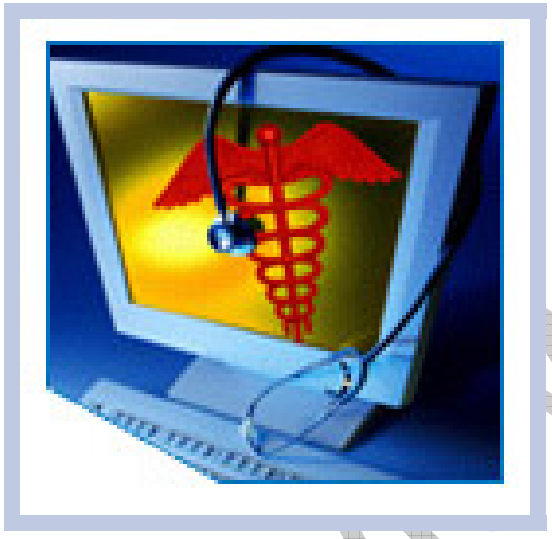
April 27, 2007
Version 1.9.6

HITSP Standards Readiness Criteria: Tier 2

HITSP 07 N 191



Submitted to:

Healthcare Information Technology Standards Panel

Submitted by:

HITSP Standards Harmonization Readiness Coordination Committee

DOCUMENT CHANGE HISTORY

Version Number	Description of Change	Name of Author	Date Published
1.0	Approved Copy	Standards Harmonization Readiness	May 12, 2006
1.1	Committee Draft	Standards Harmonization Readiness	June 6, 2006
1.2	Committee Draft	Standards Harmonization Readiness	October 13, 2006
1.3	Committee Draft	Standards Harmonization Readiness	November 9, 2006
1.4	Committee Draft	Standards Harmonization Readiness	November 21, 2006
1.5	Committee Draft	Standards Harmonization Readiness	January 19, 2007
1.6	Committee Draft	Standards Harmonization Readiness	February 9, 2007
1.7	Committee Draft	Standards Harmonization Readiness	February 15, 2007
1.8	Committee Draft	Standards Harmonization Readiness	March 9, 2007
1.9	Committee Draft	Standards Harmonization Readiness	March 16, 2007
1.9.1	Committee Draft	Standards Harmonization Readiness	March 23, 2007
1.9.4	Committee Draft	Standards Harmonization Readiness	April 6, 2007
1.9.5	Committee Draft	Standards Harmonization Readiness	April 15, 2007
1.9.6	Review Copy	Standards Harmonization Readiness	April 27, 2007

TABLE OF CONTENTS

INTRODUCTION

This document defines the Tier 2 Criteria to be used in evaluating standards' readiness to be selected for inclusion in Interoperability Specifications. Tier 2 builds on the Tier 1 criteria as approved by the HITSP at its March 2006 meeting. Tier 2 refines and provides more detail for the concepts contained in Tier 1. It also adds a method to enable the user to apply objective metrics to the Readiness Criteria. Tier 2 criteria are produced as two documents. The first, this document, lists and explains the Tier 2 criteria to be used by the Healthcare Information Technology Standards Panel (HITSP) and its Technical Committees for evaluating standards. The second document is a worksheet in which evaluators actually enter criteria scores during an evaluation.

BACKGROUND INFORMATION

The HITSP Board assigns to its Technical Committees use cases that may be initially developed by the Office of the National Coordinator (ONC), which refines the Breakthroughs identified by the American Health Information Community (the Community). The Technical Committees then perform high-level requirements analysis in which they identify specific activities that require interoperability in terms of context or information models, information exchange, terminology or content, security, and process standards. The Technical Committees then identify a pool of potential candidate standards, potential duplications and overlaps and gaps for their respective use cases. Tier 2 criteria are used to screen these candidates. Specifically, Tier 2 criteria are used to inform harmonization recommendations to select standards for use in the HITSP Interoperability Specifications. These analyses, recommendations and evaluations are sent to the HITSP for approval. Upon approval, the Technical Committees proceed to develop Interoperability Specifications, which upon further discovery may again require evaluation of new candidate standards.

