

This document provides an overview of the process for the development, review and maintenance of Health Information Standards Organisation (HISO) Standards.

Standards Processes



January 2017

Table of Contents

1	Introduction	2
	Why HISO?	2
	What role do standards play in health?	2
	Early engagement with HISO Office	3
2	Benefits of Standards	4
3	Standards Development Process	5
3.1	Stages	6
	Stage 1: Identify, Propose & Plan	6
	Stage 2: Develop and Evaluate	7
	Stage 3: Consultation	7
	Stage 4: Approve and Implement	7
	Stage 5: Review and Maintain	8
3.2	HISO's Approval	8
3.3	Timescales	8
3.4	Players	9
4	Standards Review and Maintenance Process	10
4.1	Scheduled Review	10
	Confirmed:	10
	Revised:	10
	Deprecated and Replaced:	10
4.2	Ad Hoc Change requests	11
	How to Request an Ad Hoc Change	11

*All relevant process documentation and updates are available on the
Ministry of Health website: <http://www.health.govt.nz>*

1 Introduction

This document provides an overview of the processes required for the development, review and maintenance of health information standards administered by the Health Information Standards Organisation (HISO).

HISO is an advisory body to the Ministry of Health providing them with standards related advice. In April 2016, the Ministry of Health published the *New Zealand Health Strategy* which sets the direction of health services to improve the health of people and communities. HISO supports this strategy by promoting the development, understanding and use of fit-for-purpose health information standards across the NZ health and disability sector.

Why HISO?

HISO is a publically funded standards development organisation, mandated to perform this function for the sector. The HISO Committee comprises of up to twelve appointed members from across the health sector. The HISO brand provides valuable recognition and credibility within the sector.

The HISO office, which supports the committee, has been facilitating working groups to develop, review and maintain standards for a number of years.

What role do standards play in health?

Health information standards are developed to:

- provide guidance to assist in ensuring that health information requested is provided at the right time to the right person in the right place and in a secure fashion
- support the need for secure and safe sharing of health information between all participating health providers
- provide implementation guides for applications compliant to information standards
- provide an agreed common language to encourage accuracy and consistency of recording and use, therefore supporting interoperability
- provide business processes, code sets, data sets (with agreed data definitions), and/or messaging standards, where required.

Early Engagement with HISO Office

Early engagement with the HISO office is encouraged in the initial stages of a project. The project/proposer will benefit from early engagement, as the HISO office is able to provide advice on:

- existing HISO, national (non-HISO), or international standards that could be used “as is” or adapted for New Zealand requirements.
- other standards activity that may be relevant, or
- standards development that may be required by your project.

Early engagement with HISO, ensures that information that already exists in other HISO standards can be utilised saving unnecessary time wasting and avoiding duplication. HISO also have an existing network of sector participants that can be considered when establishing working groups.

To ensure that standards gain valuable recognition and retain credibility from the sector, the HISO office administers the standards process.

For further details on HISO and how to contact the HISO office, please refer to the Ministry of Health website.

2 Benefits of Standards

Fit-for-purpose health information standards improve and enhance health information systems within the New Zealand health and disability sector.

Health information standards support the increasing need to safely and securely exchange patient information between various healthcare providers and healthcare information systems.

The benefits of a standard will:

