Canada Health Infoway | Inforoute Santé du Canada

Infoway Standards Collaborative (SC)

pan-Canadian Standards Decision Making Process

Version 2.0 Release 2.2

Approved: January 11, 2012

***INFOWAY* STANDARDS COLLABORATIVE INFORMATION DESK**

1-877-595-3471 • 416-595-3417

STANDARDS@INFOWAY-INFOROUTE.CA • NORMES@INFOWAY-INFOROUTE.CA

Copyright Notice

Disclaimer

The views expressed herein represent the views of Canada Health Infoway (or other persons as indicated), not the Minister of Health or any representative of the Government of Canada.

Table of Contents

Table of Figures

1 Executive Summary

The *pan-Canadian EHR Information Standards Decision Making Process* was approved for trial use by the Standards Steering Committee in June 2005. Refinements to this process occurred throughout 2006 as needs of early adopters were identified. The most recent publication of the *pan-Canadian Decision Making Process in the Standards Life Cycle v1.7* was released in February 2007.

In response to action items identified through meetings with the Standards Collaborative Strategic Committee (SCSC) and the Standards Collaborative Coordinating Committee (SCCC), a project was initiated to deliver an updated and more comprehensive pan-Canadian Standards Decision Making Process based on experience and lessons learned to date. A collaborative approach was followed to update the pan-Canadian Standards Decision Making Process. Various stakeholder groups were included throughout the process to ensure diverse needs were identified and all involved would be able to advocate for the resultant processes.

The pan-Canadian Standards Product Life Cycle (SPLC) explains the progression of a specification from initial phases of selection through to formal approval. This reflects processes within the early stages of identifying business definitions and requirements, to the options research and analysis of candidate specification to development and finally to the Maintenance of a pan-Canadian specification.

There are a number of Standards Support Services that are needed to support pan-Canadian Standards through the SPLC. These Standards Support Services work in parallel and in support of the SPLC. There are a number of touch points between the SPLC and Support Services based on the maturity of the specification and where the specification enters the lifecycle.

Within the context of the pan-Canadian Standards Decision Making Process, the type of specification under consideration determines the level of granularity of components that progress through the SPLC. The types of specifications of interest to the SC may include, but are not limited to:

- *Message and Terminology Specifications* - A specification Volume (for example, Volume 8 - Pharmacy or Volume 4 - Client Registry);
- *Controlled Health Terminology Specifications* - A complete specification (for example, pCLOCD);
- *Health Informatics Specifications* – A complete specification (for example, the Canadian Institute for Health Information (CIHI) Primary Health Care Data Content Standard); and

- *Integration Profiles* – A complete specification.

A specification progresses through the SPLC from Development to Maintenance. The SPLC contains Decision Points, and it is at these points that a specification is reviewed as part of the pan-Canadian Standards Decision Making Process. Once the specification reaches an appropriate level of maturity, formalized Maintenance of the specification will commence and will continue until the specification, or parts thereof, are deemed no longer viable or useful. The pan-Canadian Standards Decision Making Process and Maintenance Services intersect when the specification is designated as Canadian Draft For Use (CDFU) and when the specification, or parts thereof, are declared Canadian Deprecated (CD) (no longer viable or useful). Changes that occur to a specification throughout its Maintenance cycles will not re-enter the pan-Canadian Standards Decision Making Process.

As a specification progresses through the SPLC, it is reviewed at each Decision Point as part of the pan-Canadian Standards Decision Making Process. A series of Principles and Criteria have been developed to guide the selection and approval of pan-Canadian Standards as part of the pan-Canadian Standards Decision Making Process. The Principles are overarching considerations that must be considered in order to support approval of a specification at each Decision Point. Criteria represent specific requirements that should be considered in addressing a Principle. Application of all Principles and Criteria must be addressed at each Decision Point. However, some Principles and Criteria may not necessarily apply to all specifications nor does a specification have to be compliant with all Criteria for each Decision Point. Where a Principle and/or specific Criterion do not apply or is not relevant to the decision being made, it will suffice to list that Principle and/or Criterion as not being applicable and describe the rationale for this assertion. As the specification progresses through the SPLC, it is expected that more information will become available to assess these Principles and related Criteria.

These are the Principles identified for consideration as part of the pan-Canadian Standards Decision Making Process:

- *pan-Canadian Standards must be clinically relevant* – Includes Criteria of Clinical Appropriateness; Cross Discipline; Cross Health Care Delivery; and Clinical Outcomes;
- *pan-Canadian Standards must meet specific pan-Canadian business needs* - Includes Criteria of pan-Canadian Business Need; Maturity/Stability; Feasibility; and Workflow;

- *pan-Canadian Standards must be interoperable with the pan-Canadian EHR Blueprint* – Includes Criteria of Canadian Alignment; Vendor Neutral; Backward Compatibility[1]; and Bilingual Support, as appropriate;
- *pan-Canadian Standards must be financially viable* – Includes Criteria of Affordability and Implementation Costs;
- *pan-Canadian Standards must have established governance and processes related to all aspects of the SPLC* – Includes Criteria of Intellectual Property; Governance Structure; Canadian Influence; Other Approval Processes; Standards Support; and Sustainability; and
- *pan-Canadian Standards must be technically viable* – including, but not limited to, criteria that are Terminology and Messaging Specific.

Throughout the SPLC, the following Decision Points are included in the pan-Canadian Standards Decision Making Process:

- Canadian Strategy Selection (CSS);
- Canadian Draft For Use (CDFU);
- Canadian Approved Standard (CAS); and
- Canadian Deprecated (CD).

For each Decision Point, the purpose, key attributes and specific Principles and Criteria that must be considered are defined. Additional Criteria have been called out to facilitate interpretation among users. If a specification is proposed for a Decision Point, but has not completed the previous Decision Point(s), the Sponsor must demonstrate equivalence with those Decision Points. That is, if a specification is proposed as CAS, but has not been designated as CSS or CDFU through the pan-Canadian Standards Decision Making Process, the Sponsor must address all Principles and Criteria as required in those Decision Points.

Approval of all Decision Points is determined by the Standards Collaborative Strategic Committee (SCSC) and is based on the recommendation for approval from the Standards Collaborative Coordinating Committee (SCCC). The SCCC may request review and guidance from its Technical Sub-Committee (TSC) and/or Clinical Sub-Committee (CSC) as well as review and guidance from the Standards Collaborative

[1] Except in those situations defined in the *PRM White Paper* as accepted not to be backward compatible. This requirement is in alignment with the Product Release Management Process and will be implemented as approved in that process through Maintenance Services.

Working Groups (SCWGs). These reviews are optional and are requested at the discretion of the SCCC.

The CSS Decision Point is intended to ensure that pan-Canadian Standards Stakeholders have an opportunity to examine the implications of selecting one pan-Canadian Standards strategy over another. The approval of the CSS Decision Point affirms that the initial steps in the SPLC (i.e. Needs Identification and Business Definition and Options Research and Analysis) have been completed.

The CDFU Decision Point replaces the Stable For Use (SFU) Decision Point defined in *pan-Canadian Decision Making Processes in the Standards Life Cycle v1.7*. It has been re-named to better reflect the attributes of this Decision Point. The CDFU designation is reached after a specification has completed the development phase of the SPLC, even though it may not have been implemented or be in current use in any project or jurisdiction. The CDFU specification is ready to be implemented or used by early adopters. However, some changes should be anticipated as vendors and implementers begin reviews and development. Stakeholders must take this into consideration as they begin their risk assessment. A CDFU designation is considered when the specification is required for implementation(s) that cannot wait for the specification to reach CAS and at least one implementer has committed to using it. The CDFU designation is effective for a period of two years. After this, the specification is reviewed to determine whether it should be progressed to CAS, extended as CDFU or CD.

Canadian Approved Standard (CAS) is the third key Decision Point. A specification under review at this Decision Point must be in use for the purpose(s) or context(s) for which it was intended, and only those parts in use will be designated as CAS. For example, a Messaging and Terminology Specification is in use to manage information and/or exchange information between business partners. These implementations might be limited production rollouts or production rollouts. Other types of specifications may be published in a Request for Proposal (RFP) by a jurisdiction or be in use as a policy within a jurisdiction or system. This Decision Point signifies that the Canadian Approved Standard has now reached a recognized level of stability and is comprehensive enough that major changes are not expected. It should be noted however, that over time, Canadian Approved Standards will be updated to meet evolving business, clinical and technical requirements and that future Releases of the CAS may be published.

The Canadian Deprecated (CD) Decision Point can be considered at any time following the designation of a specification as CDFU or CAS. Deprecation within the context of the SPLC means that the specification is no longer suitable for new implementations, not in use, or has been replaced by a better method or concept.

Specifications proposed to become CAS may come into the pan-Canadian Standards Decision Making Process from a number of sources and at various stages or Decision Points. In some cases, the specification may be proposed by Canada Health Infoway (*Infoway*). However, it is possible that jurisdictions or other organizations may bring forward specifications for consideration as Canadian Approved Standards. Sponsors may develop a specification to meet a particular localized business need and will continue to support and maintain that specification as long as required to sustain the effective functioning of their health information systems.

A common process for Approval of pan-Canadian Decision Points has been defined. In addition, a separate process has been defined for extending a CDFU Designation.

The pan-Canadian Standards Decision Making Process reflects current experience and incorporates lessons learned. It provides a process for progression of specifications through the SPLC to Canadian Approved Standards.

2 Introduction

2.1 PURPOSE AND OBJECTIVES

The purpose of this document is to define the pan-Canadian Standards Decision Making Process for the progression of specifications through the pan-Canadian Standards Product Life Cycle (SPLC). This iteration of the SPLC replaces the process defined in the *pan-Canadian Decision Making Processes in the Standards Life Cycle Version 2.0 Release 2.15.* The processes defined in this document apply to any specification under consideration as a pan-Canadian Standard, including non-*Infoway* Sponsored specifications.

Within this document the term Specification is defined as a complete set of interdependent artifacts such that developers can build interfaces conformant to those artifacts. These artifacts are typically constrained from international versions of similar artifacts for use in pan-Canadian specifications.

The objectives of the document are to:

- Define Principles and Criteria for the pan-Canadian Standards Decision Making Process; and
- Define the process for reviewing specifications progressing through the SPLC.

It should be noted that the processes defined in this document for confirming pan-Canadian Standard Decision Making Process designations will continue to evolve with further experience and lessons learned.

2.2 SCOPE

2.2.1 IN SCOPE

This document defines the pan-Canadian Standards Decision Making Process. It includes definitions of the SPLC, Principles, Criteria, Decision Points, and roles and responsibilities of the *Infoway* Standards Collaborative (SC) Governance Committees and working groups (for example, Standards Collaborative Working Groups (SCWGs) as they relate to the SPLC.

Health Informatics standards that support pan-Canadian Electronic Health Record (EHR), Electronic Medical Record (EMR) and Health System Use of Electronic Health Data are in scope for consideration as Canadian Approved Standards through the pan-Canadian Standards Decision Making Process. International Standards which are under consideration for adoption or adaptation are also in scope for this process.

2.2.2 OUT OF SCOPE

The following processes are related to the pan-Canadian Standards Decision Making Process, but the scope of this document does not include detailed descriptions of processes for:

- Approval of new work items for SCWGs;
- Approval of requests for *Infoway* Standards Collaborative (SC) Support (e.g. approval that the SC will provide ongoing support for a pan-Canadian Standard);
- Maintenance processes for pan-Canadian Standards and specifications; and
- Deprecation in the context of Maintenance.

This document provides a high-level definition of the objectives for these processes to provide context and will reference them where appropriate.

2.3 AUDIENCE

Standards Collaborative members and stakeholders, including:

- Organizations responsible for implementation and maintenance of health information solutions, including jurisdictions, vendors, Point of Service (PoS) solution vendors and other organizations and agencies of health;

  Standards Collaborative Governance Committees;
- Organizations that may sponsor specifications for pan-Canadian Standard DMP designation;
- Standards Development project teams; and
- Standards Collaborative Team.

2.4 ASSUMPTIONS

The following assumptions have been used in the development of this document:

- This decision making process will enable non-*Infoway* sponsored specifications to be declared Canadian Approved Standards. There is no requirement that all Canadian Approved Standards should be maintained by the SC (e.g. Canadian Approved Standards could be maintained by organizations other than the SC.)
- Approval of a proposed specification for consideration or progression toward being a Canadian Approved Standard does not tacitly or explicitly imply financial or other support by the SC. The pan-Canadian Standards Decision Making Process is separate from the approval process used by the SC to evaluate requests for support for a Canadian Approved Standard.