In this document, the term Standard is used to refer to Specifications, Implementation Guides, Code Sets, Terminologies, and Integration Profiles. A standard should be produced through a well-defined approach that supports a business process and

1. has been agreed upon by a group of experts
2. has been publicly vetted
3. provides rules, guidelines, or characteristics
4. helps to ensure that materials, products, processes, and services are fit for their intended purpose
5. is available in an accessible format
6. is subject to an ongoing review and revision process

Although the intent of the Tier 2 Criteria is to be applicable to all "standards" as described above, the Committee expects there will be a need to refine the criteria based on experience of the Technical Committees during the standards selection process and to better accommodate use of "integration profiles, implementation guides, building blocks or services" produced by third parties who are not normally considered standards developers.

The HITSP Project Team and Technical Committee Leadership introduced several new "classifications" of standards during the first year. In developing the HITSP Framework, we went on to classify and define standards of two types:

Base - A single functional category from a single SDO.

- Base standards examples include HL7 messages or SNOMED terminology.

Composite – A constrained set of base standards for a set of functions. Although not required, the composite standards may be from more than one organization even though the composite is maintained by a single organization.

- Composite standards examples include IHE Integration Profiles or the HL7/ASTM CCD implementation guide and the HL7-OMG HSSP Project.
- The composite may contain means of linking components from different standards of SDOs to perform a use case function.

HITSP constructs (Transaction Packages, Transactions and Components) can use and constrain composite standards at any level while the HITSP Component constrains base standards. See Appendix "*HITSP Constructs*". The HITSP Project Team and TC Leadership also defined several states for standards as described in section 3.0 of HITSP approved Interoperability Specification documents (Version 1.2 as approved by the Panel on October 20, 2006.):

It is HITSP's policy to incorporate only standards that have been approved according to the formal policy of standards organization, as defined by HITSP that publishes the standard. HITSP interprets approval to include standards for trial use. The objective is to incorporate only standards that are managed within a formal life cycle process as defined by the standards organization. In some cases, where we believe a standard that is not yet approved may best meet the requirements of an Interoperability Specification, HITSP may provide a roadmap of its future intent conditional on future actions by either or both the standards organizations and the HITSP Technical Committee. Thus there are four classes of HITSP-committed standards.

- Approved for Use – standards included for unconditional use within a HITSP construct
- Interim – standards included for use now within a HITSP construct but for a defined time period or conditional on future actions, e.g., "Intended for Use" standard is available
- Provisional – standards that are not yet approved but expected to be approved prior to release of the HITSP construct. Thus the standard becomes a "Approved for Use" standard conditional on being approved by the standards organization:
  - By the time that the Interoperability Specification is released by HITSP and
  - Is substantially the same as it was when provisionally used
  - Requiring no further action by the TC if these conditions are met.
- Intended for Use – proposed standards that are road mapped for future use pending actions by the TC and/or the standards organization. Therefore a standard is defined as "Intended for Use" because:
  - It will not be approved by the time that the HITSP construct is released and/or
  - It is not sufficiently defined to enable detailed evaluation of how well it will meet technical and business requirements.

HITSP may continue to use "Provisional" or "Interim" standards as they existed when incorporated into the HITSP construct if the expected conditions are not satisfied until such time as HITSP can replace it with a more suitable standard. In this circumstance, the standards organization would have no responsibility to maintain or correct this artifact. If a standard "Intended for Use" is not developed and approved in terms of time frame or content as expected by the TC at the time of its initial selection, it may be replaced. All standards used by HITSP must meet the HITSP selection criteria. The use of interim and intended for use standards will be weighed against the alternative of simply declaring a gap for HITSP and the standards organizations to resolve.

STANDARDS READINESS EXPLAINED

Standards Readiness is determined by applying specific criteria that will allow the HITSP to select a group of standards most ready for use as an interlocking set to implement in support of breakthrough use cases while remaining compatible with existing HITSP standards' selections across all use cases.