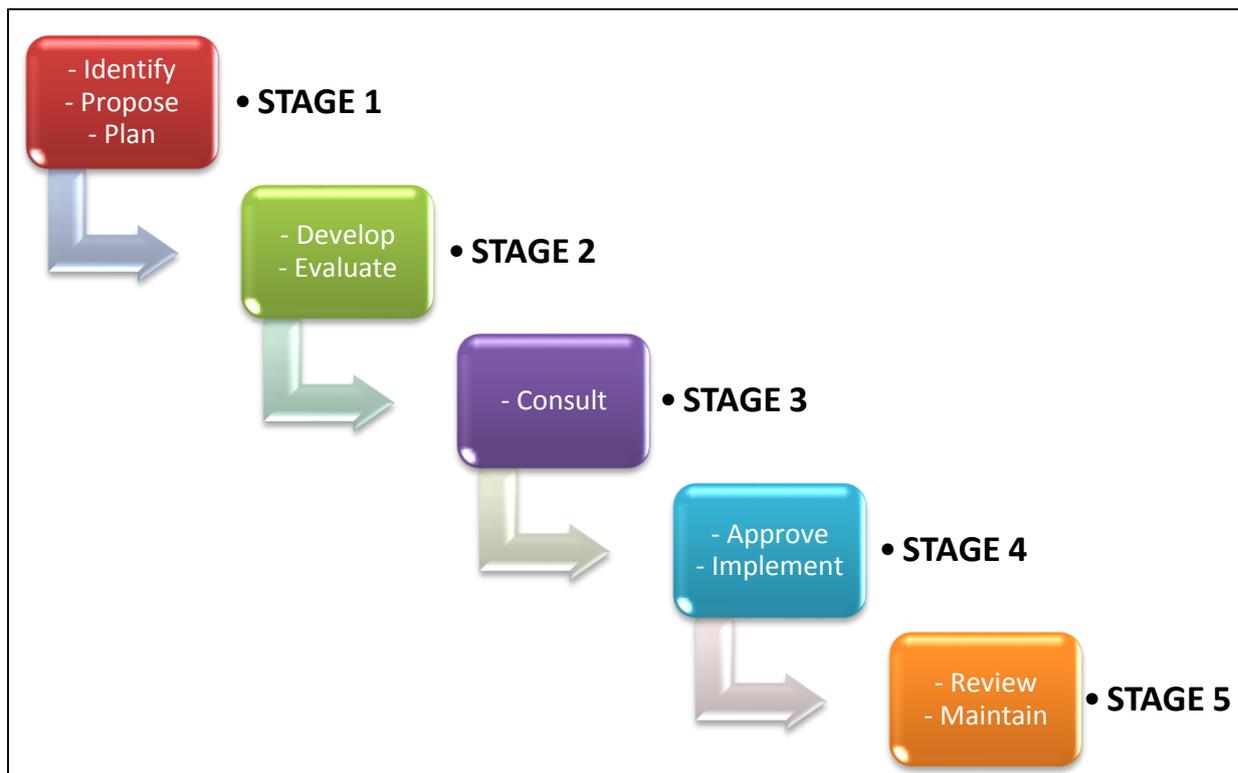
- improve services provided by the health and disability sector
- provide a consistent approach to business processes
- assist with more accurate reporting of information due to health information systems capturing information in a consistent way
- enhance opportunities for interoperability between systems
- reduce the duplication of effort
- reduce the risk of errors.

3 Standards Development Process

Health information standards are developed by subject matter experts with the aim of improving health outcomes and safety through a coordinated, consistent approach, in accordance with a five-stage process and governed by a set of [core principles](#):

- **Balanced representation:** relevant areas of the sector affected by the standard are given adequate opportunity to input to its development
- **Consensus:** sufficient support for the final version of the standard exists
- **Independence:** the standards developed are agnostic in terms of people and products
- **Transparency:** the development process is clear and open
- **Needs based:** the development of the standard is necessary
- **Fit-for-purpose:** the standard is useful, implementable and ready for application when required
- **Patient safety:** safe and appropriate for use in health.

The five stages of the standards development process are:



A more detailed *HISO Standards Development Process Map* can be found in *Appendix A* or on www.health.govt.nz.

3.1 Stages

Stage 1: Identify, Propose & Plan

Identify

When starting up a project, one of the steps to preparing the project brief should be to engage with the HISO office to determine the need for a health information standard.



