NHS Shetland

Shetland Islands Council

Framework for Document Development

Including the Production and Dissemination of Strategies, Policies, Procedures, Protocols and Guidelines

Approval date:	**July 2019**
Version number:	**6.1**
Author:	**Carolyn Hand, Corporate Services Manager**
Review date:	**May 2022**
Security classification:	**Green: Unclassified Information**

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CEFRA001

NHS Shetland Document Development Coversheet*

Name of document	Framework for Document Development		
Registration Reference Number	CEFRA001	**New or Review?**	Review
Author	Carolyn Hand, Corporate Services Manager		
Executive Lead	Michael Dickson, Chief Executive		
Review date	May 2022		
Security classification	Green: Unclassified Information		

Proposed groups to present document to:		
IMWG	eISG	
IGSG		

Date	Version	Group	Reason	Outcome
March 2010	4	Clinical Governance Committee	Revision in relation to the approval process for strategy and policy documentation	MR
May 2010	4	Board	Approval	Approved and communicated
June 2011	5	SMT	Clarifications to existing document following feedback from users	Approved and communicated
11/06/19	5.1	IGSG	C/S	PRO
30/07/19	6.0	eISG	FA	A
11/02/2020	6.1	IGSG	C/S on revisions to v6.0	PRO
25/02/2020	6.1	eISG	FA	A

Examples of reasons for presenting to the group	**Examples of outcomes following meeting**
• Professional input required re: content (PI)	• Significant changes to content required – refer to Executive Lead for guidance (SC)
• Professional opinion on content (PO)	• To amend content & re-submit to group (AC&R)
• General comments/suggestions (C/S)	• For minor revisions (e.g. format/layout) – no need to re-submit to group (MR)
• For information only (FIO)	• Recommend proceeding to next stage (PRO)

• For proofing/formatting (PF)	• For upload to Intranet (INT)
• Final Approval (FA)	• Approved (A) or Not Approved, revisions required (NARR)

***To be attached to the document under development/review and presented to the relevant group**

Please record details of any changes made to the document in the table below

Date	Record of changes made to document
October 2009	V1 Initial outline – Simon Bokor-Ingram, Director of Clinical Services
February 2010	V2 Additional detail on ratification arrangements – Kathleen Carolan, Assistant Director of Clinical Services
February 2010	V3 Additional detail on patient accessibility and document format – Pheona Horne, Acting Corporate Services Manager
March 2010	V4 Additional revisions in relation to the approval process for strategy and policy documentation – Clinical Governance Committee Members
April 2011	V5 Further clarification added following user feedback 12 months on, plus addition of Document Development Coversheet and process flowcharts – Carolyn Hand, Corporate Services Manager and Fiona Morgan, Acting Clinical Governance Facilitator
May 2019	Revisions to accommodate change in directorate structures, the introduction of the Information Governance Team, advances in technical systems underpinning the administration of documentation and to ensure compliance with information governance requirements. Saved as version 6.0.
February 2020	Revisions by the Information Governance Team and Carolyn Hand, Corporate Services Manager, to make more explicit the requirements for all official NHS Shetland documents. Saved as version 6.1
February 2022	Minor edits to flowchart to clarify process made by Sam Collier-Sewell. Saved as version 6.2

Contents

At a glance guidance

(If you are new to document development or need to refresh your understanding, please read this framework in its entirety)

- ✓ Before writing a new policy/procedure/protocol check to see if a document already exists that can be amended or updated.
- ✓ Identify and contact a non-author Sponsor/Executive Lead to discuss/inform them of the development/review of the document.
- ✓ Contact the Information Governance Team who will provide a registration number for the document. This will be recorded on a coversheet which is to be completed and attached to the draft document and updated as it proceeds through the consultation/approval process. Committee/Group Chairs are advised not to review any document that does not have a registration number and coversheet.
- ✓ The coversheet is designed to help groups with the discussion of the draft documentation and to record its progress at each stage. It will:
    - Provide any significant background information;
    - Describe what the group is being asked to do – e.g. for consultation/professional opinion;
    - Record the outcome following members' suggestions – e.g. incorporated into the document and returned to the group for final agreement; and
    - Give details of what the next stage of the document's development will be.
- ✓ If problems occur during the consultation process, guidance should be sought from the Sponsor/Executive Lead.
- ✓ Please contact the Information Governance Team if further assistance is required.