- The Standards Collaborative Strategic Committee (SCSC) has the authority to approve pan-Canadian Standards Decision Points.
- As approved in their respective terms of reference, Standards Collaborative Coordinating Committee (SCCC), Technical Sub-Committee (TSC), Clinical Sub-Committee (CSC) and Standards Collaborative Working Groups (SCWGs) endorse recommendations for approval by the SCSC.
- Decision points in the pan-Canadian Standards Decision Making Process are distinct from Standards Development Organization (SDO) balloting. However, the SDO balloting status should be considered as part of the Decision Making Process.
- Specifications may enter the pan-Canadian Standards Decision Making Process at different stages and from different Sponsors.
- At Decision Points in the pan-Canadian Standards Decision Making Process, reviewers are responsible for ensuring that an adequate process has been followed and that an appropriate level and detail of information is provided to make an informed decision.
- Maintenance of a specification will begin once it has reached an appropriate level of stability. Maintenance, and the associated Decision Making Processes, is an independent process from the pan-Canadian Standard Decision Making Process.

2.5 APPROACH FOR UPDATING THE PAN-CANADIAN STANDARDS DECISION MAKING PROCESS

The initial document (titled pan-Canadian EHR Information Standards Decision Making Process) was approved for trial use by the Standards Steering Committee in June 2005. Additions to this process occurred throughout 2006 and V1.7 was distributed in February 2007. A collaborative approach was used to update the document in 2009 with the approved Version 2.0 Release 2.15 publication taking place in October 2009.

2011 revisions to the DMP were then implemented to incorporate CAS objectives, process and criteria that were defined and approved by the SC Governance following the successful implementation of the CAS process and designations in 2010.

Additionally, a limited review and update of the DMP was undertaken in 2011 as a result of the SCSC decision to review HSU and information standards.

2.6 OVERVIEW OF CHANGES MADE TO DECISION MAKING PROCESS

The initial focus of the DMP was on the use of standards in electronic health records. It now reflects the broader use of these standards in current solutions and for other purposes (HSU, primary care, etc.).

CAS objectives, process and criteria related content was added and/or updated, including, as recommended by the Standards Collaborative Coordinating Committee, the removal of the requirement for endorsement letters from implementing organizations.

2.7 GLOSSARY AND ACRONYMS

2.7.1 GLOSSARY

For ease of understanding and future reference, Appendix A provides a collection of terms and definitions. In addition, key terms within the document that begin with a capital letter (e.g. specification) can be found in Appendix A.

2.7.2 ACRONYMS

The following acronyms are used in this document:

Term	Description
CSC	Clinical Sub-Committee
CD	Canadian Deprecated
CDFU	Canadian Draft for Use
EHR	Electronic Health Record
CAS	Canadian Approved Standard
pCCP	pan-Canadian Conformance Profile
pCLOCD	pan-Canadian Laboratory Observation Code Database
pCSG	pan-Canadian Standards Group
HIS	Health Informatics Standard
HSU	Health System Use
PoS	Point of Service
PRM	Product Release Management
RFC	Request for Change
RFP	Request for Proposal
SC	*Infoway* Standards Collaborative
SCCC	Standards Collaborative Coordinating Committee
SCSC	Standards Collaborative Strategic Committee
SCWG	Standards Collaborative Working Group
SDO	Standards Development Organization
SPLC	Standards Product Life Cycle
CSS	Canadian Strategy Selection
TSC	Technical Sub-Committee

2.8 RELATED INITIATIVES

The SC regularly reviews its processes and documentation based on industry practices and lessons learned from implementations to ensure the efficient development and support of health information specifications.

Initiative	Description
New SCWG Work Item Process	The New SCWG Work Item Approval Process facilitates the addition of new work items to the SCWG work plan between regular SCCC approval cycles for SCWG work plans. This process provides: • A mechanism for SCWGs to contribute to the scoping and development of such work items; • Feedback to the applicant on such new work items; • A mechanism to generate broader/jurisdictional/pan-Canadian support; and • A collaborative work forum for items that are accompanied by Sponsorship (e.g. through support from regional, jurisdictional or other collaborative initiatives). Approval of a new SCWG work item does not constitute approval of SC support. Further information about this process can be requested through the Standards Collaborative Infodesk (Standards@infoway-inforoute.ca).
SC Support Request Process	The SC Support Request process is intended to respond to requests from applicants to the SC to provide financial (or other) support for proposed new pan-Canadian Specifications. This process is currently being developed in consultation with the SCSC. Further information can be requested through the Standards Collaborative Infodesk (Standards@infoway-inforoute.ca).
Product Release Management White Paper – Implementation of Recommendations	The SCCC endorsed the Product Release Management White Paper and approved its recommendations on July 23, 2008. This initiative provides a comprehensive strategy, tactical plan and recommendations that will facilitate the progression of pan-Canadian specifications, the Products of the Standards Collaborative, through a structured maintenance and deployment model that is consistent with the goals and objectives of the Standards Collaborative and

Initiative	Description
	supports the maintenance requirements of stakeholders. Further information about the Product Release Management White Paper can be requested through the Standards Collaborative Infodesk (Standards@infoway-inforoute.ca).
SC Governance Manual	SC Governance has developed terms of reference, policies and procedures and committee member lists for all SC Governance committee and working groups into a single SC Governance Manual. These documents provide relevant information to all current and potential participants in the SC Governance Structure. Further information about the SC Governance Manual can be requested through the Standards Collaborative Infodesk (Standards@infoway-inforoute.ca).
Non CDFU Specification Management	New process in development for managing specifications that do not reach CDFU.

2.9 ASSOCIATED AND REFERENCED DOCUMENTS

The SC regularly reviews its processes and documentation based on industry practices and lessons learned from implementations to ensure the efficient development and support of health information specifications.

Documents are available on request through the SC Infodesk (Standards@infoway-inforoute.ca).

Document Name	Date	Author
pan-Canadian Decision Making Process in the Standards Life Cycle v1.7	February 2007	Standards Collaborative
Product Release Management White Paper V1.5	July 2008	Standards Collaborative
Standards Collaborative Guide and Standards Catalogue		Standards Collaborative
Conformance Framework White Paper – 20070618 – v2.1	June 18, 2007	Standards Collaborative
SC Governance Manual		Standards Collaborative
pan-Canadian Specification Deprecation and Support Policy	April 8, 2009	Standards Collaborative
SCCC-TSC Technical Ballot Quality Criteria	October 2008	Standards Collaborative

ISO/TS 17117:2002 *Health informatics - Controlled health terminology - Structure and high-level indicators* NOTE: This reference document is available for purchase from: www.standardsstore.ca	2002	ISO/TC215
HSU_Project Report for CDM	June 15, 2009	Health System Use Technical Advisory Committee
HSU_Project_PPT_for_CDM_JUNE12_EN_FINAL	June 12, 2009	Health System Use Technical Advisory Committee
HSU Categories of Use Framework and Examples	June 15, 2009	Health System Use Technical Advisory Committee / CIHI

2.10 ASSOCIATED AND REFERENCED TEMPLATES

Templates are available upon request through the SC Infodesk (Standards@infoway-inforoute.ca).

Template	Date	Author
Pending Approval Announcement		
Announcement of Public Review Commencement		
Standard Submission Template		
Feedback/Comment Form		

3 Pan-Canadian Standards Product Life Cycle

3.1 INTRODUCTION

The pan-Canadian Standards Product Life Cycle explains the progression of a specification from the early stages of the identification of business requirements and business definitions through the options research and analysis of candidate specifications to development and finally to the Maintenance of a specification.

Section 3 is limited to the stages within the SPLC and does not focus on the reviews and approvals that a specification may undergo throughout this life cycle. Those are fully described in Section 6.

The SPLC is composed of four stages:

- Needs Identification & Business Definition;
- Options Research and Analysis;
- Specification Development; and
- Maintenance.

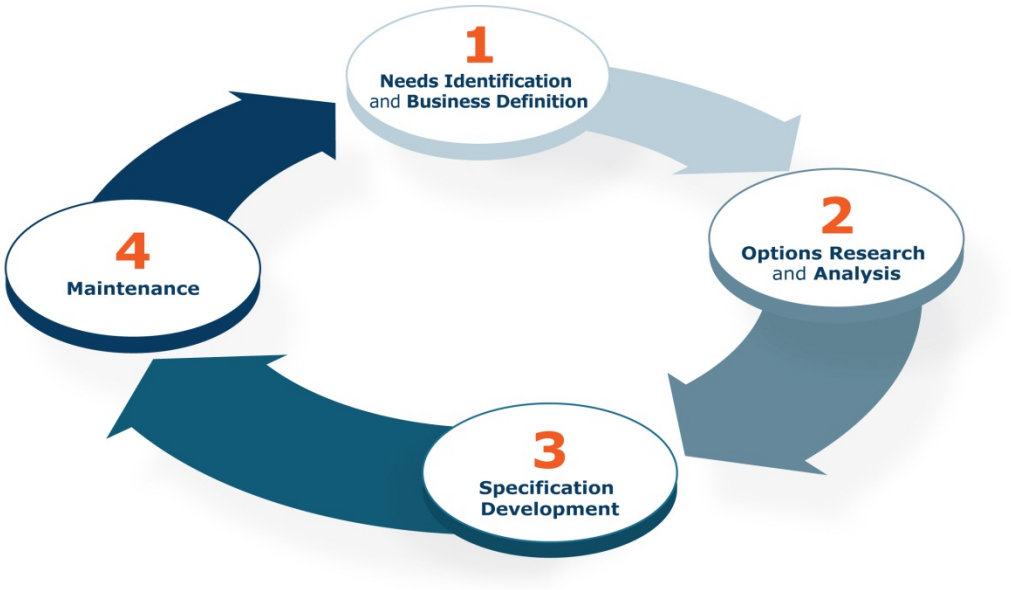


Figure 1 - pan-Canadian Standards Product Life Cycle (SPLC)

3.2 SPLC STAGES

3.2.1 NEEDS IDENTIFICATION AND BUSINESS DEFINITION

- Define the need for specifications to address specific business, clinical and technical requirements.
- Validate requirements with pan-Canadian stakeholders.
- It is recommended that a Sponsor - *Infoway* or other - launch a 'for purpose' standards consultation group to support pan-Canadian validation. Other organizations may convene working groups, or similar groups, to review and develop standards with an engagement approach that follows the DMP principles.
- Sponsors can also request inclusion on a SCWG work plan through the New SCWG Work Item Approval Process to validate requirements with pan-Canadian stakeholders.

3.2.2 OPTIONS RESEARCH AND ANALYSIS

- Identify candidate specifications.
- Review candidate specifications by applying pan-Canadian Standards Decision Making Process Principles and Criteria.
- Conduct a gap analysis.
- Conduct a risk assessment.
- Analyze indicative costs (e.g. licensing, implementation, maintenance, etc.).
- Validate results with pan-Canadian stakeholders.

3.2.3 SPECIFICATION DEVELOPMENT

- Specification development activities will vary based on the outcome of the options research analysis stage.
    - If the decision was to adopt an existing specification, some additional work to develop pan-Canadian implementation guides, etc. would occur.
    - If the decision was to adapt an existing specification, some additional development work and/or alignment with an external SDO may occur.
    - If the decision was to develop a new specification, development activities would be conducted.
- Initiate/complete appropriate SDO processes nationally and/or internationally to leverage external SDO work and, as required, to ensure international standards meet pan-Canadian needs.

- Complete supporting material for the specification (e.g. Terminology/coding, Implementation Guides, extraction specification, information or architectural models, minimum dataset, etc.). Assess specification against pan-Canadian Standards Decision Making Process Principles and Criteria.
- Validate specification with pan-Canadian stakeholders.

3.2.4 MAINTENANCE

- Specification is maintained through a structured maintenance and deployment model.
  - Maintenance is a regular and anticipated part of the SPLC and commences at the point where a specification reaches a specific level of stability. It continues until the specification, or parts thereof, are deemed no longer viable or useful.
  - A Request For Change (RFC) process that engages the SC Governance Structure including review and approval by SCWGs is part of this regular maintenance process.[2]
- Sponsor has completed appropriate SDO processes nationally and/or internationally to leverage external SDO work, as required, and ensured ongoing alignment, where appropriate.
- Required changes are identified by implementers to the pan-Canadian specification and associated knowledge objects are made in subsequent Releases as appropriate.
- Experience and lessons learned from implementation of the specification with pan-Canadian stakeholders are validated.

3.3 STANDARDS SUPPORT SERVICES

- There are a number of services needed to support pan-Canadian Standards and specifications throughout the SPLC:
  - Implementation Support Services;
  - Maintenance Services;
  - Conformance Services;
  - SC Engagement and Process Services;
  - Development Support Services;
  - Education and Training Services; and

[2] The RFC process is discussed in more detail in the Product Release Management (PRM) document.

- Client Services and Standards Development Organization Relations.

These Services work both in parallel and in support of the SPLC. There are a number of touch points between the SPLC and Support Services based on the maturity of the specification and where the specification enters the lifecycle.

