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Version 0.2

HITSP Interoperability Specification Maintenance Process

Submitted to:

Healthcare Information Technology Standards Panel

Submitted by:

Project Team

DOCUMENT CHANGE HISTORY

Version Number	Description of Change	Name of Author	Date Published
0.1	Draft	Project Team	n/a
0.2	Draft	Project Team	n/a

TABLE OF CONTENTS

FIGURES AND TABLES

BACKGROUND

Two main issues arose at the recent HITSP board meeting:

1. Discussions around the definitions of ‘minor’ and ‘major’ changes to the Interoperability Specification documents
2. Panel role in approving these changes before the final documents are submitted beyond the Panel to ONC/AHIC.

The board suggested that any documents that need to go to AHIC for approval need to pass through the HITSP panel first for their approvals of the changes made – even minor changes. A formal definition and process is needed before the Technical Committee’s begin making their changes based on feedback from the implementation testing. This document describes some of the industry definitions and methods in use today, and makes recommendations for the definitions that HITSP should use in categorizing changes, and the specification maintenance and approval process.

1.0 INTRODUCTION

As an introduction to the HITSP Interoperability Specification Maintenance Process, this section describes the purpose of the document, the intended audience for the technical content of the document, and how to use this document.

1.1 PURPOSE

The HITSP Interoperability Specification Maintenance Process document explores the different definitions that are being used by other standards organizations relating to document changes made after publication, as well as the different options that are available for document approval by the Panel after changes are made to the Interoperability Specifications. Recommendations are made for the taxonomy to be used, as well as the change approval process.

1.2 AUDIENCE

The HITSP Interoperability Specification Maintenance Process document is designed to be used by the Project Team as well as the HITSP Technical Committees to define, validate and outline the taxonomy describing the types of changes that need to be made, and the process by which changes will be made and approved for the Interoperability Specifications.

1.3 HOW TO USE THIS INTEROPERABILITY SPECIFICATION MAINTENANCE PROCESS DOCUMENT

The Interoperability Specification Maintenance Process document is divided into four main related sections. Section 1.0 provides a brief introduction to the document. In Section 2.0, you'll find the recommended definitions and document maintenance and approval process. Finally, section 3.0 provides relevant appendix material.

2.0 HITSP CHANGE APPROVAL PROCESS

For the HITSP Interoperability Specification Maintenance Process, the definitions outlined in the sections below are recommended as the baseline definitions for the categories of changes that have to be made to update the Interoperability Specifications.

2.1 MINOR CHANGES

A change can be categorized as a minor change if it is being made for any of the following reasons:

- **Corrections:** For technical errors or ambiguity in an Interoperability Specification inadvertently introduced either in drafting or in printing and which could lead to incorrect or unsafe application of the publication

- **Updates for outdated information**: outdated information that has become outdated since publication, provided that the modification has *minimal* effect on the technical solution and processes described in the Interoperability Specification. This includes updates of the versions of current standards that do not result in changes to the underlying constraints to those standards. Or updates made by the SDO that does not introduce new functionality or remove existing functionality.

- **Errata:** Grammatical corrections to errors introduced during the publishing process of an existing Interoperability Specification.

- **Clarifications:** The provision of examples or more detailed guidance and scenarios to provide a clearer definition and implementation view of the suggested processes and data outlined in the specification. These clarifications do not introduce new concepts or standards.

2.2 MAJOR CHANGES

Major Changes describe the following main categories of changes:

- **Change in Use Case:** Changes to an Interoperability Specification that involve a change in the associated use case, or requirements.

- **Change in Selected Standards:** Changes in the design of the Interoperability Specification that are due to the selection of a new or different standard or HITSP construct.

- **Updates for outdated information:** Changes made to update information that has become outdated since publication, where the modifications result in a change to the fundamental methodology of the

exchange of data, technical solution or processes described in the Interoperability Specification. This includes updates of the versions of current standards that result in changes to the underlying constraints to those standards. Or updates made by the SDO that introduce new functionality or remove existing functionality.