An interlocking (harmonized) set of standards requires:

- Selection of initial standards based on readiness criteria
- Resolution of gaps and overlaps between selected standards
- Coordinated maintenance of the set of standards based upon feedback from use and from new use case requirements.

The closer a standard meets these criteria, the less risk there will be to the success of interoperability and market acceptance.

The criteria are organized into six categories:

1. Suitability – the standard is named at a proper level of specificity and meets technical and business criteria of use case(s)
2. Compatibility – the standard shares common context, information exchange structures, content or data elements, security and processes with other HITSP harmonized standards or adopted frameworks as appropriate
3. Preferred Standards Characteristics–-approved standards, widely used, readily available, technology neutral, supporting uniformity, demonstrating flexibility and international usage are preferred
4. Preferred Standards Developer Organization and Process – meet selected criteria including balance, transparency, developer due process, stewardship and others.
5. Data Element Usage
6. Expected Total Costs of Implementation and Conformance Criteria

When selecting standards, trying to fill a gap or choosing between overlapping standards, the HITSP will determine readiness by reviewing the combination of all six criteria categories:

Readiness = Suitability + Compatibility + Preferred Standards Characteristics + Standards Organization and Process + Data Element Usage + Expected Total Costs of Implementation and Conformance Criteria

Each of these criteria categories is described in the following sections. The intent of the criteria is not to accredit or audit an organization or its processes, but to guide the selection of standards in a way that allows open processes and interested parties to be involved, for the betterment of the industry.

1.0 SUITABILITY

To be determined suitable, standard(s) must:

1.1 Be named by HITSP and evaluated at its most discrete level of designation

There are three major steps in the standards harmonization process: use case requirements/gap analysis, standards selection and interoperability specification. At each step standards' naming must be sufficiently detailed so as to match the level of requirement of the use case or specification and be discretely traceable and testable back to such requirement or specifications. Naming cannot be so generic that it encompasses other chapters or components of a family of standards not necessary for meeting the specific requirement. If not, this specificity is not

present, and further work to better define the requirement or name the standard in detail is required before proceeding to evaluate the standard or modification of the standard.

(Scoring:

3 = Is Specific to Requirement

0 = Is Not Specific to Requirement)

1.2 Meet the use case business and technical requirements

The standard under consideration must meet or exceed the use case business concept and detailed technical requirements as determined by the Technical Committee. If not, this misalignment should be addressed immediately.

(Scoring:

3 = Fully Meets Use Case Requirement

2 = Somewhat Meets Use Case Requirement, But Further Work Required

0 = Does Not Meet Use Case Requirement)

1.3 Essential data elements handled by selected standard

Formal requirements, as detailed in the *HITSP Requirements, Design and Standards Selection Template*, will list the essential data elements (requested from AHIC/ONC). A requirement is for the Technical Committee is to verify that the essential data elements starting with data elements supplied by AHIC/ONC (and supplemented as necessary), are handled by a selected standard.

(Scoring:

3 = All identified data elements are included in the selected standard,

2 = Over 50% of the identified data elements are included in the selected standard,

1 = Less than 50% of the identified data elements are included in the selected standard,

0 = No identified data elements are included in the selected standard)

1.4 Be compliant with jurisdictional laws and regulations

Applicable laws, regulations and policies may mandate the use of certain standards. We especially note the legal requirements for ensuring the origination, retention, interchange and access and use of persistent indelible electronic health records sufficient to supplant manual (including paper) record keeping. Some laws or regulations, such as HIPAA or Medicare Part D electronic prescribing actually name specific standards or versions of standards that must be used for named business purposes. Strong preference should be given to federally mandated standards. Where such mandated standards are not technically desirable, specific changes must be justified and legal and regulatory changes should be suggested to the government. Where jurisdictions, laws and regulations differ, e.g., between states, standards that support local policy options may be necessary although technically undesirable.