Propose and Plan

Initial discussions with the HISO office will determine whether a standards proposal questionnaire will need to be completed. HISO office will assist the project/proposer in completing this questionnaire. For the types of questions that may be asked, please refer to the standards proposal questionnaire on the Ministry's website - www.health.govt.nz.

The HISO office will use the information provided in the form to make an initial assessment of the proposal in the context of existing and emerging national and/or international standards¹ available. From the initial assessment and depending on the options for development, HISO office may ask the project/proposer for further information. The standards proposal questionnaire, any additional information provided, and HISO office's

¹ Organisations requiring licences or copies of international standards will be responsible for purchasing copies at their own cost.

assessment is submitted to the HISO committee for their information, consideration, and advice back to the Project / Proposer on:

- options (eg: endorsement, adaption and adoption of an existing standard, or development of a new standard)
- details of the process involved
- estimated timeframes and funding requirements

If the development of a new standard is required, the project/proposer and the HISO office create a terms of reference and establish a working group. These terms of reference are presented to the HISO Committee for their information and/or comment.

Stage 2: Develop and Evaluate

Develop

The working group develops the draft specification(s) with assistance from HISO to ensure the look, feel and content is consistent with other HISO standards. The draft is developed until consensus of the working group is reached that the draft specification(s) is ready to be handed over to HISO for the HISO process.

Part of the development stage includes scheduling a review commencement date and initial review timeframe.

Evaluate

HISO office will establish an evaluation panel to review the draft specification(s) to ensure HISO's core principles are covered. Once the evaluation is complete, the draft specification(s) is then presented as a draft standard to the HISO Committee with one of the following recommendations:

1. more work is required by the working group, prior to progressing to Stage 3.
2. approve to progress through to seek public comment (Stage 3)
3. the document remains as a specification(s) for the project only.

Stage 3: Consultation

Upon HISO's approval, the draft standard(s) is ready to progress to public consultation across the sector and interested parties. The HISO office collates the feedback received for analysis by the working group. The working group decides how to address each piece of feedback and take agreed actions to update the draft standard(s) accordingly. Once the working group reaches a consensus, the draft standard(s) is ready to be submitted to the HISO committee for approval as an interim standard(s) – Stage 4.

Stage 4: Approve and Implement

On HISO's approval, the draft standard(s) is published as an interim standard(s) and ready for the pilot implementation.

Once implemented and after a suitable trial period, an evaluation is organised by the HISO office to ascertain whether the standard is fit-for-purpose. HISO can then give approval to publish the standard as a full standard(s).

Stage 5: Review and Maintain

To ensure the standard remains current, a review, as indicated in the development stage, is undertaken. If no review date is indicated, a review should be scheduled no later than three years after implementation.

In addition to the scheduled reviews, all published HISO standards are subject to ad hoc maintenance to ensure they accurately reflect the needs of the current environment.

Please refer to section 4 for full details on the review and maintenance of standards.

3.2 HISO's Approval

A draft standard(s) is presented to HISO either for:

- **Approval**
An approved standard is where HISO has approved for use across the NZ health sector a document(s), developed by a balanced expert committee or working group taking into consideration input received through public comment consultation that represents the consensus view of those parties directly or indirectly affected by the content.
- **Endorsement**
An endorsement means to give support or approval to the use of an existing, usually international standard or to something which is internationally used but has not been approved by a recognised standards body. Parts of the standard may not necessarily be suitable for New Zealand requirements, but no additional work is required or undertaken to make it New Zealand specific.
- **Adoption**
An adopted standard is similar in that it is developed (usually) internationally and has been approved by a recognised standards body. It can be used "off the shelf" for New Zealand purposes although, as the New Zealand health sector has unique requirements, there would be very few international standards that could be used unchanged.
- **Adapt and adoption**
Another option is a combination of the above methods. The majority of an existing standard can be adopted but may need adapting to meet New Zealand specific requirements.

Note: Organisations requiring licences or copies of international standards will be responsible for purchasing copies at their own cost.