1. Purpose

The purpose of this framework is to ensure that NHS Shetland documents are produced in a consistent and accessible manner. It exists to provide a standardised organisational approach in the effective production, ratification, distribution and maintenance of official NHS Shetland documents and has a particular focus on strategies, policies, procedures, protocols and guidelines.

This document is a renamed version of the Framework for Policy Development, and incorporates and supersedes the Procedure for the Dissemination of Strategies, Policies, Procedures and Clinical Guidelines.

1.1. Introduction

The Equality Act 2010 requires public authorities to make reasonable adjustments to avoid discrimination and this includes ensuring that they provide information in an accessible format. The Accessible Information Policy provides full details of how NHS Shetland should meet this requirement. A summary of the main points of the Accessible Information Policy that are applicable to the development of official documents is provided in Appendix D.

As a public authority NHS Shetland is required to have effective librarianship of its official documents. This includes the registration of official documents and the use of reference numbers, document development coversheets and correct version numbering/control. Effective librarianship enables NHS Shetland to fulfil its organisational and statutory duties – for example, when required by law to provide a copy of the version of a policy that was extant at the time of an incident.

Strategies define a long term plan of action designed to achieve a particular goal. Policies, procedures, protocols and guidelines help NHS organisations and their staff work to a set of standards in both clinical and non-clinical functions. NHS Shetland uses best practice policies, procedures and guidelines, by developing local solutions based on national documents and best practice evidence.

Policies, procedures, protocols and guidelines are tools to assist in the delivery of high quality services by both teams and individuals, and collectively to ensure that the organisation strives to offer the best services and outcomes for patients whilst minimising the risks associated with activities.

NHS Shetland generates some documentation, such as the Annual Operating Plan or Annual Review self-assessment, where the response format is generated externally to the Board. In such instances best efforts should be made to comply with the minimum requirements for all official documents as set out in Section 5 below.

2. Definitions

2.1. Strategies

A strategy is a document that defines a long-term plan of action designed to achieve a particular goal.

2.2. Policies

A policy outlines the aims of the organisation. It needs to demonstrate that statutory requirements and best practice are embedded within the policy's development. A policy is a clear and transparent statement by the organisation about standards and principles that provide a platform for consistent decision-making.

2.3. Procedures

A procedure is a series of instructions that if followed in a systematic way, achieve a specific outcome.

2.4. Protocols

A protocol is a rule which guides how an activity should be performed. A protocol may be a series of set procedures.

2.5. Guidelines

A guideline is a set of criteria that assists in deciding how a policy should be implemented. Clinical guidelines outline the recommended way a service should be provided, a procedure is carried out or a condition is managed. Guidelines allow flexibility for health professionals to make decisions according to individual patient needs.

3. Function of policies, procedures, protocols and guidelines

The development and implementation of policies, procedures, protocols and guidelines provide the organisation with a mechanism to provide direction within, and share aims, values and priorities with the wider community.

These documents help to make decisions on the use of resources whilst ensuring high standards of care to service users through clinical and non-clinical functions. They clarify responsibilities, and provide direction and commitment from the organisation in developing a high-quality, high-performing culture.

4. Responsibilities

The Chief Executive is the accountable officer with overall responsibility for ensuring that NHS Shetland has the right strategies, policies, procedures, protocols and guidelines in place.

Executive Directors will lead on document development and implementation within the remit of their portfolios.

The Information Governance Team is responsible for maintaining the register of all official NHS Shetland documents, and for notifying Executive Directors and Clinical Leads when existing documents are due for review.

5. Minimum requirements for all official documents

All official documents must:

- comply with the requirements of the Accessible Information Policy. A summary of the main points of the Accessible Information Policy that are applicable to the development of official documents is provided in Appendix D.
- have a reference number. The Information Governance Team keeps a register of all documents and issues new/replacement numbers.
- include a Document Development Coversheet from the beginning of their development – see Section 11 for further details. Where it is not practical to include a coversheet in a published document, for instance with some forms or flowcharts, it can be removed from the published version, providing it is retained in the version held by the department.

Wherever possible, official documents should include the NHS Shetland logo. Various versions are available on the intranet[1]. Documents relating to the delivery of Community Health and Care Services should include both the NHS Shetland and Shetland Islands Council (SIC) logos. It is important not to distort or change the aspect ratio of the logo.

6. Process for the production of strategies, policies, procedures, protocols and guidelines

Each Executive Director has within their remit the responsibility for the development, implementation, monitoring and updating of strategies, policies, procedures, protocols and guidelines. This may be through a Board standing committee, a steering group, a working group, management structure or a specific work stream responsible for the document development.

