NHS Scotland eHealth Programme

Standards Framework:
Standards Development Process

Version: 1.3
September 2009
# Document Control

<table>
<thead>
<tr>
<th>Title</th>
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<tbody>
<tr>
<td>Owner</td>
<td>Head of Architecture and Design, Scottish Government eHealth Directorate</td>
</tr>
<tr>
<td>Version</td>
<td>1.2</td>
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## Version Control

<table>
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<tr>
<th>Date</th>
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<th>Author</th>
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<tr>
<td></td>
<td>0.01-0.20</td>
<td>Colin Howarth</td>
<td>Various drafts&lt;br&gt;Updated following review by eHealth leads</td>
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<tr>
<td></td>
<td>0.21-1.0</td>
<td>Paul McLaren</td>
<td>Added fast-track process&lt;br&gt;Updated following review by Infrastructure leads</td>
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<tr>
<td>03/07/2009</td>
<td>1.1</td>
<td>Jonathan Meddes</td>
<td>Modified structure to improve readability.</td>
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<tr>
<td>25/08/2009</td>
<td>1.2</td>
<td>Jonathan Meddes</td>
<td>Minor amendments following second review by eHealth leads.</td>
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<tr>
<td>01/09/2009</td>
<td>1.3</td>
<td>Jonathan Meddes</td>
<td>Version 1.2 approved by eHealth Programme Board. Minor update on ‘Standards Compliance’ to include reference to lifecycle.</td>
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1 Introduction

This document describes the NHSScotland eHealth Standards Framework, and the process for the development and approval of eHealth standards in NHSScotland. The standards process puts the Health Boards and end users of standards at the heart of the development and review process ensuring that standards are robust, accurate and supported.

In this document the term ‘standard’ refers to:

*Specification or configuration documents which reflect national agreements on products, configurations, practices or operations regarding some aspect of NHSScotland eHealth.*

2 The Standards Development Process

2.1 Development Routes

There are two routes for the development of standards:

- **full**: where agreement is complex and with a potentially wide reaching impact;
- **fast-track**: for existing undocumented standards, where a general acceptance (de facto) or widespread use already exists within NHSScotland.

2.2 Roles in the Standards Process

The key roles in the standards development process are:

- the **owner** establishes the business case for the standard and is responsible for ensuring that the standard is updated at appropriate intervals. The owner is a long term role and should change infrequently;
- the **author** has specialist expertise to produce the standard, developing all content and incorporating comments received. They may be seconded, or they may represent a development team of people working on a particularly large standard, or a standard that is an integrated part of a project;
- the **reviewers** are the stakeholders who will be affected by the development and adoption of the standard and should be consulted.
- the **approvers** are authoritative groups that approve the final standard for publication in the standards library.
2.3 Resources

The resources available to support the development of standards are available from the Architecture and Design section of the eHealth website\(^1\) and include:

- the standards dashboard and library, where URLs, descriptions and other document metadata is collated to manage the standards development process and enable rapid access to standards;
- full and fast-track standard templates;
- design checklists (under development) for projects to assess their own level of compliance with standards.

The current and in force version of all eHealth standards will always be available in the Standards library.

2.4 Standards Compliance

Levels of compliance are categorised as:

- **Mandatory:** this standard should be adopted by all unless a very compelling reason exists to adopt an alternative.
- **Recommended:** it is the NHSScotland preferred standard.
- **Information:** a reference for information.

Over time standards may have different levels of compliance. For example, a standard may be recommended for a period of time in preparation for it becoming mandatory.

2.5 Version control

Standards will be version controlled throughout the process and will include several metadata items: publish date, next planned review date, planned validity period, etc.

\(^1\) [http://www.ehealth.scot.nhs.uk/?page_id=88](http://www.ehealth.scot.nhs.uk/?page_id=88)
## 2.6 Standards Approval

<table>
<thead>
<tr>
<th>Anticipated national cost of development and implementation</th>
<th>SG eHealth / eHealth Leads</th>
<th>Clinical Change Leadership Group (CCLG)</th>
<th>eHealth Programme Board</th>
<th>Strategy Board</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; £50,000</td>
<td>Approve</td>
<td>Approve clinical informatics standards</td>
<td>For information</td>
<td></td>
</tr>
<tr>
<td>£50,000 - £500,000</td>
<td>Approve</td>
<td>Approve clinical informatics standards</td>
<td>Approve</td>
<td>For information</td>
</tr>
<tr>
<td>&gt; £500,000</td>
<td>Approve</td>
<td>Approve clinical informatics standards</td>
<td>Approve</td>
<td>Approve</td>
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</table>
3 Summary of the Standards Process

The stages of the Standards Development Process are illustrated in Figure 1 and are:

- **Stage 1: establish the case**: establish the scope and if a business case is required for the standard, identify list of reviewers and produce outline implementation plan.

- **Stage 2: develop the standard**: the content of the standard is written and made available in the standards library, reviewed and updated accordingly until all reviewers have signed it off.

- **Stage 3: approve**: the standard is approved and the status marked as issued.

- **Stage 4: publish and implement**: the standard is published, communicated and established for implementation in the target environments.

- **Stage 5: maintain and dispose**: review at regular intervals and if necessary update the standard.