4 Progression of a Specification through the pan Canadian Standards Product Life Cycle

In this document the term specification is defined as a complete set of interdependent artifacts such that developers can build interfaces, applications, or solutions conformant to those artifacts. These artifacts are typically constrained from International versions of similar artifacts for use in pan-Canadian Specifications.

The types of specifications that are of interest to the SC may include, but are not limited to:

- *Message and Terminology Specifications* – Artifacts that define Messages and Dependent Terminologies to support a message interchange environment.
    - For example, the pan-Canadian HL7 V3 specification, published as MR2007 (Maintenance Release 2007), which includes Terminologies dependent upon HL7 Mood codes and HL7 Gender codes;
- *Controlled Health Terminology Specifications* - ISO/TS 17117:2002 defines a controlled health terminology as a set of terms intended for clinical use. NOTE: This implies enough content and structure to provide a representation capable of encoding comparable data, at a granularity consistent with that generated by the practice within the domain being represented, within the purpose and scope of the terminology.
    - For example, pan-Canadian Laboratory Observation Code Database (pCLOCD);
- *Health Informatics Specifications* – The specifications required to support health informatics, which is the intersection of clinical, IM/IT and management practices to achieve better health (includes content standards, data element lists/minimum datasets, data extract specification, data models, etc.)[3]
    - For example, CIHI's Primary Health Care Data Content Standard
- *Integration Profiles*[4] - Artifacts that describe additional constraints on an existing specification (known by IHE as a technical framework).

In addition, other specifications are of interest to the SC. These do not include artifacts used by developers to build interfaces, but rather define high-level business requirements or policies (for example, Electronic Medical Records, Architecture or

[3] Available from COACH website: http://www.coachorg.com/health_informatics

[4] An Integration Profile is different than a conformance profile. The focus of a conformance profile is on the testing of a Specification. An Integration Profile is a constraint of a Specification for implementation purposes.

Health System Use Specifications) that may be used in Requests for Proposals (RFPs) or as part of an EHR implementation.

Within the context of the pan-Canadian Standards Decision Making Process, the following are the components that progress through the SPLC for each type of specification:

- *Message and Terminology Specifications* – Specification Volume and associated artifacts, for example, Volume 8 – Pharmacy or Volume 4 – Client Registry;
- *Controlled Health Terminology Specifications* - Complete specification. For example, pCLOCD (microbiology, chemistry, etc.);
- *Health Informatics Specifications* (e.g. information, data or content) – Complete specification, for example EMR data content standard (e.g. data element list, data extract specification, or terminology reference sets); and
- *Integration Profiles* – Complete specification.

4.1 RELATIONSHIP BETWEEN PAN-CANADIAN STANDARDS DECISION MAKING PROCESS AND MAINTENANCE

A specification progresses through the SPLC from Development to Maintenance. At various steps along this progression a specification is reviewed as part of the pan-Canadian Standards Decision Making Process. The output of the Decision Making Process includes decisions to:

- Adopt, adapt or develop a specification (i.e. at the CSS Decision Point);
- Approve a specification (i.e. at the CDFU or CAS Decision Points); or
- Deprecate a specification (i.e. at the CD Decision Point).

These outputs reflect varying stages of a specification in the pan-Canadian Standards Decision Making Process. These steps are referred to as Decision Points and are discussed in detail in Section 6.

The Decision Points of the pan-Canadian Standards Decision Making Process and the Maintenance stage of the SPLC intersect when the specification reaches an appropriate level of maturity and when the specification, or parts thereof, is declared no longer viable or useful. Changes that occur to a CAS or CDFU specification that are published as Releases during Maintenance will not re-enter the pan-Canadian Standards Decision Making Process.

Figure 2 depicts the relationship between the SPLC and the maintenance of a specification. The output of the DMP are specifications at various stages (CSS, CDFU, CAS and CD) while the output of Maintenance are new Releases of a specification.

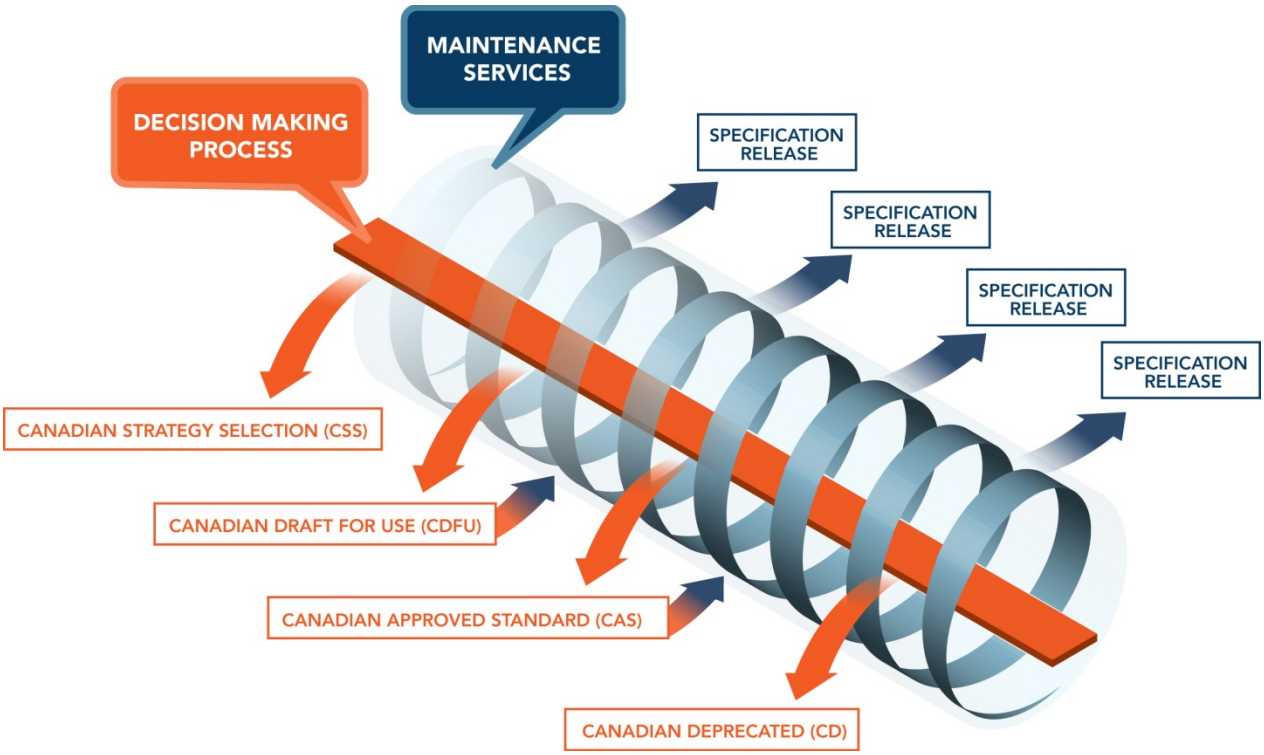


Figure 2 – Relationship between Decision Making Process and Maintenance (Draft)

5 Principles and Criteria for Selection/Approval of pan-Canadian Standards

Principles and Criteria have been developed to guide the selection and/or approval of pan-Canadian Standards as part of the pan-Canadian Standards Decision Making Process.

Some Principles and Criteria may not apply to all specifications nor does a specification have to comply with all Criteria for each Decision Point.

- Principles are overarching considerations that must be considered in order for a specification to be approved at a particular Decision Point.
- Criteria represent specific requirements that should be considered in addressing a Principle.

An assessment of all Principles and Criteria should be addressed at each Decision Point. However, Section 6 outlines specific Principles and Criteria that must be addressed in the Decision Point. Where a Principle and/or specific Criterion does not apply to a specification, or is not relevant to the decision being made, it is sufficient to list that Principle and/or Criterion as not applicable and to describe why it is not applicable.

Analyzing a specification in light of the Principles and related Criteria is an ongoing activity throughout the SPLC, especially during the Decision Points. As the specification progresses through the SPLC, it is expected that more information will become available to assess these Principles and related Criteria.

The Principles are listed below with supporting Criteria for addressing each Principle. Sponsor Representatives, those responsible for preparing the Standards Submission Template and other material for the Approval Package on behalf of the Sponsor, and decision-makers should not feel limited by the Criteria. Instead they are encouraged to consider any aspect of a Principle that will aid in the ability to make an informed decision.

1. pan-Canadian Standards must be clinically relevant.

1.1. *Clinical Appropriateness* – Where relevant, the specification must support clinical practice either directly or indirectly.

1.2. *Multi-disciplinary* – Where relevant, the specification should be provider neutral, e.g. used across disciplines (physicians, nurses, pharmacists, laboratory professionals, allied health professionals etc.)

1.3. *Health Care Delivery Setting* – When the specification is for the purpose of delivering care, it should be health care delivery setting independent, i.e. appropriate for use across health sectors (acute care, community, long-term care, etc.).

1.4. *Clinical Outcomes* – The specification should support patient/client care.

2. pan-Canadian Standards must meet specific pan-Canadian business needs.

2.1. *pan-Canadian Business Need* – The specification should be developed based on a defined pan-Canadian business requirement and should be validated to ensure it meets the business requirements.

2.2. *Maturity/Stability* – The specification must be assessed to determine how widely it has been implemented and tested as well as to determine if it requires further development.

2.3. *Feasibility* – It should be possible to implement the specification within a reasonable time, budget, and resource skill set. Known critical dependencies impacting implementation must be identified (e.g., other components or specifications that are not yet developed)

2.4. *Workflow* – The use of this specification must be assessed in regard to the user's workflow or workload. Impact to workflow must be balanced with improvements to patient care either directly or indirectly.

3. pan-Canadian Standards must be interoperable with the Blueprint.

3.1. *Canadian Alignment* – Where appropriate, the specification must align with current Canadian Approved Standards and the *Infoway* Blueprint.

3.2. *Vendor Neutral* – The specification should be vendor and application independent.

3.3. *Backward Compatibility* – Where appropriate, the specification should be backwards compatible and interoperable with previous data.

3.4. *Bilingual Support* – The specification should support both official languages of Canada.

3.5 The current SC governance structure facilitates interdependencies with a variety of governance processes, including international SDOs, and domestic organizations such as Health Canada, CIHI, etc. The DMP principles and

guidelines allow organizations to demonstrate that their governance or engagement process follows the same principles and guidelines as the SC.

4. pan-Canadian Standards must be financially viable.

4.1. *Affordability* – The specification should have viable licensing and maintenance fees as well as a feasible funding strategy.

4.2. *Implementation Costs* – The implementation of the specification should be financially viable.

5. pan-Canadian Standards must have established governance and processes related to all aspects of the SPLC.

5.1. *Intellectual Property* – Documentation of any intellectual property or licensing issues relating to the specification.

5.2. *Governance Structure* – From a pan-Canadian Standards Decision Making Process perspective, the designation of a Standard as pan-Canadian is governed by the Standards Collaborative governance structure.

5.3. *Canadian Influence* – The specifications should have been developed and maintained through an open and transparent process with opportunity for Canadian stakeholders to be engaged.

5.4. *Other Approval Processes* – Formal approval processes that the specification has undergone or is undergoing (e.g. SDO approval processes, etc.) are documented.

5.5. *Standards Support*[5] - There is an identified organization that will support the pan-Canadian Standard through the SPLC.

5.6. *Sustainability* – Document the established or planned processes and resources to maintain this specification, to enhance the specification when necessary, and monitor conformance to the specification.

6. Relevant pan-Canadian Standards must be technically viable.[6]

---

[5] Non-*Infoway* Sponsors seeking SC support for pan-Canadian Standards must follow the SC Support Request Process.

[6] This principle is only relevant to some types of Specifications under consideration as pan-Canadian Standards. Additional Criteria may need to be developed as other types of Specifications are considered under the pan-Canadian Standards Decision Making Process.

6.1. *Terminology Specific* – The vocabulary specification meets the required technical Criteria for a terminology (see Appendix B.1 Technical Criteria for the Selection of Terminology Standards).

6.2. *Messaging Specific* – The Messaging and Terminology Standard meets the required technical Criteria for this type of specification (see Appendix B.2 Technical Criteria for the Requirements of a Messaging and Terminology Standard) and the SCCC – TSC Technical Ballot Quality Criteria.

6.3 Other - to include specifications, such as integration profiles, and architecture specifications, in which the technical requirements may only be partially applicable, or may have new requirements. Such submissions will be required to provide detailed explanations of technical requirements.

6 pan-Canadian Standards Decision Points

The SPLC provides the overall framework for a specification from the initial expression of requirements through maintenance.

Figure 3 – Standards Product Life Cycle (SPLC)

In the progression of a specification from the initial selection of a strategy to fulfill the business definition to the final Canadian Approved Standard, there are four possible Decision Points. The following four Decision Points are included in the pan-Canadian Standards Decision Making Process:

- Canadian Strategy Selection (CSS);
- Canadian Draft for Use (CDFU);
- Canadian Approved Standard (CAS); and
- Canadian Deprecated (CD).