(Scoring:

3 = Is Compliant with Jurisdictional Laws and Regulations

0 = Is Not Compliant

NA = Not Applicable)

2.0 COMPATIBILITY

2.1 Be compatible with other standards, framework, architecture and models as determined by HITSP.

Compatibility means sharing common context or information model(s), information exchange structures, terminology or content, security and processes. In some cases, where commonality cannot be readily achieved, sharable or mappable data elements may be used. Compatibility is applied to standards already selected by HITSP as well as to any direction, framework, architecture or model adopted in the future. Standards must broadly support uniformity and commonality. It is suggested that review of previous Tier 2 spreadsheets and criteria discussions for applicability take place.

(Scoring:

3 = Fully compatible

2 = Can be integrated/mapped

0 = Is not compatible)

2.2 Support the goal of information reuse for appropriate clinical, administrative, financial and public health purposes.

Whenever possible, a standard should be fully compatible or able to be integrated with existing standards widely used by healthcare stakeholders so that information is understood and represented in a shared or sharable formats across clinical administrative, financial and public health domains. In some cases, the standard will have been named based on industry support and acceptance. In other cases, the standard may point to a version the industry is moving towards with established implementation dates.

(Scoring:

3 = Fully compatible

2 = Can be integrated/mapped

0 = Is not compatible)

2.3 Be compatible with other appropriate sets of standards

The Contractor shall use as a starting point the health domains and standards adopted by the Consolidated Health Informatics (CHI) initiative in the Federal government, unless they demonstrably do not meet the relevant requirements posed by the use-cases. All other things being equal, preference should be given to standards included in other harmonization and implementation initiatives. Special consideration should be given to standards selected by Certification Commission for Healthcare Information Technology (CCHIT) and the Nationwide Health Information Network (NHIN) projects during this period of parallel ONC contracts. It is anticipated that these will be harmonized by HITSP and their appropriate SDOs in future years. Other sources to consider for preferences to be given to their standards recommendations are:

- National Committee on Vital and Health Statistics (NCVHS)
- Health Insurance Portability and Accountability Act (HIPAA)
- International Interoperability Initiatives

The standard has been named by one or more of these sources

(Scoring:

3 = Named

0 = Not named

NA = Not Applicable)

3.0 PREFERRED STANDARDS CHARACTERISTICS

This section is to be completed by the TC for each standard. The term "standards" in this section's title applies broadly as described in the Background Information section of this document. Note this includes code set standards.

3.1 Formal approval and degree of maturity may provide indications of standards readiness

There are six stages to a standards life cycle: development, evaluation, formal approval, in use (support in products), widespread use and maintenance, adoption maturity, and retirement. Standards are also often revised or extended.

Standards shall have passed the evaluation stage and be formally adopted or be very close to formal adoption. In all cases a HITSP Interoperability Specification cannot be finalized unless all referenced standards are formally adopted by the source development organization.

The degree of adoption maturity of a standard needs careful consideration. There may be instances where marketplace adoption is not the lead consideration - especially where currently adopted standards ensure limited interoperability. So some standards may have low adoption relative to others and yet may be the most appropriate standard to recommend because it is best aligned with the broader goals of the Strategic Framework and interoperability of health information exchanges or other Tier 2 criteria.

3.1.1 Current Industry Environment

Note this section is for ***current industry usage*** of a standard.

(Scoring:

4 = "Widely Used" - Standard approved and in wide use,

3 = "Used" - Standard approved and supported in products but not yet in wide use,

2 = "Not in Use" - Standard approved, but not currently in use

1 = "Provisional" - Standard not approved, but expected to be approved prior to release of the HITSP construct

0 = "Intended for Use" – Proposed standard road mapped for future use pending actions by the standards organization)

3.1.2 Technical Committee Review

Note this section is the determination ***for usage in the HITSP use case***.

3.1.2.1 First level review

(Scoring:

2 = "Widely Used" - Standard approved and in wide use,

1 = "Used" - Standard approved and supported in products but not yet in wide use,

0 = Standard approved, but not currently in use)

3.1.2.2 Second level review

See section *"Background Information"* above for more discussion of the states for standards.

