The Information Standards Assurance Process:
An Overview for Developers

Why standards matter

"Standards make an enormous contribution to most aspects of our lives - although very often, that contribution is invisible. It is when there is an absence of standards that their importance is brought home."

International Standards Organisation (ISO)

The Information Standards Assurance Process

The Information Standards Assurance Process supports sponsors, developers and users of information standards by adopting a structured approach to reviewing standards development.

This approach ensures appropriate areas are considered during the development and implementation of a standard such as: business requirements; funding and resources; consultation and engagement; security and confidentiality; and comparison with existing and developing standards.

A historic lack of appropriate information standards assurance processes had led to the identification of a number of issues by those involved in the process, e.g. a lack of co-ordination in data demands, data standards and definitions. Therefore, the Information Standards Assurance Process was developed and established in 2006 after approval by the Department of Health and Social Service (DHSS) Management Board and was introduced in WHC (2006) 083. (This was initially called the Information Governance Process and the appraisal board was called the Welsh Information Governance & Standards Board. Some changes to terms, names and roles were made to take account of the establishment of the NHS Wales Informatics Service and the Wales Information Governance Board.)

The outcome of the Information Standards Assurance Process should be that data is captured, transmitted and used effectively, efficiently and securely and that the burden of capturing data for secondary purposes is minimised.

The Welsh Information Standards Board

A key requirement for ensuring effective sharing of quality data is to ensure all requests for information flows and standards are reviewed through a formal and robust governance process. This process is overseen by the Welsh Information Standards Board (WISB).

WISB is responsible for co-ordinating information standards issues for health and healthcare in Wales. Its scope covers clinical, administrative and managerial informatics standards to be used in NHS Wales and with its partner organisations. A co-ordinated process ensures that duplication of effort is minimised in developing and implementing information standards.

Sponsoring a new or changed standard

A Sponsor shall be the person(s) responsible for ensuring that the conditions for effective implementation of the new requirement, including funding, are present.

The Sponsor will usually work for the Welsh Government. If in exceptional circumstances this is not the case, the Sponsor must obtain support from a suitable individual within the Assembly who has the authority to request a Ministerial letter or issue a 'Officials' letter or equivalent.

The Sponsor is likely to have identified the need for a new or changed standard and will drive the development of the standard. The Sponsor will oversee the engagement with WISB and ensure that effective documentation is supplied to WISB to enable consideration of proposals.

Developing a new or changed standard

Within the Information Standards Assurance Process the development role has a number of assigned responsibilities. They include producing the development plan, developing the standard, producing proposals for consideration by WISB and finally implementation of an approved standard.

Development is a role that may be undertaken by a number of people during the lifecycle of an information standard.

Developers will be expected to liaise with the Sponsor and other key roles such as the WISB secretariat and teams responsible for DSCN (information mandate) and Welsh Government official letter (policy mandate) development.

Submissions to WISB

At different stages of the process WISB will require the following information:

- The business justification including purpose, scope and funding arrangements.
- The fit with other information related developments.
- Impact assessment including stakeholder consultation.
- Plans for development, implementation, maintenance and review.

The developer will work closely with the Sponsor to ensure appropriate information is made available to complete the submission documents.

The types of changes that will be notified to WISB are:
- a new standard,
- a change to an existing standard,
- the formal adoption of an existing standard that has not previously received formal approval from WISB,
- the retirement (cessation) of an existing standard.

The submission process

At various points in the Information Governance Process documents will be submitted to WISB for consideration. If WISB approves the requirement then the standard will continue to the development stage and eventually on to implementation and review.

The process is intended to introduce good governance and not to be overly bureaucratic. Although a standardised process has been introduced it is recognised that each standard presented to WISB will be different in nature and developers should discuss with the WISB secretariat the appropriate pathway for each standard and the level of documentation required.

Submission documentation

Submission documentation and guidance are available from the WISB secretariat. There are four submission templates for: Requirement Notification, Development Proposal, Final Proposal and Review Submission.

Developers will be expected to contribute significantly to two key documents, the Development Proposal and the Final Proposal, but may also contribute to other documents in conjunction with the Sponsor.

The key purpose of the **Requirement Notification** is to notify WISB of the prospective requirement so they can make any comments at this stage. This includes documenting the business requirement for the proposed standard and identifying the potential developer for the standard.

The key purpose of the **Development Proposal** is to notify WISB of a prospective information standard development so they can make any comments at this stage and approve development work if they so choose.

The information required for the Development Proposal submission includes an outline of the proposed standard; details of impact assessment and consultation; and an outline development plan including timescales, responsibilities, costs and risks.

During development it may be necessary to inform WISB of progress at key points such as after design and after impact assessment. This would be agreed with the Sponsor, Developer and WISB Secretariat.

The key purpose of the **Final Proposal** is to notify WISB of the planned implementation or adoption of a new or changed standard (or cessation of existing standard) for consideration and approval if they so choose.

The information required for this submission includes details of the proposed standard; an outline implementation plan including timescales, responsibilities, costs and risks; and details of how maintenance and review processes will be undertaken.

The key purpose of the **Review Submission** is to notify WIGSB of the outcomes of the implementation, adoption or cessation of a standard for consideration of recommendations