For each Decision Point, the purpose, key attributes and specific Principles and Criteria that must be considered are defined. As outlined in the previous section, the

Principles and Criteria should be considered at each Decision Point. Specific criteria have been identified for some Decision Points that must be considered.

Figure 4 illustrates the pan-Canadian Standards Decision Points overlaid as part of the SPLC. Specifications may enter the SPLC at different points. If a specification is proposed for a Decision Point, but has not completed the previous Decision Point(s), then the Sponsor must demonstrate due diligence to an equivalent process for the Decision Points not completed. That is, if a specification is proposed as CAS, but has not been designated as CSS or CDFU through the pan-Canadian Standards Decision Making Process, the Sponsor must address all Principles and Criteria, as required, in those Decision Points.

The timelines to progress through the Decision Points will vary depending upon the specification under review.

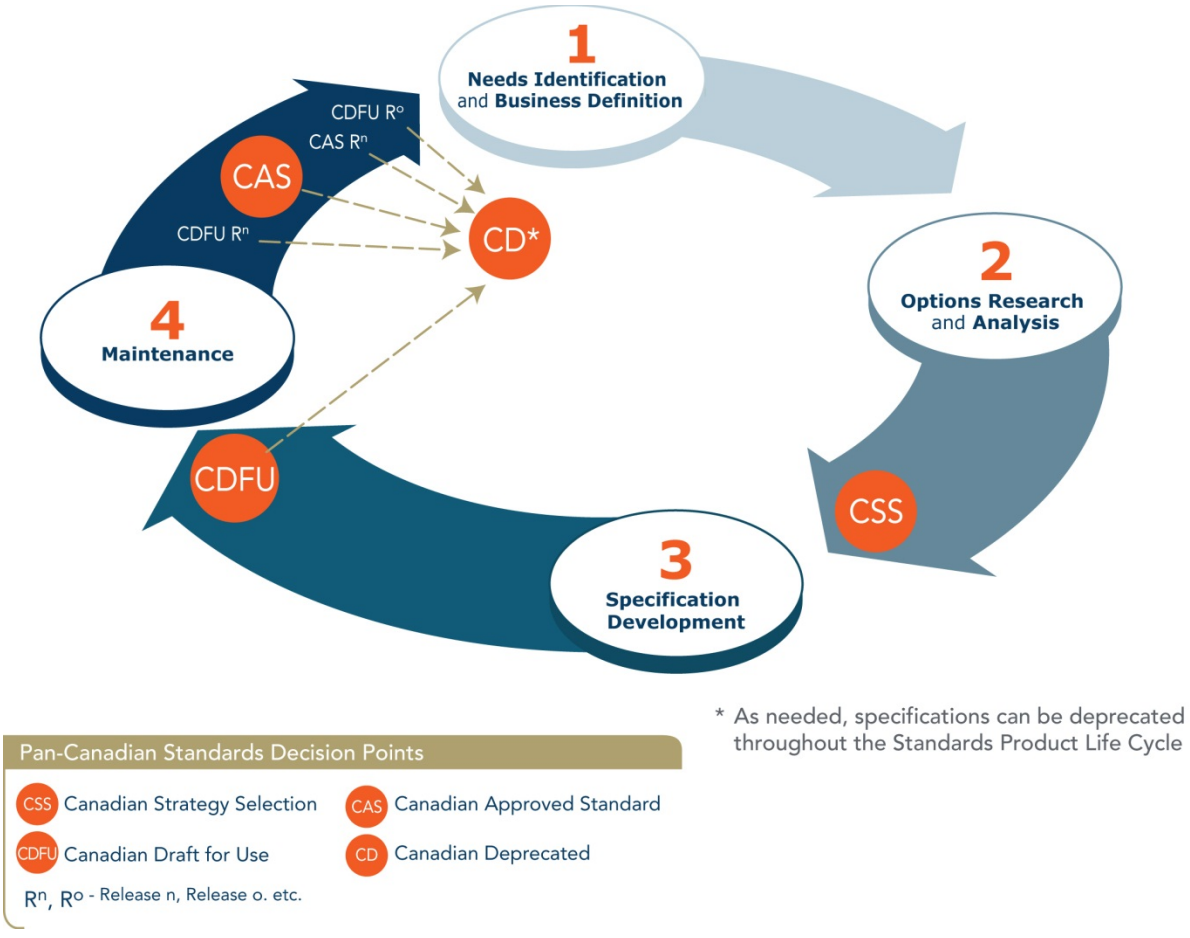


Figure 4 – pan-Canadian Standards Product Life Cycle (SPLC) & Decision Points (Draft)

Once a specification has reached a designation of CDFU, it is included in a Maintenance Process with the expected output to be updated Releases of the specification. Maintenance and the Decision Making Processes used in Maintenance are out of scope for this document.

6.1 CANADIAN STRATEGY SELECTION DECISION POINT

Because of the significant cost and time required to implement a specification, and to ensure that a specification meets specific business, clinical and technical needs, a strategy addressing whether a specification should be adopted, adapted or developed is required before initiating further work on the specification. That strategy is the Canadian Strategy Selection (CSS).

A decision regarding CSS is required following Needs Identification and Business Definition and Options Research and Analysis stages of the SPLC and before the specification Development stage of the SPLC. The work leading up to this Decision Point needs to include an in-depth options analysis and will result in one of the following decisions:

- Adopting an existing specification with no modifications; or
- Adapting an existing specification by completing additional development work; or
- Developing a new specification.

6.1.1 PURPOSE

The purpose of this Decision Point is to ensure that pan-Canadian Standards stakeholders have an opportunity to examine the implications of selecting one pan-Canadian Standard strategy over another.

An approval of this decision is determined by the SCSC and is based on the recommendation for approval by the SCCC which may be supported by review and guidance from the SCWG (if applicable) and TSC and/or CSC (if applicable).

6.1.2 KEY ATTRIBUTES

The key attributes of the Canadian Strategy Selection Decision Point are:

- This Decision Point is typically completed well in advance of reaching the Decision Point for Canadian Approved Standard.
- Where a specification is brought forward by a Sponsor to the pan-Canadian Standards Decision Making Process at a later stage in the SPLC, this Decision Point may be combined with the other Decision Points or it must be demonstrated that it went through an equivalent process.

- The approval of a Canadian Strategy Selection affirms that Steps 1 (Needs Identification and Business Definition) and 2 (Options Research and Analysis) of the SPLC were completed as part of the selection process and that the Decision Making Principles and Criteria have been addressed and that this is the direction that should be taken – supporting the need to move into the Specification development stage where detailed work will be carried-out.
- A request for a Canadian Strategy Selection decision does not constitute eventual approval of the specification as a Canadian Approved Standard.
- Neither a request for a Canadian Strategy Selection decision nor approval of the decision to select a Canadian Strategy Selection will constitute approval of SC support.

6.1.3 SPECIFIC PRINCIPLES AND CRITERIA TO BE REVIEWED

In addition to the overarching Principles and Criteria outlined in Section 5, the following must be considered as part of a CSS Decision Point.

- The specification is in alignment with international standards, where possible. Where the specification is not conformant to the international Standard, the rationale must be provided.
- The specification being selected should be backward compatible with existing specifications, where appropriate.

6.2 CANADIAN DRAFT FOR USE (CDFU) DECISION POINT

The Canadian Draft for Use (CDFU) Decision Point is reached after a specification has completed the development phase of the SPLC. At this point, the specification may have or may not have been implemented in any project or be in use in a jurisdiction or project. The specification is ready to be implemented or used by early adopters. However, change is probable as the stakeholders begin reviews and development. Stakeholders must take this into consideration as they begin their risk assessment. The specification at this stage has been shown to include the requirements[7] defined by stakeholders during development. However, there is a potential for new or changed requirements to be identified through implementation experience and through other development or balloting activities. It is anticipated that implementation projects will identify necessary changes to the CDFU specification. There is no requirement for updates to the CDFU specification to be backward compatible.

[7] There may be circumstances where a project may not be able to include all requirements, for example, due to time and budget. In these cases, this must be described.

The approval of a specification as CDFU means that it meets the business, clinical and technical requirements as identified by stakeholders and that the specification is technically complete.

6.2.1 PURPOSE

The purpose of this decision is to determine whether a specification should be designated as Canadian Draft for Use. The CDFU designation recognizes that pan-Canadian Standards stakeholders agree that the specification has completed the development stage of the SPLC and is ready to be implemented or used by early adopters.

Approval of this decision is required by the SCSC and is based on the recommendation for approval by the SCCC which may be supported by review and guidance from the SCWG (if applicable) and TSC and/or CSC (if applicable).

6.2.2 KEY ATTRIBUTES

The key attributes of the CDFU Decision Point are:

- The specification is required for implementation(s) that cannot wait for the specification to complete the Canadian Approved Standard Decision Point. At least one implementer has committed to using the specification within a project.
- The specification meets intended business, clinical and technical requirements as defined by stakeholders, but may be subject to change based on experience and lessons learned from implementers. The specification is ready to be implemented by early adopters.
- The specification has gone through SPLC stages 1 through 3.
- The Canadian Strategy Selection for this specification has been approved, or there is an equivalent demonstration of due diligence to support the Canadian Strategy Selection Decision Point (that is, the Sponsor can demonstrate that the Principles and Criteria have been addressed as appropriate for this Decision Point).
- The specification will be promoted for use by SC members.
- A responsible SCWG (where appropriate) has approved the content and appropriate documentation related to review of the proposed “Canadian Draft for Use” version and supports the request to seek approval.
- In order to be considered for designation as CDFU, the recommendation must be endorsed by three major stakeholder groups as represented on the SCCC.

- A review of the CDFU designation will be initiated during or upon conclusion of two years if it has not progressed to the pan-Canadian Standard Decision Point with one of the following outcomes:
    - Decision to deprecate portions of or the entire specification; or
    - Decision to extend the CDFU designation; or
    - Decision to recommend progression to CAS designation.
- The approval of the decision for a CDFU does not constitute approval of SC support for the specification.
- Once approved as CDFU, a specification enters the SPLC Maintenance Phase.

6.2.3 SPECIFIC PRINCIPLES AND CRITERIA TO BE REVIEWED

In addition to the overarching Principles and Criteria outlined in Section 5, the following must be considered as part of a CDFU Decision Point:

- The specification artifacts must be complete, based on what is known at the time of development, and published.
- Any potential change influences, where known, are identified and well documented (e.g., change influences from specifications currently under development; SDO approval or balloting; incomplete artifacts such as terminology.)
- At least one implementer in Canada has committed to using the specification.
- There is a commitment from implementer(s) using the specification to share feedback and lessons learned with the SC or Sponsor of the specification from the use and implementation of the specification.
- There is an identified organization, *Infoway* or other, that will support this specification, including the ongoing maintenance of the specification which includes the incorporation of feedback and lessons learned from the use and implementation of the specification into subsequent Releases; continued alignment with pan-Canadian Standards and international standards where appropriate; and support for bug fixes and corrections to the specification.

6.3 CANADIAN APPROVED STANDARD DECISION POINT

The Canadian Approved Standard Decision Point (CAS) is the third Decision Point in the pan-Canadian Standards Decision Making Process.

1. A specification under review at this Decision Point must be in use for the purpose(s) or context(s) for which it was intended. For example, a Messaging and Terminology Specification is in use to manage information and/or exchange

information between business partners. The solution/system which demonstrates implementation or “in use” must be:

a) in Canada;
b) in production or test/pilot; and
c) may have local extensions of the standard but only in a manner consistent with the underlying standard.

Other types of specifications may be published in an RFP by a jurisdiction or be in use as a policy within a jurisdiction or system.

The breadth and depth of the implementation or use must be considered as part of the Criteria. If only part of the specification has been implemented or is in use, only the implemented parts can progress to consideration as CAS. This Decision Point signifies that the Canadian Approved Standard has now reached a level of stability and is comprehensive enough that major changes are not expected. It should be noted that over time, Canadian Approved Standards will be updated to meet evolving business, clinical and technical requirements and that future Releases of the Canadian Approved Standard may be published.

Where possible, the specification should have completed any formally recognized and appropriate Standards Development Organization (SDO) balloting or approval processes. While this is an ultimate goal for all Canadian Approved Standards, it is recognized that this may not be possible for some specifications due to SDO timelines and priorities and available resources to champion this work at the international level. The review at this Decision Point will include the status of the SDO balloting and approval activities as well as any implications for changes to the specification.

The approval of a specification as a Canadian Approved Standard means that consensus has been reached indicating that the specification has met the business, clinical and technical requirements that it was intended to meet. A Canadian Approved Standard ensures backward compatibility[8] with any future Releases of the Canadian Approved Standard.