6.1. Strategies and Policies

The Information Governance Team will assign a reference number at the commencement of any new strategy or policy development. Executive Directors must advise the Information Governance Team of any new strategy or policy development in order for a reference to be assigned. The reference number will include alphabetical prefixing to indicate the area of responsibility, as follows:

CE	Chief Executive
CH	Director of Community Health and Social Care
FI	Director of Finance
HR	Director of Human Resources and Support Services
MD	Medical Director
NA	Director of Nursing and Acute Services
PH	Director of Public Health
IB	Integration Joint Board

[1] https://intranet.nhsshetland.scot.nhs.uk/corporate/identity.html

Where a document exists and has a unique reference identifier in line with previous directorate structures, this will be given a new reference number at its next review date. The new reference will be linked in the document database to the previous reference to ensure there is no duplication during the transitional phase.

6.2. Procedures, protocols and guidelines

The Information Governance Team will also include a reference number at the start of the development of any new procedure, protocol or guideline that relates to clinical practice. This reference will be generated so that tight control of the librarianship of the overall register can be maintained. The reference will include alphabetical prefixing to indicate the area of responsibility, as illustrated in 6.1.

6.3. Impact assessment

NHS Shetland is required to show that the impact of any strategy or policy has been fully considered so that any part of the community which might be disadvantaged by the strategy or policy direction can be identified before implementation.

Direct and indirect discrimination, harassment and victimisation are all unlawful on the grounds of race, disability, gender, gender reassignment, sexual orientation, pregnancy, marriage, civil partnership, religion or belief and age. A rapid impact assessment checklist[2] must be carried out for all strategy and policy development. This assessment may, on occasion, lead to a full Equality Impact Assessment being undertaken.

It is good practice to assess the impact of procedures, protocols and guidelines, as these may also have a negative impact on parts of the community.

Executive Directors are responsible for ensuring that impact assessments are carried out.

6.4. Legal considerations

Strategies, policies, procedures, protocols and guidelines need to comply with legal duties, such as those enshrined within Freedom of Information, Human Rights and Data Protection legislation.

It is important that document development includes professional advice in relation to legal, regulatory and statutory requirements, if required. Advice should be sought in the first instance from the Executive Director who is responsible for the area covered by the document. That Executive Director will advise on the need to identify additional input from external bodies (Central Legal Office, General Medical Council, etc.) on a case-by-case basis.

6.5. Security Classification

NHS Shetland has adopted the NHSS Green, Amber, Red system for the classification of information. All official documents must be classified by the author and the classification should be shown in the Document Development Coversheet and, where used, on the title page. Please see Appendix A for guidance.

[2] http://www.shb.scot.nhs.uk/healthcare/support/hr/Documents/EqualityAndDiversityPolicy.pdf

7. Consultation

Strategies, policies, procedures, protocols and guidelines need to be consulted on appropriately to ensure that there is the right amount and level of expertise applied to the development or appraisal of the document, and to obtain the engagement of the relevant stakeholders so that implementation is done positively and substantially. Advice should be sought from the Chair of the Area Partnership Forum as to whether or not the document should be considered there.

Strategies, policies, procedures, protocols and guidelines must document where and when they have been consulted on.

8. Ratification

Strategies, policies, procedures, protocols and guidelines will be consulted on and approved at various levels within the organisation, up to and including Board level. Ratification must be recorded by the relevant committee or group, and a review date assigned. The instructions on content and format set out in the appendices at the back of the framework are mandatory and approving bodies such as standing committees and the Board will not ratify strategy or policy documents if they do not conform to the format and content principles. A fully completed Document Development Coversheet will be required for any document to be approved (attached at Appendix B).

The ratification process is as follows:

Strategy direction – must be approved at Board level.

Policy direction – unless stated as part of the regulatory framework[3], policies will be approved at standing committee or Board level. Standing Committees and the governance structure are shown in the Organisational Framework diagram[4].

Procedures and Protocols – should be approved by a group with the technical expertise to comment on the content. For clinical procedures and protocols the approval process can sit with either specialist advisory groups such as Managed Clinical Networks (MCNs), or an appropriate management team, e.g. Hospital Management Team, Community Health and Social Care Management Team, Executive Management Team (EMT), Senior Nurses Group etc. Non clinical procedures and protocols should follow the same approval convention and seek ratification through the appropriate technical advisory group and EMT as required.