- **Re-categorizations of minor changes:** Changes that are by definition minor changes, however, that are elevated as major changes by Technical Committee leadership due to the global repercussions of the changes. Technical Committee leadership is defined in the HITSP Technical Committee Operating Guidelines.

2.3 CHANGE APPROVAL PROCESS

This section will provide a detailed description of the recommended change approval process. Different options were analyzed (See appendix 3.1 for detailed definitions), and the process described below was chosen as the most effective method to make changes to Interoperability specifications and to have those changes approved by the relevant bodies.

2.3.1 HITSP INTEROPERABILITY SPECIFICATION MAINTENANCE LIFECYCLE

The document lifecycle is presented in the diagram shown in section 3.3.2. The main steps are described in the table below:

Table 2.3.1-1 HITSP Document Lifecycle

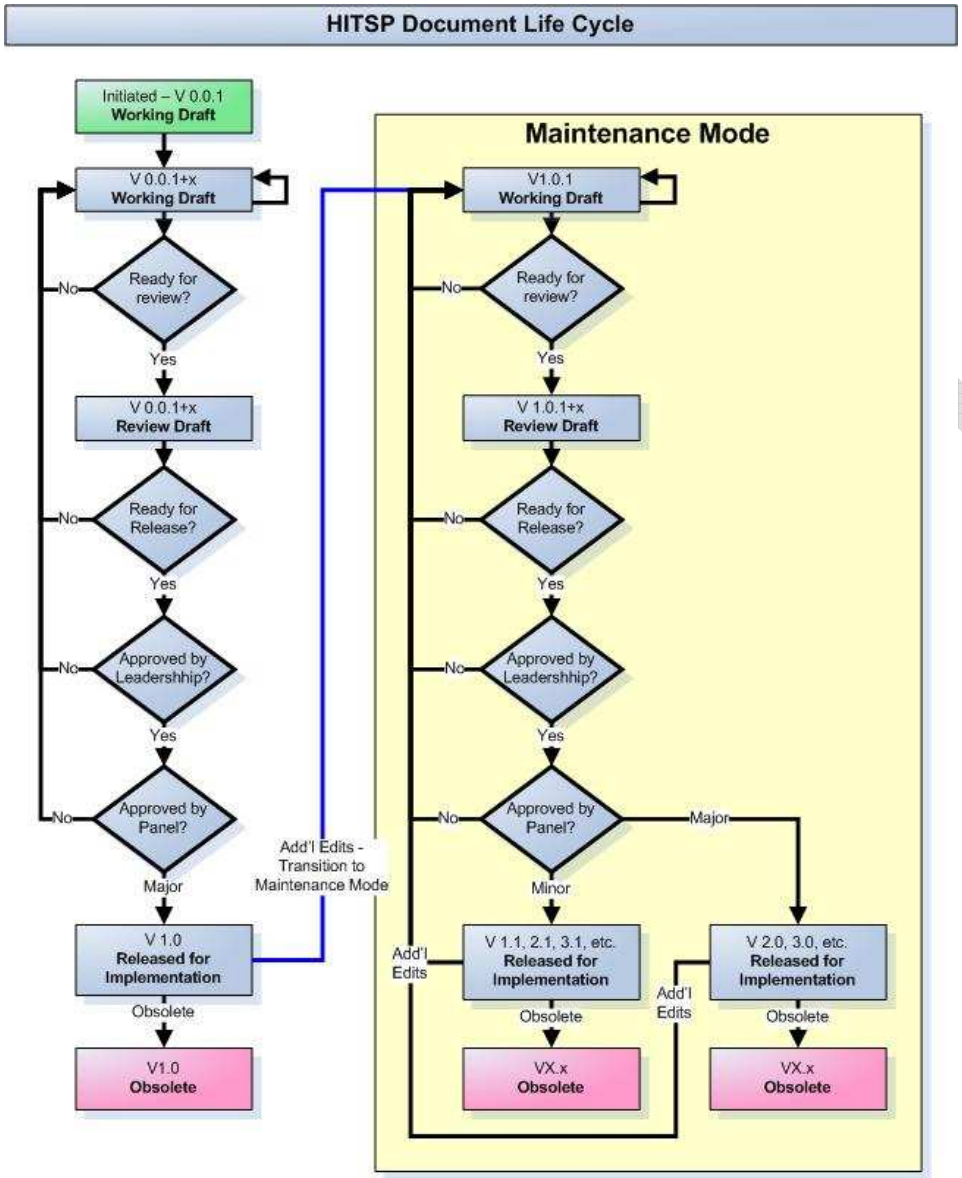
Lifecycle Step	Document Version
New Interoperability Specification	
1. Technical Committee or Workgroup creates a new Interoperability Specification	v0.0.1
2. New Interoperability specification is cycled through the Technical Committee to make necessary changes and to produce a Working Draft	v0.0.1+x
3. Working Draft Interoperability Specification is reviewed and either a Review Draft is produced, or the document returns to the Technical Committee for further work	v0.0.1+x
4. Review Draft Interoperability Specification is submitted for a Public and Panel comment period after which the Technical Committee dispositions comments and updates the document to produce a Final Draft Interoperability Specification	v0.0.1+x