(Scoring:
1 = "Provisional" - Standard that is not yet approved but expected to be approved prior to release of the HITSP interoperability specification construct. Thus the standard becomes a "Approved for Use" standard conditional on being approved by the standards organization:

- By the time that the Interoperability Specification is released by HITSP and
- Is substantially the same as it was when provisionally used
- Requiring no further action by the Technical Committee if these conditions are met.

0 = "Intended for Use" – Proposed standard that is road mapped for future use pending actions by the Technical Committee and/or the standards organization. Therefore a standard is defined as "Intended for Use" because:

- It will not be approved by the time that the HITSP interoperability specification is released and/or
- It is not sufficiently defined to enable detailed evaluation of how well it will meet technical and business requirements.

NA = Not Applicable)

Note: "Interim" - Standard included for use now within a HITSP construct but for a defined time period or conditional on future actions, e.g., until *"Intended for Use" standard is available.*

3.1.2.2.1 Intended For Use Criterion

If the Scoring in the above question is 0 ("Intended for Use"), a timeframe must be demonstrated for the movement of a standard from this stage to approved standard. Use the best estimate available.

If the Scoring in the question above is 0 ("Intended for Use"), the timeframe for the standard to move to approved standard is

(Scoring:

3 = less than 1 year

2 = 1 year to 2 years,

1 = 2 years to 5 years,

0 = 5 years or more

NA = Not Applicable)

3.2 Lack of barriers and ease of access

The standard should be available in electronic form to all authorized users. Similar access to previous versions, guides, instructions and other artifacts is desirable. If the standard differs in terms of intellectual property or licensing from a general policy of the standards organization (see section 6), then these terms, whether the difference increases or diminishes barriers, should be considered in this section.

(Scoring:

3 = Availability Demonstrated

0 = Availability Not Demonstrated)

3.3 Technology architecture and vendor neutrality

The standard should not have an undesired bias toward a given technology architecture or toward the platform of a particular vendor.

(Scoring:

3 = Neutrality Demonstrated

0 = Neutrality Not Demonstrated)

3.4 An International Standard

In the case where two standards meet the use case and all other criteria, preference should be given to international standards, whether an ISO standard or not, that are in use in other nations or are supported by international organizations, such as WHO, over an otherwise equivalent U.S. specific standard. This is to promote global harmonization when possible.

(Scoring:

3 = International standard meeting all other requirement

0 = US only where comparable international standard exists

NA = no available international standard)

3.4.1 International - HITSP Harmonization

(Scoring:

3 = International organization has agreed to HITSP harmonization

0 = International organization has not agreed to HITSP harmonization

NA = not applicable)

3.5 Code Set Standards

3.5.1 Code Sets used in standard harmonize with other standards named

The code sets used in the standard use codes sets in common with other standards? (Note if NA is chosen because the standard does not have code sets, the other subsections of this section are NA as well.)

(Scoring:

3 = Yes

0 = No

NA = not applicable)

3.5.2 How often are code set terms updated and published?

(Scoring:

5 = Daily

4 = Weekly

3 = Quarterly

2 = Monthly

1 = Yearly

0 = Has not been updated

NA = not applicable)

3.5.3 Versioning of updates/releases of codes sets

It is understood that software must be modified to accept the introduction of code sets into the workflow. We are seeking to understand if each update or release of code sets is versioned and if the codes are unique (previously issued codes are not reused).

(Scoring:

3 = Versioning is maintained and previously issued codes are not reused

0 = Versioning is not maintained or previously issued codes are reused

NA = not applicable)

3.5.4 Mapping

Will users need to perform mapping from the standard to internal (other industry) code sets?

(Scoring:

3 = No mapping required

2 = Mapping not anticipated

0 = Mapping expected

NA = not applicable)

3.5.5 Robustness and/or deficiencies in a code set

Does the code set evaluated have known deficiencies for this use case requirement? For example, if a code set is needed for physician services, but it is known that it does not include surgical services, 2 code sets may need to be used.