6.3.1 PURPOSE

The purpose of this decision is to ensure that Canadian Approved Standards stakeholders have an opportunity to examine the implementation of the specification as well as its progress for SDO approval. In addition, the specification must be reviewed to ensure that it meets business, clinical and technical requirements. This is

[8] Except in those situations defined in the *PRM White Paper* as accepted not to be backward compatible. This requirement is in alignment with the Product Release Management Process and will be implemented as approved in that process through Maintenance Services.

a decision that indicates that pan-Canadian stakeholders agree that the specification is ready to be approved as a Canadian Approved Standard and commence widespread implementation.

The objective of designating a standard CAS is to:

a) promote the uptake, use and/or implementation of standards across Canada by giving confidence to our stakeholders that the standard is implementable, for the purpose(s) or context(s) for which it was intended in Canada, as substantiated by the standard having met the CAS criteria;

b) guide implementations and users to the best choice of a standard or set of standards (see definition further in this document) that should be used in Canada for a specific purpose;

c) leverage the CAS designation to promote jurisdiction, vendor and industry adoption;

d) illustrate that there is endorsement of the standard by those parties whose solutions were used to demonstrate implementability or in use;

e) to ensure sustainability;

f) to substantiate the priority of the standard(s) receiving sustainable support and funding;

It is not the objective of designating a standard CAS to:

a) evaluate the content of the standard or to receive requests for changes to the standard;

    i. The purpose of the review process during the CDFU stage is to provide the evaluation of the content of the standard and for the sponsoring organization to make changes if necessary. Once the standard receives CDFU status any new requirements or changes are addressed through the sponsoring organization's usual maintenance process. This is independent from the CAS status and process. For standards sponsored by Infoway the relationship between maintenance and the standards statuses of CDFU and CAS is defined in the DMP (Decision Making Process) and PRM (Product Release Management) papers.

b) measure conformance or certification of an implementation against a standard; or

c) develop and execute an uptake strategy for the standard.

Approval of this decision is required by the SCSC and is based on the recommendation for approval by the SCCC which may be supported by review and guidance from the SCWG (if applicable) and TSC and/or CSC (if applicable).

6.3.2 KEY ATTRIBUTES

The key attributes of the Canadian Approved Standard Decision Point are:

- The specification meets defined business, clinical and technical requirements.
- The specification is in use for the purpose(s) or context(s) for which it was intended.
    - For Messaging and Terminology specifications, the specification has been implemented in limited production rollouts or production rollouts that sufficiently demonstrate that it can be successfully implemented.
        - At a minimum, it is expected that the specification has been implemented in a real-world implementation in order to demonstrate that the specification is both technically viable and meets business and clinical needs. This includes being used to manage information and/or exchange information between business partners.
        - The requirement for real-world implementations is included to mitigate risks that the Specification is not either technically viable or does not meet business and/or clinical needs. The demonstration of how the specification has been implemented is considered critical to the assessment of the stability of the specification.
        - These implementations may be limited production rollouts or full production rollouts.
        - There may be specifications for which a reference implementation can demonstrate technical viability. However, this would need to be considered on an ad hoc basis for a particular specification.
        - Specific criteria of the implementation (e.g., what business functions have been implemented, the types and number of sites and/or users) must be considered for each specification under review for CAS designation.
    - For other types of health informatics standards or specifications, including health system use specifications, the specification must be in use.
        - For example, it may be published as part of an RFP or be in use as a policy within a jurisdiction.

- Only specifications that have been implemented can be considered for approval as a Canadian Approved Standard. If all of the artifacts in the specification Volume have not been implemented, extension of CDFU or CD should to be considered prior to approving a specification as CAS.
- The specification has gone through SPLC stages 1 through 3 or can demonstrate equivalence.
- The Canadian Strategy Selection for this specification has been approved, or there is an equivalent demonstration of due diligence to support the Canadian Draft for Use specification (that is, the Sponsor can demonstrate that the Principles and Criteria have been addressed as appropriate for this Decision Point).
- The specification has been approved as Canadian Draft for Use, or there is an equivalent demonstration of due diligence to support the CDFU designation.
- The specification will be promoted for use by SC members.
- The appropriate SCWG has signed off on content and appropriate documentation related to the review of the proposed specification version and supports the request to seek approval.
- In order to be considered for designation as CAS, the recommendation must be endorsed by three major stakeholder groups as represented on the SCCC.
- The approval of the designation for CAS does not constitute approval of SC support for the specification.
- A review of the CAS designation will be initiated during or upon conclusion of three years to determine if the CAS continues to meet pan-Canadian clinical, business, and technical needs with one of the following outcomes:
    - Decision to reconfirm the specification as a CAS; or
    - Decision to deprecate portions of or the entire specification; or
    - Decision to develop a new specification to meet pan-Canadian needs.

6.3.3 SPECIFIC PRINCIPLES AND CRITERIA TO BE REVIEWED

In addition to the overarching Principles and Criteria outlined in Section 5, the following must be considered as part of a CAS Decision Point:

- The specification must have been successfully implemented in a limited production or production rollout.
    - Details of the scope of implementation must be provided.
    - The parties involved in at least two independent implementations must endorse the specification to go forward as a CAS.

    - Multiple implementations may be required to demonstrate all parts of the specification have been implemented.
- The approach for implementation must be considered to ensure that it adequately demonstrates implementation of the specification.
- Stability Assessment form of the specification must be completed.
    - Details of how the specification has evolved as a result of implementation including experience and lessons learned during its implementation.
- Where possible, related SDO balloting and approvals should be completed and the following information should be made available:
    - Details of SDO balloting and approval activities status;
    - Documentation of conformance to international Standard; and
    - If non-conformant, details of how and rationale as to why the specification is non-conformant.
- There is an identified organization that will provide on-going support and maintenance for this specification.
- Outstanding issues from the CDFU process have been resolved, have an acceptable plan to be resolved or if not resolved reasons why they would not prevent the standard from achieving CAS status.
- Any applicable DMP principles and guidelines that remain outstanding from CDFU need to be identified, including plans for how they will be resolved or why they would not prevent the standard from achieving CAS status.

6.4 CANADIAN DEPRECATION DECISION POINT

The Canadian Deprecation Decision Point is the fourth key Decision Point in the pan-Canadian Standards Decision Making Process and can be considered at any time following the designation of a specification as CDFU or CAS.

Deprecation within the context of the SPLC means that:

- The specification is no longer suitable for new implementations;
- The specification is not in use or in use in any other context within other pan-Canadian specifications; or
- The specification has been replaced by a better method or concept.

A specification will become Canadian Deprecated as approved by the SC Governance structure.

6.4.1 PURPOSE

The purpose of this decision is to ensure that SC Members, through the decision making process for CDFU and CAS, have an opportunity to confirm the need to deprecate a specification.

Approval of this decision is required by the SCSC and is based on the recommendation for approval by the SCCC which may be supported by review and guidance from the SCWG (if applicable) and TSC and/or CSC (if applicable).

6.4.2 KEY ATTRIBUTES

The key attributes of the Canadian Deprecation Decision Point are:

- The specification either no longer meets business, clinical or technical requirements or has been replaced by an updated specification;
- The specification will no longer be promoted for use by SC members;
- A responsible SCWG has approved the content and appropriate documentation related to review of the proposed specification version and supports the request to seek deprecation; and
- A deprecated specification may continue to be supported as per the Support Organization Service Level Agreement for maintenance.

6.4.3 SPECIFIC PRINCIPLES AND CRITERIA TO BE REVIEWED

The overarching Principles and Criteria outlined in Section 5 must be considered as part of the Deprecation Decision Point. There are no additional Principles or Criteria to consider in the Deprecation Decision Point.

7 pan-Canadian Standards Decision Making Process

This section describes the pan-Canadian Standards Decision Making Process.

7.1 GUIDING PRINCIPLES

The following are the guiding Principles for the pan-Canadian Standards Decision Making Process:

Each Decision Point requires a documented process[9] that is:

- Fair;
- Transparent;
- Consensus based;
- Timely; and
- Involves broad pan-Canadian Stakeholder input.

- SC Governance committees strive to ensure that there is not a perceived or actual preponderance of influence of any one stakeholder group, in the review and approval processes.
- The decision-making process needs to provide enough structure and information to support making an informed decision but must also be flexible enough to address the following challenges:
  - An informed decision requires sufficient information about the specification and an indication that due process has been observed;
  - An evaluation system based on formal measurements can be difficult and time consuming;
- Not all specifications will require the same type of evaluation (for example, evaluations may be different for messaging, terminology, data structure, data content, data messaging; information and data management, application integration, network, security, and technology management specifications.); and
  - Not all committees/groups need the same level of details.

[9] These processes are documented in the Terms of References for the SC Governance Committees and Working Groups.

7.2 SPONSORS OF SPECIFICATIONS

A specification proposed to become a Canadian Approved Standard may come into the pan-Canadian Standards Decision Making Process from a number of sources. In some cases, the specification may be proposed by *Infoway*. However, it is possible that jurisdictions or other organizations may bring forward specifications for consideration as a Canadian Approved Standard. Sponsors may have developed the specification to meet a particular localized business need and will continue to support and maintain that specification as long as required to sustain the effective functioning of their health information systems.

In cases where the specification was initially developed by the jurisdiction or other sponsoring organization, there is a potential for escalation to Canadian Approved Standard status. These specifications would be processed through the SCWGs to evaluate pan-Canadian interest and/or business use cases using the SCWG New Work Item Process. The progression toward CAS status may continue to be supported and maintained by the original Sponsor or may be submitted for SC support. Original Sponsors seeking to have the SC assume responsibility for maintaining the specification would engage the SC Request for Support process, potentially concluding with the SC assuming responsibility for all phases of development, maintenance and implementation services.

In all cases, the process to be designated as a Canadian Approved Standard is the same.

7.3 OVERARCHING PROCESS FOR APPROVAL OF PAN-CANADIAN DECISION POINTS

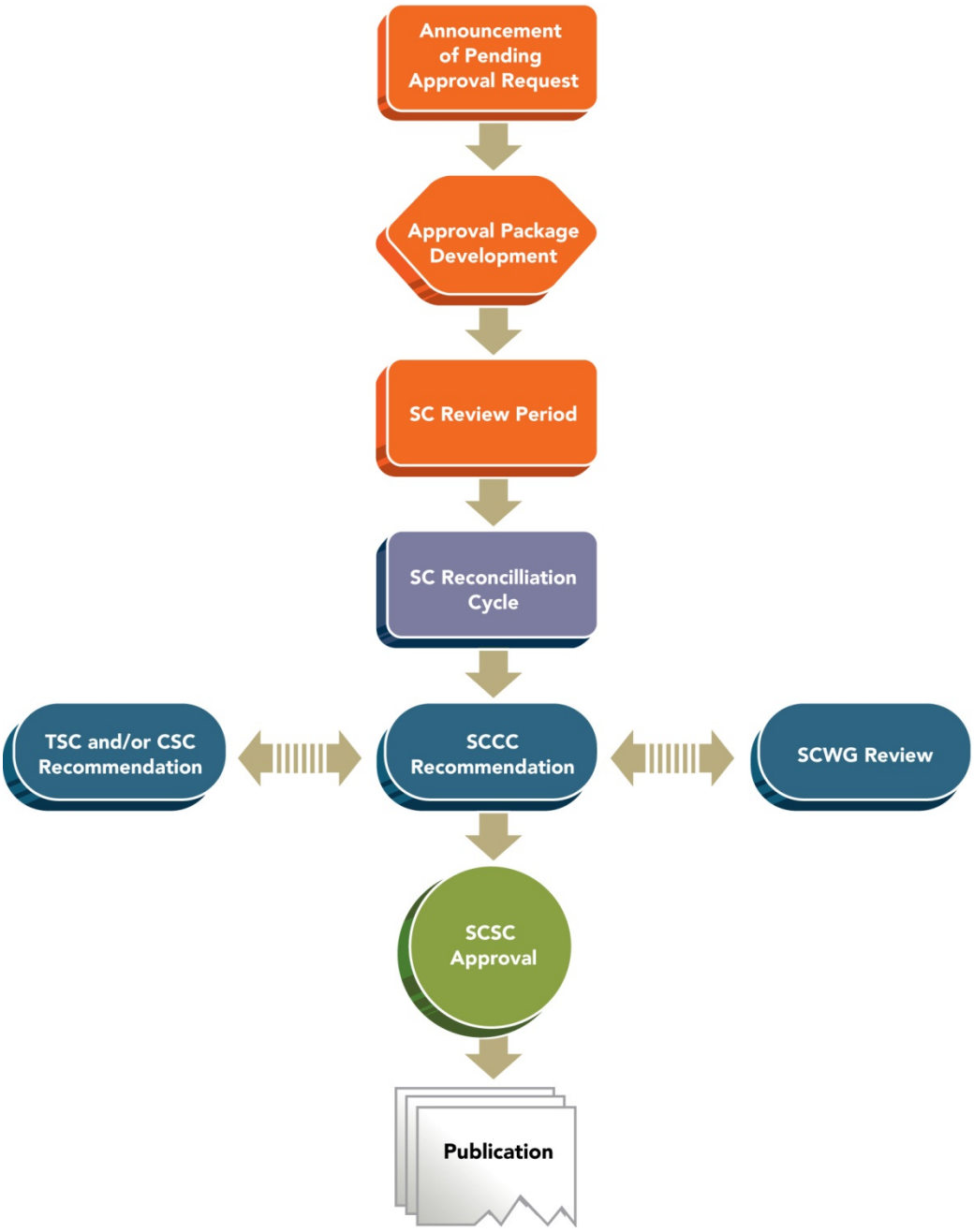
Figure 5 outlines the high-level steps in the pan-Canadian Standards Decision Making Process. The process may vary slightly depending on the requirements of the various Decision Point. While Figure 5 depicts a linear process, the process may in fact be iterative. In cases where an endorsement or approval cannot be made, further information or review may be requested. If the SCSC does not approve the Specification at any Decision Point, it would return to the SCCC for further discussion and action.