The consultation process for all Board strategies, policies, procedures and protocols should consider seeking advice from one or more of the following professional advisory groups as appropriate:

- Area Clinical Forum (ACF);
- Area Nursing & Midwifery Advisory Committee (ANMAC);
- Area Medical Committee (AMC);
- Area Dental Committee (ADC);
- Area Pharmaceutical Committee (APC);
- Area Advisory Committee for Allied Health Professionals (AACAHP).

If there is any doubt about the consultation or ratification process then advice should be sought from the appropriate executive lead.

The executive lead can also advise if document updates are considered so minor in nature that they do not need to follow the ratification process described (e.g. change of job titles, change of revision date only).

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[3] As an example, health and safety policy direction has to be approved at Board level, as set out in the Board's Scheme of Delegation.

[4] Board Standing Committees are shaded on the chart at http://intranet/corporate/documents/OrganogramMay2019.pdf

9. Librarianship

The Information Governance Team must be informed that a new official document has been approved / ratified and provided with a copy of the final version of the document for registration in the master database and for online publication. This is to ensure strict version control to reduce the risk of incorrect or out of date policy guidance being made available to staff across the organisation.

10. Format of documents

A unified approach must be adhered to in order for there to be a managed document control system in place.

This will ensure that the development and distribution of documents is carried out in such a way that only the final approved versions are used within the organisation; that documents valid for use are easily recognisable as being so; and that any documents not authorised by the organisation are easily identified and removed.

The principles and best practice for document numbering and version control are set out in the Document Version Control – Good Practice Guidance document.

Appendix C is a checklist of key requirements, and sets out the mandatory headings that must be followed. Additional headings can be added, but this is the basic information that should be included in all policies, protocols and procedures. This checklist should be used by all groups that are asked to approve documents.

Appendix D sets out the format and layout of documents.

Appendix E provides a title page cover template.

11. Additional help with document development

A sample Document Development Coversheet is included at Appendix B. This document will act as a record of document consultation and approval as well as for version control. Document authors should start the completion of this document, including seeking a unique reference number from the Information Governance Team at the outset. No committee or group will sign off a document without this coversheet being fully completed.

Appendix F provides a quick overview flowchart for document development.

12. Communication arrangements

In line with the Board's Communication Strategy, all new policies and strategies will consider the communication aspect from the outset and will set out an action plan to ensure that essential messages are communicated effectively to stakeholders. The plan will include the methodology of communication and the appropriate consultation with staff, patients, public and stakeholders.

All Board-wide strategy, policy and procedure documentation will be made available on the website in a specific portal area.

Procedures and protocols will be posted on the internet/intranet as appropriate unless there is a specific risk attached to publication.

The executive director and standing committee responsible for the strategy/policy area will manage strategy and policy dissemination instructions. Team Brief will carry information about strategy and policy approval. Procedures and protocols will be disseminated through clinical and management team arrangements.

Appendix A – Security Classification [ISO/IEC27001:2013 8.2.1]

NHS Shetland has adopted the NHSS Green, Amber, Red classification of information:

eHealth Guidance	NHS Shetland Examples	Equivalent UK Government Security Classification
GREEN: Unclassified information This is information which is unlikely to cause distress to individuals, breach confidence, or cause any financial or other harm to the organisation if lost or disclosed to unintended recipients. This can include information which mentions only a person's name (e.g. routine appointment confirmation letter) **as long as it does not contain anything that is judged to describe a person's physical or mental state.**	Most NHS Shetland corporate documents fall within this category, including: • Names, posts of employees • Most management correspondence and minutes • Work contact details	**OFFICIAL**
AMBER: Protected information In most boards the largest proportion of patient information can be said to require extra protection because it is defined as 'special category data' by the Data Protection Act. In particular: • Any information about an individual (i.e. anything clinical or non-clinical) that would cause short-term distress, inconvenience or significant embarrassment if lost • Any information which if lost or disclosed to unintended recipients would lead to a low risk to a person's safety (e .g. loss of an address but no evidence to suggest direct harm would result). • Any information if lost that would be likely to negatively affect the efficiency of that service (e.g. cancellation of appointments).	• Patient medical details or the performance or health of individual colleagues • Commercially sensitive procurement information during the tendering process • Home contact details • Sensitive management discussion	**OFFICIAL**