Lifecycle Step	Document Version
5. Final Draft Interoperability Specification is voted on and approved by the Panel and released as a "Ready for Implementation" specification	v1.0
Specification in Maintenance Mode	
1. Existing Interoperability specification is cycled through Technical Committee to make necessary changes and to produce first a Working Draft, and then finally a Review Draft of the specification	v1.0.x
2. Pre-released Interoperability Specification with **minor changes** is reviewed by the Technical Committee and either a final draft is produced, or the document returns to the Technical Committee for further work	v1.0.x
3. Final Draft Interoperability Specification with **minor changes** is voted on and approved by the Panel and released as a "Ready for Implementation" specification. There is no Public or Panel comment period for minor changes. Specifications with minor changes are presented to the Panel a minimum number of days before a Panel meeting. At the Panel meeting, Panel gives an up or down vote on the document with the minor changes. If the document is approved, there is a change in the minor part of the version number, e.g. v1.1 or 2.1, etc.	v1.x
4. Working Draft Interoperability specification with **major changes** is reviewed by the Technical Committee and either a Review Draft is produced or the document returns to the Technical Committee for further work	v1.0.x
5. Review Draft Interoperability Specification with **major changes** is submitted for a Public and Panel comment period after which the Technical Committee dispositions comments and updates the document to produce a Final Draft Interoperability Specification	v1.0.x
6. Final Draft Interoperability Specification with **major changes** is submitted to the Panel a minimum number of days before a Panel meeting. At the Panel meeting, Panel gives an up or down vote on the document with the major changes. If the document is approved, there is a change in the major part of the version number, e.g. v2.0 or 3.0, etc.	vY.0

2.3.2 MAPPING OF HITSP DOCUMENT LIFECYCLE

See section 2.3.1 for a description of the steps outlined in the lifecycle diagram shown below.

Figure 2.3.2-1 Mapping of HITSP Document Lifecycle



3.0 APPENDIX

The following sections contain background information and links to relevant materials referenced throughout this document.

3.1 INDUSTRY DEFINITIONS

This section explores the specific definitions that are being used by Standards Development Organizations to describe the different types of comments/requests that require updates to the specifications. It also documents how those updates will be processed by the Technical Committee's and Panel. Note that these definitions were extracted from policies used by ISO, DICOM, HL7, IHE and IEEE.

Amendments
An amendment alters and/or adds to previously agreed technical provisions in an existing standard.

Errata
Only grammatical corrections to errors introduced during the publishing process of an existing standard.

Change Proposals
Change proposals describe small scale changes and editorial changes. This becomes a change item when approved.

Corrections
Corrections describe changes made to correct technical issues causing non-interoperability of implementations without introducing changes in functionality of a stable Integration Profile.

Clarifications
For clarifications, text that can be misunderstood or is ambiguous is made easier to understand or disambiguated, without introducing any technical changes.

Major Changes
Major changes are changes to an Interoperability Specification that involves a change in the associated use case, requirements, or functional design, or the selection of new or different standards or different HITSP constructs.