(Scoring:

3 = No deficiencies known

0 = Deficiencies known

NA = not applicable)

4.0 DATA ELEMENT USAGE

When standards are being chosen for the use case by a Technical Committee, the choice should, first, take into account the comprehensiveness of data elements in the standards under review compared with those needed in the use case. That is, are all the data elements needed to satisfy the use case needs present in the standard under review? Second, the choice should consider the compatibility of those elements with the elements of other standards chosen for that use case. Third, the choice should consider the compatibility of the data elements for the use case with those for similar concepts by other HITSP work products. Compatibility means the equivalence of the data elements in terms of their names, definitions, data representations, and the context in the use case of the concepts to which they refer.

The goals of these comparisons (with other standards in the use case and across use cases and Technical Committees) are to increase the semantic understanding of terms across the HITSP-chosen standards, to increase the level of meaningful health information exchanges

among software vendors whose products support the use case, and to encourage SDOs to harmonize their data elements, definitions, and representations with each other.

4.1 Comprehensive

Existing data elements (vocabulary, code sets, other) in the standards chosen for the specific use case are sufficiently comprehensive to enable the use case.

(Scoring:

3 = Yes

0 = No)

4.2 Compatibility

The data elements in the chosen standard are compatible in terms of their names, definitions, representations, and the context in the use case of the concepts to which they refer with the data elements to other standards chosen by HITSP for existing use cases.

4.2.1 Representation with other standards that could be chosen

Are the representations of the data elements in the chosen standard compatible with the representations of data elements in other standards that could be chosen for the use case (less important if the choice has already been made), and

(Scoring:

3 = Yes

0 = No)

4.2.2 Representation with other standards of other closely related use cases

Are the representations of data elements in chosen standard compatible with representations of data elements in other standards that support other closely related use cases?

(Scoring:

3 = Yes

0 = No)

4.2.3 Data Element Representation Compatible

Is the data element representation compatible? (Numeric, decimal points, text strings, data lengths)

(Scoring:

3 = Yes, the same

0 = No, not the same)

4.2.4 Compliant with Federal regulations

Compliant with Federal regulations that name specific vocabulary or code sets for such data elements or purposes as in this use case, such as HIPAA-designated transaction and code set standards?

(Scoring:

3 = Yes

0 = No)

4.3 Mapability

The data elements in the use case may not be fully compatible across all HITSP use cases. However, the elements of the chosen standard may be mapped into the data elements of other HITSP use-case standards or to a reference terminology that includes the concepts of the other HITSP use-case standards' data elements.

4.3.1 Compatible with use cases and CHI

Fully compatible with other HITSP uses of the data elements and to CHI data element definitions.

(Scoring:

3 = Yes

0 = No)

4.3.2 Mapable for use cases

Mapable into the data elements of other HITSP use case standards or to a reference terminology that includes the concepts of the other HITSP use case standards' data elements

(Scoring:

3 = Yes

0 = No)

4.3.3 SDO create mapping

If mapping has not already been done, will the SDOs involved create and maintain the mapping?

(Scoring:

3 = Yes

0 = No)

4.4 Constraining

Data elements and their value sets and/or qualifiers that are flexible and/or reusable within a standard may need to be constrained for the use case. (For example a reference data element with a qualifier that points to different code lists, or a large value set that should be constrained.)

Does the data element (and its qualifier) need to be constrained by the use case?

(Scoring:

3 = Yes

0 = No)

4.5 Harmonization

SDOs are willing to adopt mutually equivalent definitions and representations for the data elements used in their standards

(Scoring:

3 = Harmonized set already created

2 = Development underway

1 = Willing to discuss

0 = Not willing)

5.0 EXPECTED TOTAL COSTS OF IMPLEMENTATION AND CONFORMANCE CRITERIA

5.1 Expected total costs including implementation and ongoing use

Consideration must be given to the expected total costs of implementation across the industry, disruption of current processes due to conversion, coordination and communication costs born by implementers or the lost revenue of current solutions in place that will no longer be useful. AHIC should be responsible for the cost benefit analysis with the given use case submitted, as part of the initial analysis. It is important that the initial business case meets the needs of the industry. The benefits and cost benefit analysis should continue take place throughout the steps of the evaluation.