1. Announcement of Pending Approval Request
2. Approval Package Development
3. SC review period (public review)
4. SC reconciliation cycle
5. TSC and/or CSC review and SCWG review (as requested by the SCCC)
6. SCCC recommendation
7. SCSC approval

8. Publication

The SC Infodesk is the initial point of contact for Sponsors of Standards (Standards@infoway-inforoute.ca). The SC Infodesk will forward the request to the SC Governance Services. The SC Governance Services is responsible for assigning process support for the Sponsor as the specification progresses through the pan-Canadian Standards Decision Making Process.

Figure 5 – pan-Canadian Standards Decision Making Process Flow



7.3.1 PROCESS DETAILS

1. Announcement of Pending Approval Request

1.1. Purpose: To provide members of the SC and SC Governance Committees with enough time to make arrangements for the review of the proposed specification within their stakeholder group.

1.2. Process:

1.2.1. Prior to the initiation of the Canadian Strategy Selection (CSS) process, approval from the SC Governance Structure is required. This approval will be managed by the SC Secretariat.

1.2.2. The Sponsor Representative, will work with the SC Secretariat to determine the best date to send out an announcement of the Pending Approval Request (via e-mail message), and to determine the best time to start the review period as well as the length of the review period. The Sponsor Representative is responsible for completion of the process.

1.2.3. The Sponsor Representative of the proposed specification will work with the SC Secretariat to create the announcement of the pending approval including development of an e-mail announcement message and message title (in French and in English) for public review of a Pending Approval Request using the template available from the SC Secretariat.

The announcement will state:

- The name of the specification for approval;
- A short summary of the specification proposed for approval;
- The name of the SCWG(s), or other group that performed the evaluation;
- The type of Decision Point (i.e. Canadian Strategy Selection, Canadian Draft for Use, Canadian Approved Standard or Canadian Deprecated); and
- The review period start and end dates.

1.2.4. The announcement of the public review for a Pending Approval Request will be sent to all members of the SC including SC Governance

Committees by the SC Secretariat at least 14 calendar days prior to the start of the public review.

2. Approval Package Development

2.1. Purpose: To compile information required for public review of a Pending Approval Request for a proposed specification.

2.2. Process:

2.2.1. The Sponsor Representative is responsible for compiling the Approval Package using the template available from the SC Secretariat. The Package will contain the following:

- Announcement of public review commencement (one in French and one in English) – a template is available from the SC Secretariat. The announcement will state:
  - The name of the specification for approval;
  - The name of the SCWG(s), or other group that performed the evaluation;
  - The type of Decision Point (i.e. Canadian Strategy Selection, Canadian Draft for Use, Canadian Approved Standard or Canadian Deprecated);
  - The specific dates for the review period;
  - Relevant dates for information and reconciliation meetings; and
  - The Approval Package may be attached or provided as a link to an SC Forum.
- Standard Submission Template[10] - the template will include:
- Cover page (executive summary):
  - Sponsor information – Name, title, contact information, organization;

[10] The Sponsor Representative is responsible for ensuring that the Approval Package does not contain any intellectual property that would prevent it from being freely shared amongst SC members.

- Name of specification;
- Brief description of specification;
- Type of specification;
- Business domain (if appropriate);
- Type of decision;
- Statement regarding how it aligns with and benefits the pan-Canadian EHR solution;
- Relationship to International or other pan-Canadian Standards – including status of related balloting and/or harmonization activities; and
- Summary of any outstanding issues.

- Section 1 – Background and Overview:
  - Key functional areas included in specification;
  - Development activities undertaken; and
  - Review or evaluation activities undertaken.
- Section 2 – Due Process Information:
  - pan-Canadian stakeholder consultation (e.g. SCWG or other group involved in consultation).
- Section 3 – Principles and Criteria Assessment
- Section 4 – Links to detailed specification material
- Additional reference material at the discretion of the Sponsor Representative.
- Feedback/Comments Form –

  This template will be provided by the SC Secretariat. For each comment, the following will be captured:

  - Comment ID;

- Comment Sponsor Representative (Contact Name) – who raised the comment and can be contacted for more details;
- Comment status;
- Impact – this is the impact to the person raising the comment;
- Urgency – this is an indication of how urgent it is to the person raising the issue; and
- Affected artifacts – if known.

2.2.2. The Sponsor Representative is responsible for sending the Approval Package to the SC Secretariat for distribution.

3. SC Review Period

3.1. Purpose: To give the SC membership an opportunity to review the proposed specification.

3.2. Process:

3.2.1. The SC Secretariat will ensure that the Announcement of the opening of the review period is published and the Approval Package is available to the SC membership and SC Governance Committees by 12:00 PM Eastern on the first day of the review period.

3.2.2. The SC Secretariat is responsible for posting the information in an appropriate forum if one is available. The announcement of the review period will also be posted to all SCWG Forums to ensure that SCWG members have the opportunity to participate in the review cycle.

3.2.3. After the package has been published[11], the Sponsor Representative may elect to forward the package to other stakeholder groups.

3.2.4. The review period will start as soon as the Approval Package has been made available to the SC membership.

3.2.5. The review period will last no less than 30 calendar days and no more than 90 calendar days and will be defined in the announcement and

[11] Package will be published and distributed in accordance with SDO Intellectual Property policies and requirements.

Approval Package. It is anticipated that most reviews will be 30 calendar days in length.

3.2.6. The Approval Package contains a feedback form for the stakeholders to capture their questions and comments.

3.2.7. Stakeholders can submit feedback forms to the SC Secretariat at Standards@infoway-inforoute.ca any time before the close of the SC review period.

3.2.8. The SC Secretariat will forward the feedback forms to the Sponsor Representative of the specification as they are received.

3.2.9. In addition, the SC Secretariat will collate all of the spreadsheets submitted during the review period and will send them to the Sponsor Representative once the review period has closed.

4. SC Reconciliation

4.1. Purpose: To resolve any questions, concerns or outstanding issues raised during the review period. The reconciliation process may involve consultation with the commenter, TSC, CSC and/or SCWG as appropriate.

4.2. Process:

4.2.1. The SC Secretariat will collate all of the spreadsheets submitted during the review period and will send them to the Sponsor Representative once the review period has closed. The SC Secretariat may consult with the commenter, SCWGs or TSC/CSC to clarify comments received.

4.2.2. The Sponsor Representative will categorize the comments by category/type – for example, Missing information; Error in information; Typos/spelling mistakes; Questions; Suggestions with recommendations on how to meet the reviewer's needs; Suggestions without recommendations on how to meet the reviewer's needs; and Out of scope.

4.2.3. With the comments grouped, the Sponsor Representative will work with the SC Secretariat to inform the SCCC Co-Chairs of the depth and breadth of the comments received.

4.2.4. The SC Secretariat will distribute the reconciliation plan to the SC membership including the people who submitted the comments.

4.2.5. All comments received must be considered. For each comment a description of the comment and its resolution will be documented.

- Suggestions for reconciling comments:
  - If a person submitted a suggestion for a change without proposing a solution, request that he/she propose one;
  - Try to understand urgency of need. If there is a pressing need then the need should be closely examined. If it is not something anyone plans on implementing for the next 5 years, it may be a good candidate as an update on a future version;
  - Is the need local, (e.g. only one jurisdiction needs it). If so it may not be a good fit for a pan-Canadian Standard and may be something that needs to be documented in the local jurisdiction's implementation;
  - A perfect resolution cannot always be achieved., At a minimum, the resolution should be something that majority find acceptable and the minority can live with;
  - Is the need appropriate for this specification and its goals/scope; and
  - If the need has been discussed before and resolved, but the person is raising it again just to have it 'officially logged', allow the comment to stand and ask the person if they would accept the previously discussed resolution.

4.2.6. Once the responses/resolutions to the comments have been proposed to the people who submitted the comments, one of two things should happen:

- If the person who submitted the comments agrees with the proposed responses/resolutions, that person should send an e-mail message to the Sponsor Representative with the SC Secretariat copied stating that he/she is happy with the proposed resolutions;
- If the person who submitted the comments does not agree with the proposed responses/resolutions, the SC issue management process should be initiated.

- If an issue management process is required to resolve a comment resolution dispute, the onus should be put on the comment Sponsor Representative to fill out the necessary templates explaining why the proposed resolution does not meet his/her needs. If an issue was raised to either the SCCC or the SCSC, it would be helpful for them to know the following information in addition to the usual issue management information required:

    - Perceptions of the SCWG regarding the issue, (e.g. a vote taken that showed a majority view in one direction);

    - Opinions of the SDO and/or Canadian Affiliate of the SDO on the matter at hand;

    - History of the need (e.g. meetings at which it was discussed, previous resolution attempts): and

    - In a worst-case scenario, if the Sponsor Representative of the comment cannot be accommodated, the SCCC would likely be the party responsible for hearing the issue out, and taking a vote on it. Situations may arise where all parties agree on a resolution, but acting on that resolution would have a great impact on the materials previously reviewed, sometimes referred to as a substantive change.

4.2.7. The Sponsor Representative must work with the members of the SCWG to review the disposition of comments, allowing participation from people who submitted comments.

4.2.8. Once all the comments have been responded to and resolved, the feedback and comment spreadsheet will be updated along with the other material in the Approval Package.

5. TSC, and/or CSC Review and SCWG Review (as requested by the SCCC)

5.1. Purpose: To review and provide guidance to the SCCC on any technical or clinical issues related to a pan-Canadian Standards Decision Point as needed. These reviews are considered optional and may be requested at the discretion of the SCCC. Guidelines to assist in making the decision to request reviews will be developed.

5.2. Process:

5.2.1. If requested by the SCCC, the SC Secretariat will work with the TSC, CSC and/or SCWG Co-Chairs to arrange a meeting to review the Approval Package. The updated material will be made available to the SCCC 10 business days in advance of their meeting. The Committees will only review specific sections of the Approval Package as determined by their mandate.

5.2.2. The TSC, CSC and/or SCWG will be responsible for reviewing technical and clinical aspects, respectively, of the Approval Package in order to develop recommendations for the SCCC.

5.2.3. The TSC, CSC and/or SCWG may ask for clarification on specific parts of the specification under review prior to making a decision. In this case, the review will be tabled until further information is received.

5.2.4. After any clarifications requested have been made, if required, the TSC, CSC and/or SCWG Co-Chairs may call for a formal motion to vote to recommend the specification to the SCCC.

5.2.5. The TSC, CSC and/or SCWG policies regarding quorum and decision-making as described in their Terms of Reference and other related policies, including policies for record keeping, can be found in the *SC Governance Committee Manual*.

5.2.6. The recommendations of the TSC and/or CSC and the results of the SCWG Review will be made available to the SCCC to support their decision making.

6. SCCC Recommendation

6.1. Purpose: To recommend the review and endorsement of the specification to the SCSC for their review and approval.

6.2. Process:

6.2.1. The SC Secretariat will work with the SCCC Co-Chairs to arrange a meeting to review the Approval Package with the SCCC members. The updated material will be made available to the SCCC 10 business days in advance of their meeting.

6.2.2. The SCCC Recommendation step can be an iterative process.

- The SCCC may ask for clarification on specific parts of the specification under review prior to making a decision. In this case, the review will be tabled until further information is received.

- The SCCC may ask that the TSC, CSC and/or SCWG review specific parts of the specification under review prior to making a recommendation. In this case, the review will be tabled until the TSC, CSC and/or SCWG have made their recommendations.

- After any clarifications requested have been made, if required, the SCCC Co-Chairs may call for a formal motion to vote to recommend the specification to the SCSC.

6.2.3. The SCCC policies regarding quorum and decision-making as described in the Terms of Reference and other related policies, including policies for record keeping, can be found in the *SC Governance Committee Manual*.