Minor Changes
These are all changes that do not fall under the major category. For example, editorial changes, further detail or explanation of examples for existing documents, or the update of a referenced standard's version

number, or HITSP construct, presuming that no substantive change is required to the Interoperability Specification.

Technical Corrigenda

A published International Standard may subsequently be modified by the publication of a technical corrigendum (or a corrected reprint of the current edition) or an amendment. Technical corrigenda and amendments are published as separate documents from the edition of the International Standard affected remaining in print. A technical corrigendum is issued to correct either:

1. A technical error or ambiguity in an International Standard, a Technical Specification, a Publicly Available Specification or a Technical Report, inadvertently introduced either in drafting or in printing and which could lead to incorrect or unsafe application of the publication
2. Information that has become outdated since publication, provided that the modification has no effect on the technical normative elements (see ISO/IEC Directives, Part 2, 2004, 6.3) of the standard.

NOTE: Technical corrigenda are not issued to correct errors that can be assumed to have no consequences in the application of the publication, for example minor printing errors.

SDO Change Approval Process Main Points

The following list contains the main points from the SDO Change approval processes that were analyzed:

- "Minor" Changes are provided as often as necessary to maintain the effectiveness and correctness of the specification in question
- A committee or change board evaluates the change requests to validate the need for the request, and to make suggestions on the process forward
- Some changes (usually minor changes) are only approved by the Technical Committee in question and are not put to a public comment period
- Supplements (containing major changes) require public comment periods and formal disposition of those comments
- Maintains backward compatibility of specification definitions and constraints to support implementations claiming conformance to previous versions of the specifications
- Formal updates are provided on a regular cycle according to specific paths (new work, or maintenance) Annual updates are provided for major revisions.

3.2 ISO DEFINITIONS AND PROCESS DESCRIPTION

The **ISO Procedures for Technical Work** is available for review.

3.3 DICOM DEFINITIONS AND PROCESS DESCRIPTION

The **DICOM Handbook for Preparing Supplements** is available for review.

In addition, the following notes were captured at a HITSP Project Team Change Process meeting in December 2006:
DICOM has two categories of document updates:

- Change proposal: small scale changes and editorial changes. This becomes a change item when approved
- Supplements: new capabilities or major changes to capabilities

Supplements can be anywhere from 10-200 pages. The supplements and change items only have a life of their own until the next annually updated version of DICOM is released. The overall DICOM document is published once a year and incorporates all supplements and change items. At any given time, users must refer to the currently published version of DICOM and all approved supplements and change items. Old supplements and change items are archived, though they are no longer useful after the next published version of the document. Supplements are usually created as a result of new technologies.

Supplements and change proposals are updates to all parts of the document- much like an amendment to a law. For example, the supplement may state "After section 1.2.3, add the following paragraph: ….."

Process:
A new technology emerges and a group realizes the need for a supplement. The group preparing the supplement comes before the quality control body of DICOM and presents the issue and identifies a way to deal with the new issue. The QC body provides suggestions about how to proceed and the group then drafts the supplement. The draft supplement then goes to the QC body for review and then goes out for public comment. The draft is then updated based on public comment and then goes to balloting among DICOM members.

There is a set publishing period for supplements and change proposals every other month. On average, there are 12 supplements produced each year and 100+ change items. The QC body of DICOM meets 5 times a year for 5 days at a time.
DICOM provides update after each meeting on status of change proposals, update website with status info as well. The onus is on the user to some extent to pay attention to what affects them. The status is tracked on the minutes of this committee.

DICOM Standards Committee's Working Group Six (WG-06) addresses errors in and clarifications to the Standard. WG-06 reviews questions and comments on the standard and determines whether a correction is required. Questions and comments may be submitted in numerous ways – i.e., a letter to WG-06, issues raised by Working Group members, etc. After WG-06 approves the proposed corrections, a ballot

is sent to the DICOM Standards Committee members. If approved, the corrections are incorporated into the DICOM Standard.

3.4 IHE DEFINITIONS AND PROCESS DESCRIPTION

Any of the IHE technical framework documents will provide the change process and description of document changes. The **IHE Cardiology Technical Framework** is available for review.