We believe that while total costs and ease of implementation and deployment are important criteria, we are unlikely to be able to determine this for individual standards before they are incorporated into an Interoperability Specification that can be evaluated against the benefits of fulfilling the use case requirements. Similarly the ease or complexity of implementation and deployment will not be determinable independent of the entire Interoperability Specification.

We have intentionally not created criteria for this aspect.

5.2 Readiness Criteria for these Conformance Criteria

All HITSP Interoperability Specification (IS) constructs contain a Conformance Clause[1] (Section 5.1 Conformance) that defines what is considered to be a correct implementation of the IS. The conformance clause points to conformance criteria[2]. Conformance criteria must be usable in the Inspection Testing process and forms the basis for determining correct implementation. A strong indicator of sound conformance criteria is the ease to which tests can be derived from the criteria, and conversely the ease to which tests can be directly traceable back to the criteria.

5.2.1 Conformance Clause and Conformance Criteria

Preference will be given to standards that contain a conformance clause and conformance criteria mandated by the standard's owner.

(Scoring:

4 = a clear unambiguous conformance clause exists, pointing to conformance criteria contained within the standard (explicit or implicit). 'Statements of conformance' declared by vendors and based on the conformance clause, are recognized and accepted in the community as a communication between vendors and purchasers.

3 = a clear unambiguous conformance clause exists, pointing to conformance criteria contained within the standard (explicit or implicit) from which objective, robust conformance tests have been derived, but have limited use in the community.

---

[1] A conformance clause is a section of a specification that states all the requirements that must be satisfied to claim conformance to the specification. A conformance clause addresses: 1) who may conform (i.e., the types of entities), 2) how do the entities conform (e.g., implement all of the mandatory statements in the specification), 3) define the permissibility for extensions, options, or alternate approaches and how these are specified for conformance purposes and 4) define a permissible conformance statement that can be declared by the entities (or optionally that no conformance statement should be made).

[2] Conformance criteria are objective statements of requirement that can be used to determine if a specific behavior, function, interface, code set has been implemented correctly.

2 = a clear unambiguous conformance clause exists, pointing to conformance criteria contained within the standard (explicit or implicit) from which objective, robust conformance tests could easily be derived but do not currently exist.

1 = language exists that generally addresses conformance; however the language is somewhat ambiguous; the language cannot be used to easily derive conformance tests.

0 =neither a conformance clause nor conformance criteria exist.)

5.2.2 Conformance Test Methods

HITSP relies on the conformance test methods, test tools and other test-related material produced by or under the auspices of standards developers, profiling organizations and implementation guide producers as part of its collaborative implementation testing effort. Efforts to produce conformance test methods, tools, etc. may be produced internal to the organization or by an external organization.

Preference will be given to standards that are supported by conformance test methods, test tools and other test-related material.

(Scoring:

3 = Conformance test methods, tools, etc. exist and are widely recognized and used by the community; the conformance test development process is strongly linked to the standards development process and produced in conjunction (i.e., the test development process is not temporally sequential to the standards development process).

2 = Conformance test methods, tools, etc. exist and are widely recognized and used by the community; the conformance test development process is not strongly linked to the standards development process and produced in conjunction (i.e., the test development process is not temporally sequential to the standards development process).

1 = Conformance test methods, tools, etc. exist; however this material is not widely recognized by the community; the material is developed as a separate process from the standards development process (i.e., it is developed after the standards are well into the development process).

0 = No conformance test methods, tools, etc. exist)

6.0 PREFERED STANDARDS DEVELOPER ORGANIZATION AND PROCESS

This section is completed once per standards organization. We recommend that this evaluation be conducted using these criteria by a standards organization HITSP board member or other standards organization designated HITSP contact. (There needs to be some oversight of this self-evaluation and a process to normalize evaluations across standards developers.) In some cases, where the TC believes a particular standard from an already evaluated standards organization was based on a process substantially different from the organizations evaluated process, the TC may conduct this evaluation.

The term "standards" applies broadly as described in the Background Information section of this document.

