks.

Appendix 1 - Derogation Recording Form Template

The following form is an example of the type of information required and details/signatures required to record an approved derogation.

Element	Detail / Comment	Signature
HTM/HBN Reference No of Standard	*For example HBN/HTM reference*	
Specific Clause Reference		
Derogation/Clarification	*Details of what is being proposed for derogation including a the exact extent and scope of the derogation requirement.*	
Derogation Reason/Driver	*Details of the reason/explanation of why, 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 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		
Comments by Authorising Engineer (AE) (if considered necessary)	*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 proposed derogation.*	
Date		
Risk Assessment / Details of potential consequences	*Details of any risks or potential consequences as a result of the proposed derogation*	

Mitigation / Control measures to address identified risk elements.	*Details of any mitigation or supplementary control or management issues which could be used to reduce or address identified risks*	
Comments/Review Recommendations for Board Level Designated Person consideration	*Consensus assessment of all stakeholders to the proposed derogation with if practical a recommendation to accept or reject.*	
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).*	