Table 1 defines the objectives and activities of each stage. It also provides guidance on how the standards development process is simplified for fast-track standards. Sections 3.1 to 3.4 provide detail to the table.

![Figure 1: Key stages in the standards development process.](image-url)
<table>
<thead>
<tr>
<th>Stage and Objective</th>
<th>Activity [who]</th>
<th>Fast-track</th>
</tr>
</thead>
<tbody>
<tr>
<td>1: Establish the case</td>
<td>1. Establish the business case. [Owner]</td>
<td>The standard will already be a de facto standard and implementation will have limited impact.</td>
</tr>
<tr>
<td>Identify and confirm the need for the standard</td>
<td>2. Identify the author and reviewers who represent key stakeholders. [Owner]</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3. Determine if this standard will be mandatory, recommended, or information. [Owner]</td>
<td></td>
</tr>
<tr>
<td></td>
<td>4. Assign reference number and placeholder in the standards library. [eHealth A&amp;D]</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2: Develop the standard</td>
<td>1. Create the standard. [Author]</td>
<td>Review via publishing a draft standard in the standards library for up to three months.</td>
</tr>
<tr>
<td>Develop a standard that has been consulted upon with stakeholders.</td>
<td>2. Consult with key stakeholders. [Author/Reviewers]</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3: Approve</td>
<td>1. Submit for approval by appropriate group (see Section 2.6). [eHealth A&amp;D/Approvers]</td>
<td>Only expected to be approved by SG eHealth and eHealth leads.</td>
</tr>
<tr>
<td>Approve the standard for publication.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4: Publish and implement</td>
<td>1. Publish in the eHealth Standards Library and communicate. [eHealth A&amp;D]</td>
<td></td>
</tr>
<tr>
<td>Publicise and use the standard.</td>
<td>2. Incorporate into Design Authority reviews. [eHealth A&amp;D]</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3. Implement where appropriate.</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5: Maintain and dispose</td>
<td>1. Review in line with the agreed review cycle. [Owner/Author]</td>
<td></td>
</tr>
<tr>
<td>Keep the standard up to date and relevant.</td>
<td>2. Significant modification will require re-approval.</td>
<td></td>
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</table>

Table 1: The stages of the standards development process.
3.1 Stage 1: Establish the case

The purpose of this stage is to identify and confirm the need for the standard and to agree that the benefit of producing the standard will outweigh the costs and impact of developing and implementing the standard on the target system.

A short business case is produced that answers the following questions:

- what will the standard do?
- is there an existing standard that already does this?
- what is the scope of the standard? (e.g. users, systems, timescales, etc.)
- what are the quantified benefits of implementing the standard?
- What are the development and implementation costs?
- what is the impact of not implementing the standard?

Standards are categorised to indicate the expected level of compliance as either mandatory, recommended, or information (see Section 2.4).

The compliance level will also determine the anticipated cost, which will be used to indicate approval (see Section 2.6).

3.2 Stage 2: Develop the standard

The detail of the development process will be different for each standard and dependent on the content of the specific standard. The process is managed at the discretion of the author and reviewers with the support of the eHealth Directorate as needed.

The production of the standard is carried out by the author and consists of a normal document authoring cycle including peer review, consultation with stakeholders and user communities, incorporating comments, workshops, through as many iterations as needed to achieve consensus.

Development of a standard by a project is an opportunity to deliver benefits simultaneously to both the project and the wider NHS community and is encouraged; in particular, it instantly demonstrates an implementation of the standard.

3.3 Stage 3: Approve

The draft standard is presented to an appropriate body for approval, which is based on the table in Section 2.6. Of particular significance to the approving body is identifying the consulted groups and any statements of support particularly from those who will need to commit resources to implement the standard.

The approving body will also confirm when the standard is to become active, the validity period of the standard and the categorisation of the standard (mandatory/recommended/information).

3.4 Stage 4: Publish and implement

The eHealth Programme communicates the standard to the target projects and environments identified the implementation plan produced in stage 1. Primary means of communication will be via email, and it is anticipated that the primary points of contact will be eHealth Leads, Chief Execs and the other environments/projects identified in the implementation plan.
The standard will also be incorporated into the day to day governance processes of the Design Authority; e.g. incorporate into design reviews when project solution designs and business cases are submitted to the eHealth Programme Board for approval. A self certification approach using a design checklist will enable projects to measure compliance, and to ensure rapid progress through the project governance arrangements.

3.5 Stage 5: Maintain and dispose

Standard owners are responsible for arranging the review of standards at regular intervals. An updated standard may need to be submitted for approval again if there is a cost implication or significant impact of the changes made to the standard (i.e., start the standards development process from Stage 2).

It is the responsibility of the standard owner to monitor the context of the standard and to ensure the standard is reviewed and updated whenever it is needed and in line with established change control procedures for example:

- due to evolving technology;
- to meet the requirements of upcoming or in-flight projects;
- after changes in national or international guidance;
- to comply with changes in strategy or with legislation.

When the standard has reached end of life it is disposed and removed from the active section of the standards library. End of life standards are identified by the standard owner:

- the standard is considered no longer relevant during a maintenance/review period;
- the technology to which the standard relates is no longer in service;
- the standard is replaced by a new standard.