6.2.4. If the SCCC does not endorse the decision request, the rationale will be logged and the request to seek endorsement will be declined. If the SCCC endorses the decision request, the SCSC will be engaged for approval.

7. SCSC Approval

7.1. Purpose: To approve Decision Points in the pan-Canadian Standards Decision Making Process.

7.2. Process:

7.2.1. After the SCCC has reviewed and recommended endorsement of the approval of a specification, the SC Secretariat will work with the SCSC Co-Chairs to arrange a meeting to review the Approval Package. The updated material will be made available to the SCSC 15 business days in advance of their meeting.

7.2.2. The SCSC may ask for clarification on specific parts of the specification under review prior to making a decision. In this case, the review will be tabled until further information is received.

7.2.3. After any clarifications requested have been made, if required, the SCSC Co-Chairs may call for a formal motion to vote to approve the specification.

7.2.4. The SCSC policies regarding quorum and decision-making as described in the Terms of Reference and other related policies, including policies for record keeping, can be found in the *SC Governance Committee Manual.*

8. Publication

8.1. Purpose: To ensure the final version of specification or the decision is identified and made publicly available.

8.2. Process:

8.2.1. After the SCSC or SCCC has reached a decision on a specification, a public announcement will be made regarding the decision as well as the information about the availability of an approved pan-Canadian Standard.

8.2.2. Information regarding the decision will be published in a centralized place for all SC members to access.

7.4 PROCESS FOR EXTENSION OF CANADIAN DRAFT FOR USE DESIGNATION

As noted in section 6.2.2 of this document, a key attribute of the designation Canadian Draft for Use is that a review will be initiated during or upon conclusion of two years if the Standard has not met the criteria for progression to CAS with one of the following outcomes:

- Decision to deprecate the specification; or
- Decision to extend the CDFU designation to allow for additional time to progress toward CAS designation.

7.4.1 PROCESS DETAILS

1. Review Package Development

1.1. Purpose: To compile information required for SCCC and SCSC review of a request to extend the CDFU designation of a Canadian Approved Standard after two years since last approved as CDFU.

1.2. Process:

1.2.1. The Sponsor Representative is responsible for compiling the CDFU Review Package using the template available from the SC Secretariat. The package will contain the following:

- Updated Standards Submission Template; and
- Recommendations from Sponsor Representative on whether the specification should be:
- Extended with the designation of CDFU for another 2 years[12]; or
- Canadian Deprecated

2. SCCC Recommendation

2.1. Purpose: To review the CDFU designation of a pan-Canadian Standard and determine whether the designation of CDFU should be extended for another two years.

2.2. Process:

2.2.1. The SC Secretariat will work with the SCCC Co-Chairs to arrange a meeting to review the CDFU Review Package. The updated material will be made available to the SCCC 10 business days in advance of their meeting.

2.2.2. The SCCC may ask for clarification on specific parts of the pan-Canadian Standard under review prior to making a recommendation. In this case, the review will be tabled until further information is received.

2.2.3. The SCCC may ask that the TSC, CSC and/or SCWG review specific parts of the pan-Canadian Standard under review prior to making a recommendation. In this case, the review will be tabled until the TSC, CSC and/or SCWG have made their recommendations.

2.2.4. After any reviews and/or clarifications requested have been made, the SCCC Co-Chairs may call for a formal motion to vote to recommend the extension of a CDFU designation of a pan-Canadian Standard for another two years.

3. SCSC Approval

3.1. Purpose: To approve the recommendations to extend the CDFU designation of a specification for another two years.

3.2. Process:

[12] The specification may be reviewed before two years, as appropriate.

3.2.1. The SC Secretariat will work with the SCSC Co-Chairs to arrange a meeting/teleconference/web cast to review the CDFU Review Package. The updated material will be made available to the SCSC 15 business days in advance of their meeting.

3.2.2. The SCSC may ask for clarification on specific parts of the pan-Canadian Standard under review prior to making a decision. In this case, the review will be tabled until further information is received.

3.2.3. After any clarifications requested have been made, if required, the SCSC Co-Chairs may call for a formal motion to vote to approve the extension of a CDFU designation for a specification for another 2 years.

3.2.4. The SCSC policies regarding quorum and decision-making as described in the Terms of Reference and other related policies, including policies for record keeping, can be found in the SC Governance Committee Manual.

4. Publication

4.1. Purpose: To ensure the extension of CDFU designation decision is made publicly available.

4.2. Process:

4.2.1. After the SCSC has reached a decision on the recommendations of the CDFU review, a public announcement will be made regarding the decision as well as the information about the availability of the specification.

4.2.2. Information regarding the decision will be published in a centralized place for all SC members to access.

Appendix A. GLOSSARY

The following list of definitions and acronyms describe terms used in this document.

Please note that this list of definitions will be removed from this document in 2009. The definitions will be consolidated with all other Standards Collaborative related definitions and presented in a separate document available in both English and French.

Term	Definition
Artifact	Any output resulting from the discovery, analysis and design activities leading to the creation of specifications. Artifacts may be business or technical in nature. Examples include: Visio model, Implementation Guide, Scope and Tracking Framework and Controlled Terminology Worksheet.
Backwards Compatible	The ability for a new artifact to interoperate with an older version of the same artifact. A backwards compatible change made to an artifact does not override a previous version of the same artifact. For example, if you add an optional attribute to an HL7 interaction, it is backwards-compatible.
Canadian Approved Standard (CAS)	The status of specification denoting formal approval, assuming approval Principles and Criteria have been met. Designation as a Canadian Approved Standard suggests more formal rules on maintaining backwards compatibility and / or stricter change approval processes. Note: this concept is currently known as pan-Canadian Standard – Formally Approved.
Canadian Deprecated	Specification that should be avoided as it no longer has a meaningful purpose or has been replaced by a better method or concept.
Canadian Draft for Use (CDFU)	The status of a specification denoting that it has completed the specification development stage of the SPLC and is ready for use by early adopter implementation projects at moderate risk. Note: this concept is currently known as Stable for Use.
Canadian Strategy Selection Process (CSS)	The purpose of this Decision Point is to ensure that pan-Canadian Standards stakeholders have an opportunity to examine the implications of selecting one pan-Canadian Standard strategy over another.

Term	Definition
Classification	A classification groups like information into a limited number of mutually exclusive statistical categories (and sub-categories) to organize it for easy retrieval and reference.
Clinical Sub-Committee (CSC)	An SC Governance Committee which supports and facilitates harmonization of health information Standards from a clinical perspective in Canada within the mandate of the Standards Collaborative and in alignment with policies of the Custodian and Standards organizations as appropriate.
Coding	the process of assigning data to categories for analysis[13]
Concept Domain	The set of all concepts that can be taken as valid codes in an instance of a coded attribute or field; a constraint applicable to code codes. Formerly known as vocabulary domain.
Conformance Profile	Conformance profiles were defined to demonstrate testable packages for a computer application from the perspective of integration of the pan-Canadian Messaging and Terminology Specifications. The conformance profiles provide the foundation for the functionality that is included in jurisdictional electronic health record systems (for example, a Laboratory Information System (LIS) or a Drug Information System (DIS)) as well as the functionality that must be included in any Point of Service (PoS) systems that connect to the EHR system (for example, an Electronic Medical Record (EMR) or a Pharmacy Management System (PMS)).
Controlled Health Terminology	ISO/TS 17117:2002 defines a controlled health terminology as a set of terms intended for clinical use. NOTE: This implies enough content and structure to provide a representation capable of encoding comparable data, at a granularity consistent with that generated by the practice within the domain being represented, within the purpose and scope of the terminology.
Criterion	In the context of the Standards Collaborative pan-Canadian Standards Decision Making Process, a specific requirement that should be considered in addressing a Principle.

[13] Available from: www.skmtglossary.org

Term	Definition
Decision Point	The step(s) in the progression of a Standard through the pan-Canadian Standards Product Life Cycle (SPLC) where a specification is considered for designation as a Canadian Approved Standard. The following four Decision Points are included in the pan-Canadian Standards Decision Making Process: Canadian Strategy Selection (CSS); Canadian Draft for Use (CDFU); Canadian Approved Standard (CAS); and Canadian Deprecated (CD)
Electronic Health Record (EHR) System	'Back-end' systems or repositories that capture information, for example a Drug Information System or a Lab Information System
Electronic Medical Record	An electronic medical record (EMR) is a computer-based medical record specific to one clinician's (e.g. physician) practice or organization. It is the record clinicians maintain on their own patients, and which detail demographics, medical and drug history, and diagnostic information such as laboratory results and findings from diagnostic imaging. It is often integrated with other software that manages activities such as billing and scheduling.[14]
Health Informatics (Specification)	The specifications required to support health informatics, which is the intersection of clinical, IM/IT and management practices to achieve better health (includes content standards, data element lists/minimum datasets, data extract specification, data models, etc.).[15]
Health System Use	Health system use of information (or HSU) refers to the use of health information to improve the health of Canadians through a better health system, and includes: • Clinical Program Management - Use of data to improve front-line health care programs and services • Health System Management – Use of data to improve the effectiveness and efficiency of the health care system • Public Health – Use of data to understand the health of the public and for public health activities • Research - Use of data for health research

[14] Available from *Canada Health Infoway* website: https://www.infoway-inforoute.ca/lang-en/working-with-ehr/solution-providers/certification/what-infoway-certifies/electronic-medical-record-certification

[15] Available from COACH website: http://www.coachorg.com/health_informatics

Term	Definition
Implemented	Used to indicate that at least one product exists that expresses they are conformant to indicated artifact or business function.
Integration Profiles	Artifacts that describe additional constraints on an existing specification (known by IHE as a technical framework)
Interaction	A unique association between a specific message type, a particular trigger event (that initiates the transfer) and the application roles that send and receive the message type. It is a unique, one-way transfer of information.
Message and Terminology Specification	Artifacts that define Messages and Dependent Terminologies to support a message interchange environment.
pan-Canadian Conformance Profile (pCCP)	pCCPs define testable packages based on pan-Canadian specifications. The pCCPs are defined at the level of "building blocks" – logical groupings of message transactions that should be implemented within an application to provide all of the functionality related to a particular business workflow (for example, dispense a prescription or order a lab test).
pan-Canadian Standard Decision Making Process	The Standards Collaborative process of review and approval of a specification through the Standards Product Life Cycle from the initial selection of a strategy to fulfill the business needs to the final Standard. Four decision points are included in the process: Selection Strategy (CSS), Canadian Draft for Use (CDFU), Canadian Approved Standard (CAS), and Canadian Deprecated (CD).
pan-Canadian Standards Group (pCSG)	This is now a generic term used by a variety of organizations. *Infoway* no longer formally uses this term as this function is now performed by SCWGs and *Infoway* Project Teams.
Partnership	The Partnership Conference is a semi-annual meeting where members and other stakeholders collaborate on pan-Canadian and international Standards and architecture, share progress and lessons learned and stay informed on what's new in Canada's health information Standards community. The Partnership Conference is also the principal venue for the face-to-face meetings of the Standards Collaborative Working Groups and Standards Development Organization constituency meetings. The Partnership Conference is the principal event for the domestic health information Standards and architecture community, and is open to all interested attendees.

Term	Definition
Point of Service (POS) System	A system that is used by end-users at the point of care or service. For example, an Electronic Medical Record (EMR), a Pharmacy Management System (PMS), a Hospital Information System (HIS).
Principle	In the context of the Standards Collaborative pan-Canadian Standards Decision Making Process, an overarching consideration that must be considered in order for a specification to be approved at a particular Decision Point.
Product Release Management (PRM)	Union of policy, process, methods, tools and procedures for: Configuration Management; Problem Management; Change Management; and Release Management.
Reconciliation Spreadsheet	Document of technical errors, suggestions for change, and questions submitted by a reviewer of a Release, submitted for reconciliation and possible correction of artifacts.
Reference Implementation	A software example of a specification. They are intended to help others implement their own version of the specification or find problems during the creation of a specification
Request for Change (RFC)	Formal request for a change to an artifact published in a pan-Canadian Specification.
Review Period	A public review period of 30 – 90 calendar days where stakeholders can provide feedback.
SC Member	A member in good standing with current paid membership to the *Infoway* Standards Collaborative.
SC Secretariat	Resources assigned by the SC Governance Management Team to support the pan-Canadian Standards Decision Making Process.
Specification	A complete set of interdependent artifacts such that developers can build interfaces, applications, or solutions conformant to those artifacts. These artifacts are typically constrained from International versions of similar artifacts for use in pan-Canadian Specifications. A specification may have the following designations: Canadian Strategy Selection, Canadian Draft for Use, Canadian Approved Standard, and Canadian Deprecated. Example types of specifications include Message and Terminology Specifications, Controlled Terminology Specifications, Health Informatics Specifications (HSU), and Profile Specifications (e.g. IHE Profile Specification).