3.3 Timescales

The time it takes to develop a standard will depend on the complexity of the topic. HISO office will work with the project/proposer to keep the timescales to a minimum.

3.4 Players

Those involved in the development of a health information standard are:

Individual / Group	Definition	Responsible for:
Project / proposer	Identifies the need for a standard to be developed, engages early with the HISO office about the proposed development, and is the driving force in terms of progressing the development work through to the public comment stage.	<ul style="list-style-type: none"> • Collaborating with the HISO office • Establishing (in conjunction with HISO office) and managing the working group • Gathering evidence around standard's fit-for-purpose and implementability.
HISO office	The operation arm of the HISO committee.	<ul style="list-style-type: none"> • Providing support, advice and expertise on standards development • Working collaboratively with the project/proposer. • Assisting with development of the working group to ensure balanced representation. • Providing early advice on what standards may be required. • Ensuring development processes are followed appropriately. • Managing stages 2, 3 and 4 of the HISO development process.
HISO committee	Its purpose is to support and promote the development, understanding and use of health information standards across the New Zealand health and disability sector.	<ul style="list-style-type: none"> • Providing standards related advice to the Ministry of Health. • Ensuring standards support the future direction of the New Zealand Health Strategy. • Ensuring health information standards are developed in accordance with approved processes. • Approving/endorsing standards for publication.
Working group	Group of individuals selected for their specialist knowledge of the topic on which the standard is based on.	<ul style="list-style-type: none"> • Developing the specification(s). • Working with HISO office through the development. • Reviewing and agreeing actions on comments received during public comment period.

4 Standards Review and Maintenance Process

Scheduled reviews and ad hoc maintenance are critical parts of the standards life cycle. They work together to ensure that published standards are living, fit-for-purpose documents that reflect current practices, regulations, user needs and/or updates required as a result of other external factors. They support increased uptake/adoption.

A detailed HISO Standards Review and Maintenance Process Map can be found in Appendix B or on the Ministry's website.

4.1 Scheduled Review

Scheduled review cycles will vary depending on the nature of the standard. The review cycle should be formally agreed as part of the development of the standard. A review may be requested outside the scheduled review period if the standard is believed to not be fit-for-purpose (refer to ad hoc change requests).

The HISO office maintains and publishes a 'scheduled review' diary, covering all implemented HISO standards. When a standard comes up for review, the HISO office posts a notice on the website. The HISO office will seek feedback from interested parties whether the standard is fit-for-purpose and gain an indication of its usage and uptake. Recommendations are provided to the HISO Committee whether the standard is:

- confirmed
- revised
- deprecated and replaced.

Further descriptions of review paths follow.

Confirmed:

If the review indicates that a standard is deemed fit-for-purpose and no changes are required, notification will be posted on the Ministry's website.

Revised:

Minor

If the review indicates that minor changes are required, HISO office action the relevant changes, republish the standard and establish a new review date.

Major

If major changes are required to the standard, a working group will be established to review the standard. Depending on the outcome of this review, further public comment may be sought.

Deprecated and Replaced:

If the standard is no longer fit-for-purpose, a new standard will be developed and put through the HISO process. Once the replacement standard has been published and implemented the old standard is deprecated.

4.2 Ad Hoc Change requests

Ad hoc change requests to a standard can take place at any time and come from any stakeholder.