eHealth Guidance	NHS Shetland Examples	Equivalent UK Government Security Classification
RED: Highly sensitive information Most boards also hold some information which is highly sensitive. In particular: • Any information which if lost could directly lead to actual harm (e.g. to mental health or put the person at physical risk from themselves or others in any way). • Any information that would in the opinion of a qualified person cause substantial distress and/or constitute a substantial breach in privacy (e.g. identity theft, loss of professional standing) to the subject. This is likely to include for example information on a person's sexual health. • Information that affects the privacy or could cause distress to more than one individual (e.g. several family members or several linked persons contained in a file). Information relating to vulnerable persons' health (e.g. child protection cases). • Information governed by legislation that requires additional layers of security and recognises the substantial distress that would be caused by loss (e.g. embryology, human fertilisation and gender re-assignment). • Information if lost that is likely to result in undermining confidence in the service or would cause significant financial loss to the organisation, prejudice investigation of crime etc.	• Highly sensitive patient medical information or staff equality & diversity information identifying individuals, particularly sexual orientation • Serious allegations against individual staff • Banking or credit card details of individuals	***OFFICIAL – SENSITIVE PERSONAL**

* When communicating with UK or Scottish Government agencies, local authorities or the Police, Red data must be labelled as:

OFFICIAL – SENSITIVE PERSONAL. [ISO/IEC27001:2013 8.22]

Appendix B – NHS Shetland Document Development Coversheet

Name of document			
Registration Reference Number		**New or Review?**	
Author			
Executive Lead			
Review date			
Security classification			

Proposed groups to present document to:		

Date	**Version**	**Group**	**Reason**	**Outcome**

Examples of reasons for presenting to the group	**Examples of outcomes following meeting**
• Professional input required re: content (PI)	• Significant changes to content required – refer to Executive Lead for guidance (SC)
• Professional opinion on content (PO)	• To amend content & re-submit to group (AC&R)
• General comments/suggestions (C/S)	• For minor revisions (e.g. format/layout) – no need to re-submit to group (MR)
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• Final Approval (FA)	• Approved (A) or Not Approved, revisions required (NARR)

***To be attached to the document under development/review and presented to the relevant group**

Please record details of any changes made to the document in the table below

Date	Record of changes made to document

Appendix C – Mandatory content for all strategy, policy, protocol and procedural documents

Requirement	Compliance
Fully completed Document Development Coversheet	
Standard title page, including: • Logo • Title • Author • Version number • Date of approval • Date of review • Security Classification • Statement on how to ask for the document in alternative language or format • Document reference number	
Table of contents (mandatory for strategy and policy documents only)	
Purpose of the document, including whether the document is new or has been reviewed, and whether it replaces any existing documents. Reference should also be made to any documents that should be read in conjunction	
Introduction	
Summary of the national policy driver, legal or regulatory framework underpinning the local strategy, policy or procedural documentation	
Clear summary of the key message, objectives, guidance or standards which the local strategy, policy or procedural documentation has been developed to convey	
Roles and responsibilities associated with the implementation, monitoring and delivery of the local strategy, policy or procedural documentation	
Communication arrangements associated with the implementation, monitoring and delivery of the local strategy, policy or procedural documentation to include methodology of communication and appropriate consultation	
Organisational chart denoting the reporting arrangements (mandatory for strategy and policy documents only)	
Key performance indicators (KPIs) – mandatory for strategy and policy documents only	
Rapid Impact Assessment Checklist	

Appendix D – Format and layout for all strategy, policy, protocol and procedural documents

All documents should use the standard title-page layout and document development coversheet (see Appendices E and B).

Accessibility is central to the Board's approach to providing information and is detailed in the Board's **Accessible Information Policy**[5]**.** A summary of the main points includes the following:

- Font size: it is recommended that no lower than 12 point Arial is used throughout
- Text should be unjustified
- Plain English should be used
- Any abbreviations used should be explained
- Page numbering should be numerical (1,2) not text (one, two)
- Footer should include date and version of document on each page
- Use bold for emphasis, not italics or underlining
- Avoid the use of capitals for emphasis (except for common usage such as EXIT)
- Do not centre text or logos or align to the right margin

[5] http://9.200.150.6/documents/pphandbook/documents/AccessibleInformationPolicy-FinalVersionOct2008.pdf

Appendix E – Title Page

[Title of Document]

Approval date:

Version number:

Author:

Review date:

Security classification:

If you would like this document in an alternative language or format, please contact Corporate Services on 01595 743069.

[Document ref]

Appendix F – Document Development Flowchart