Term	Definition
Sponsor	In the context of the pan-Canadian Standards Decision Making Process, a Sponsor is an entity that proposes a specification or Standard for pan-Canadian Designation and who will be responsible for on-going support and maintenance of the Standard (unless a different Sponsor has been confirmed to provide on-going support and maintenance). A Sponsor may be an individual or group entity such as jurisdiction, Ministry of Health or other organization, including *Infoway*.
Sponsor Representative	The individual(s) who is responsible for preparing the Standards Submission Template and other material for the Approval Package on behalf of the Sponsor. The Sponsor Representative will work with the SC Secretariat during the Review Process. The Sponsor Representative considered the first point of contact between the Sponsor and the SC.
Stable for Use (SFU)	Deprecated term. Please refer to Canadian Draft for Use for further information.
Standard	A health informatics specification
Standards Collaborative (SC)	The pan-Canadian organization responsible for the coordination of health information Standards. The *Infoway* Standards Collaborative provides: a single point of contact for coordination of pan-Canadian Standards throughout the Standards life cycle: development, implementation support, education, maintenance and conformance; a streamlined governance, processes and operations; efficiencies gained by combining administrative services such as communications, website management, event planning/management, education and administrative support; and coordination of development, maintenance and balloting processes, such that they are harmonized in a way that each adds value without duplication.

Term	Definition
Standards Collaborative Coordinating Committee (SCCC)	The Standards Collaborative Coordinating Committee is responsible for coordinating health information standards activities in Canada within the mandate of the Standards Collaborative and in alignment with policies of the Custodian and standards organizations as appropriate. Its purpose is to: • Make decisions and/or recommendations on pan-Canadian health information standards activities throughout the Standards Lifecycle (SLC); • Coordinate and guide its sub-committees; • Coordinate and guide activities across the business domains; and • Provide guidance on the processes and services provided by the Standards Collaborative (e.g. education & training, communications, etc.)
Standards Collaborative Strategic Committee (SCSC)	The Standards Collaborative Strategic Committee is responsible for strategic level decisions on policies, priorities, strategies, operations and finance aligned with the Custodian and Standards Development Organization policies. Its purpose is to: Provide strategic direction to the development, maintenance, conformance and support of pan-Canadian Standards; Make decisions regarding recommendations on key items in the standards life cycle for pan-Canadian Standards; To recommend National Standards of Canada to Standards Council of Canada; Provide strategic leadership to the Standards Collaborative; and Provide strategic guidance on the long-term structure and sustainability of the Standards Collaborative and the sustainability of the collaborative approach.
Standards Collaborative Working Group (SCWG)	The Standards Collaborative Working Groups are accountable to the SCCC. The role of the SCWG is to provide recommendations on the adoption and use of Standards; and to review and vote on the content of health information Standards, particularly those in maintenance.

Term	Definition
Standards Development Organization (SDO)	Organization responsible to develop, support and maintain Standards (sometimes called specifications, Products or protocols) for a particular domain such as messaging (e.g. HL7 or Health Level 7), terminology (e.g. International Health Terminology Standards Development Organization for SNOMED CT©) or technology (e.g. XML).
Standards Life Cycle	The process or methodology used in the development and maintenance of a Standard.
Standards Product Life Cycle (SPLC)	The process or methodology used in the development and evolution of a pan-Canadian Standard. The SPLC includes the following four stages: • Needs Identification & Business Definition; • Options Analysis; • Specification Development; and • Maintenance.
Substantive Change	A change to an Artifact that breaks Backwards Compatibility and / or significantly changes the interpretation of the Artifact.
Support Services	The types of services that are required to support a Standard through the Standards Product Life Cycle (SPLC). In the Standards Collaborative, these include: • Development Support Services; • Education and Training Services; • Implementation Support Services; • Maintenance Services; • Client Services and Standards Development Organization Relations; and • SC Engagement and Process Services.
Technical Sub-Committee (TSC)	An SC Governance Committee that coordinates and facilitates harmonization of health information Standards from a technical perspective in Canada within the mandate of the Standards Collaborative and in alignment with policies of the Custodian and Standards organizations as appropriate.

Term	Definition
Terminology	A set of concepts, designations and relationships for a specialized subject area. The terms that are characterized by special reference within a discipline are called the terms of the discipline and collectively form the “Terminology”. Terms that function in general reference over a variety of languages are simply words, their totality is a “Vocabulary”.

Appendix B. TECHNICAL CRITERIA[16]

B.1 SELECTION OF TERMINOLOGY STANDARDS

These technical Criteria for the selection of Controlled Terminology Standards are an excerpt of the United States National Committee on Health and Vital Statistics (US NCHVS) Desired Technical Criteria for the Core Terminologies.

Certain recognized "desiderata" of controlled medical terminologies should be applied to the selection of terminologies[17] [18]. These technical Criteria express properties that enable or enhance accurate analysis of data encoded using the terminology. In applying these Criteria, it is important to distinguish essential properties (without which the core terminology group will fail to meet its goals and requirements) from desired but not essential features (which may simply facilitate maintenance, promote uptake, etc.). In other words, it's important to distinguish the "must haves" from the "nice to haves".

B.1.1 ESSENTIAL FEATURES

Concept orientation - Elements of the terminology are coded concepts, with possibly multiple synonymous text representations, and hierarchical or definitional relationships to other coded concepts.

Concept permanence - The meaning of each coded concept in a terminology remains forever unchanged. If the meaning of a concept needs to be changed or refined, a new coded concept is introduced. No retired codes are deleted or re-used.

Non-ambiguity - Each coded concept in the terminology has a unique meaning.

Explicit version identifiers - Each version of the terminology is designated with a unique identifier, such that parties exchanging data can readily determine if they are using the same set of terms.

---

[16] Additional Technical Criteria may need to be added for other types of Specifications considered under the pan-Canadian Standards Decision Making Process.

[17] NCVHS Patient Medical Record Information Terminology Analysis Reports (December 23, 2002) – Version 3 (NCVHS Patient Medical Record Information Term) Analysis031105rpt1.pdf), page 11

[18] Cimino JJ,"Desiderata for controlled medical vocabularies in the twenty-first century," Methods Inf Med, 37, Nov 1998, 394-403.

B.1.2 DESIRABLE FEATURES

Comprehensive Domain Coverage - The terminology includes most of the concepts and terms needed for primary clinical documentation in the defined domain area.

Meaningless identifiers - The unique codes used to identify concepts in the terminology are unrelated to the meaning of the concepts or to their locations in the concept hierarchy.

Multi-hierarchies - A coded concept may be the child of more than one other coded concept in the terminology's hierarchy.

Non-redundancy - Each unique meaning is represented by just one coded concept in the terminology. Each concept may have multiple synonymous terms, but the relationship of the terms to the concept must be explicitly represented.

Formal concept definitions - The terminology includes logical definitions of coded concepts, allowing redundancy to be automatically detected and appropriate hierarchical relationships to be automatically inferred.

Infrastructure/tools for collaborative terminology development - The terminology is maintained using tools that (1) allow many people to work on a terminology at the same time and (2) support the assignment, scheduling, collection, and integration of their work.

Change sets - Each new version of the terminology includes a complete accounting of the added, retired, and modified concepts and terms (i.e. a “delta” file).

Mappings to other terminologies - The content of the terminology includes mappings to other relevant terminologies, and these mappings have been validated.

Support for local customization - Tools and processes exist that allow users of the terminology to make local additions and customizations.

In addition to these technical Criteria, a model for mapping and/or integrating the core terminologies to create the envisioned cohesive and mutually consistent whole should also be considered. This model may have implications for the required technical features of the constituent terminologies.

B.2 REQUIREMENTS OF A MESSAGING AND TERMINOLOGY STANDARD

HL7 V3, like V2.x, is a Standard for exchanging messages among information systems that implement healthcare applications. However, V3 strives to improve the V2 process and its outcomes. The original process for defining HL7 messages was established in 1987. It has served well since. However, as HL7 membership grew and

its Standards became more widely used, HL7 has become aware of opportunities to revolutionize healthcare interface computing. HL7 interfaces substantially reduce costs and implementation times when compared to the industry's experience with proprietary interfaces. However, these costs and times vary considerably by vendor, and the industry sees a need for improvement. Substantial optionality in HL7 V2 makes it difficult to specify precise contract terms for HL7 interfaces. This can lead to unrealistic expectations that hurt vendors and buyers equally. The development principles behind HL7 V3 lead to a more robust fully specified Standard. Infoway has proclaimed that all new messaging investments will be made in HL7 v3.

The strength of Version 3 messaging is precisely enabling the exchange of fine-grained data without the original research and bilateral negotiations that leading-edge organizations have attempted.

In reading the messaging artifacts, you will see that the four conceptual models that form the basis of Version 3 messages:

- The Reference Information Model (RIM), which is now an ANSI Standard has evolved into a simple abstract framework which addresses the heterogeneous and interlinked nature of clinical data with only six important classes.
- The Domain Information Model (D-MIM) demonstrates how the abstract RIM is made specific to define the information elements for a domain of healthcare or specialty area.
- The Refined Message Information Model (R-MIM) demonstrates how the D-MIM is refined to define the information elements of a family of messages.
- The Vocabulary Model provides the tools to deal with previously intractable problems of multiple vocabularies across organizational or jurisdictional boundaries.

Finally, the messages are represented as technical artifacts that include message models (wrappers, CMETs, payload), datatypes, terminology, MIF (Message Interchange Format), Excel views, Table views, Word Design views, and XML schemas.

These deliverables are the basis of the Version 3 Messaging Standards and will allow them to be extended over time to incorporate new requirements and deal with unanticipated requirements.

Process Requirements	Explanation	Relevance	Notes
Followed the HL7 message development methodology	Storyboard, RIM, Interaction Models.	☐Relevant ☐N/A	
Completed and developed the XML Schemas	Completed the XML schemas for all messages within the specification including the payload and wrappers.	☐Relevant ☐N/A	
HL7 Inc. Ballot	Identify where the messages are in the ballot process. • Draft for Comment; • Completed Informative Ballot; • Completed Normative Ballot; or • Draft Standard for Trial Use (DSTU).	☐Relevant ☐N/A	
HL7 Canada Realm Localization Ballot	Identify if the messages require constraining to meet Canadian requirements. In addition, identify if the Realm Localization ballot is completed.	☐Relevant ☐N/A	
Other outstanding issues & processes	Identify if other alignment work will need to be done. (e.g. How will alignment between the pan-Canadian Standard	☐Relevant ☐N/A	

Process Requirements	Explanation	Relevance	Notes
	and the International Standard be maintained if balloting is not yet completed?)		

Appendix C. ACKNOWLEDGEMENTS

C.1 INFORMATION GATHERING INTERVIEWS

The following individuals and committees, in addition to the SC Standards Team, have provided input and insight into the development of this pan-Canadian Standards Decision Making Process document:

- Dave Cattran
- Clinical Sub-Committee
- Heather Cooper
- Andrew Cripps
- Garry Cruickshank
- Jean Duteau
- Shari Dworkin
- Grant Gillis
- Kathryn Hannah
- Beverly Knight
- Marc Koehn
- Patrick Loyd
- Don Newsham
- Bhavana Patel
- George Power
- Helen Stevens Love
- Gavin Tong
- Michael van Campen
- Ann Vivian-Beresford

C.2 PEER REVIEW

The following individuals/organizations participated in the Peer Review and provided additional input into the development:

- Fred Agyepong - AB Health and Wellness
- Michel Boivin - DSQ

- Taha Chaabouni - Laval University
- Heather Cooper - AB Health and Wellness
- Andrew Cripps - Canada Health Infoway
- Garry Cruickshank - Canada Health Infoway
- Tim Flewelling - NB Department of Health
- Kathryn Hannah
- Jane Ann Hendricks - Emergis
- Jeff Horii - AB Health and Wellness
- Peter Humphries
- Mark Koehn - Canada Health Infoway
- Jan Labovich - Manitoba e-Health
- Mike Leavy - Canada Health Infoway
- Patrick Loyd - Canada Health Infoway
- Marion Lyver
- David Mah - AB Health and Wellness
- Aaron Middleton - Global Village Consulting
- David Miller - IBM Global Business Services
- Debra Mills - AB Health and Wellness
- Dale Smith - BC Ministry of Health

C.3 SCCC TASK FORCE

The following individuals participated in the SCCC Task Force and provided additional input into the resolution of outstanding issues:

- Jean Duteau
- Jane Curry
- Neil Gardner
- Jan Labovich
- Gavin Tong

C.4 RISK ASSESSMENT TASK FORCE

The following individuals participated in the Risk Assessment Task Force and provided additional input into the assessment of risk for CDFU specifications:

- David Miller
- Aaron Middleton
- Gavin Tong
- Dale Smith