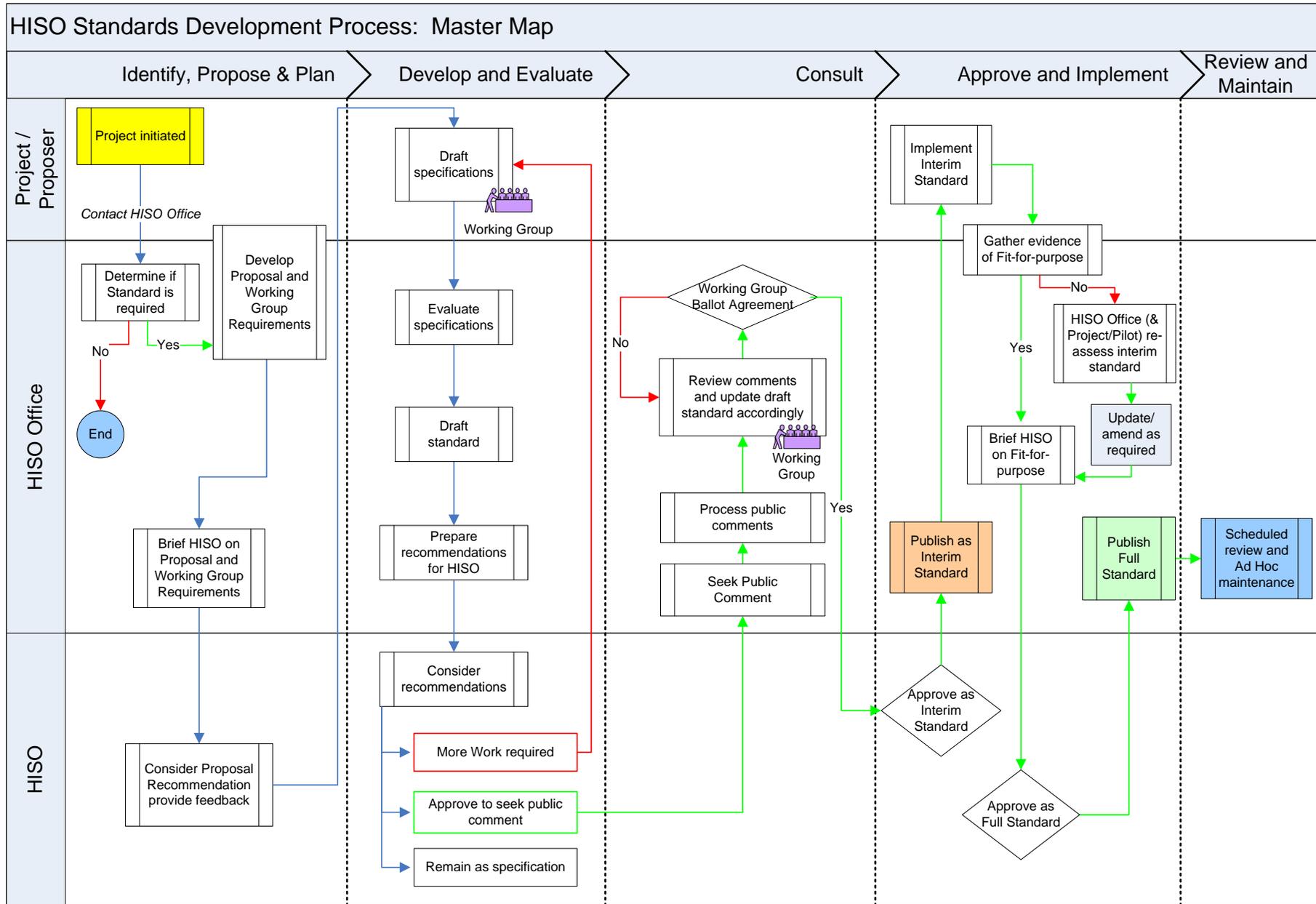
Change requests can cover a broad spectrum – from correction of administrative / typographical errors, changing code sets through to more significant changes which might require a standard to be significantly revised and/or re-developed.

How to Request an Ad Hoc Change

To request a change to the standard, complete the Standard - Change Request form, available on the Ministry's website, and submit this to the HISO office by emailing to standards@health.govt.nz.

HISO office will be in touch to discuss the form.

APPENDIX A – HISO STANDARDS DEVELOPMENT PROCESS MAP



APPENDIX B – STANDARDS REVIEW AND MAINTENANCE PROCESS MAP