The term "standards developer organization" or "standards developing organization" refers to an organization that produces one or more of these documents/artifacts as defined in the Background Information.

A HITSP recognized organization that maintains code sets or terminologies may approach the modification process differently than a standards development organization that develops implementation guides. For example, when maintaining a code set, ultimately one organization is responsible for the integrity of the code set, while industry input is sought during discussion of a request. It is expected that the basic tenets of openness, lack of dominance, barriers, etc be supported by code set organizations. Organizations that develop standards should support the process and the criteria put into place by HITSP.

All criteria must be filled out. If a specific criterion does not apply to an organization, the organization must explain why in the comment.

A standard is preferred when it is developed by an organization exhibiting the following:

6.1 Openness & Transparency

Participation in the development of the standard was/is open to all persons who are directly and materially affected by the activity in question. There shall be no undue financial barriers to participation. For example, voting membership on the consensus body shall not be conditional upon membership in any organization, nor unreasonably restricted on the basis of technical qualifications or other such requirements.

Openness is demonstrated by one or more of the following, as applicable to the particular standard:

- Timely and adequate notice of a standards action to create, revise, reaffirm, or withdraw a standard.
- Predictable update schedule and readily available mechanisms for requesting changes or additions and obtaining feedback regarding such requests.

(Scoring:

3 = Notification Demonstrated

0 =Notification Not Demonstrated)

- A clear and meaningful description of the purpose of proposed activities, significant changes in formats, release schedules, etc., identifying a readily available source for further

information.

(Scoring:

3 = Closely aligns to requirement

2 = Moderate alignment

1 = Minimal alignment

0 = Does not align)

6.2 Balance and lack of dominance

The standards development process shall not be dominated by any single interest category, individual or organization.

- This is demonstrated by the lack of positional or de facto authority, leadership, or influence by reason of superior leverage, strength, or representation to the exclusion of fair and equitable consideration of other viewpoints, or in cases where ownership of the standard does not rest with a consensus-based SDO, by policies and procedures that give due consideration to the views of all affected stakeholders who provide input.

(Scoring:

3 = Lack of Dominance

0 = Dominance)

- Participants from diverse interest categories shall be sought with the objective of achieving balance. This applies to providing input leadership and within approval process, as these are applicable. Prompt consideration shall be given to the written views and objections of all participants.

(Scoring:

3 = Balance Demonstrated

0 = Balance Not Demonstrated)

- Is the process of discussion and consideration of updating code sets open to the public?

(Scoring:

3 = Open to the Public

2 = Open to members only

0 = Not open to the public)

6.3 Consensus

Evidence of consensus in accordance with the requirements and procedures of the standards developer shall be documented with special emphasis on attempts to reconcile negatives.

(Scoring:

3 = Consensus Demonstrated

0 = Consensus Not Demonstrated)

6.4 Appeals

Written procedures shall contain an identifiable, realistic, and readily available appeals mechanism for the impartial handling of procedural complaints regarding any action or inaction. Procedural complaints include whether a technical issue was afforded due process. Appeals shall be addressed promptly and a decision made expeditiously. Appeals procedures shall provide for participation by all parties concerned without imposing an undue burden on them. Consideration of appeals shall be fair and unbiased and shall fully address the concerns expressed. Otherwise, the standards developer shall carefully review and respond to complaints related to the substance of the standard.

(Scoring:

3 = Appeal Process Demonstrated

0 = Appeal Process Not Demonstrated)

6.5 Written policies and procedures

Formal, written procedures shall govern the methods used for standards development and approval processes and shall be available to any interested person.

Cite where the procedures may be found.

(Scoring:

3 = Policies/Procedures Available

0 = Policies/Procedures Not Available)

6.6 Be an effective steward

The organization must demonstrate effective and open governance and adequate funding sources to maintain the standard for which this criterion is being applied. It must be able to show the standard has been maintained with backward compatibility when appropriate, updated in the past when appropriate, published with procedures for enhancing the standard in the future and able to show examples of timely response to requests for enhancements.

(Scoring:

3 = Open Governance/Adequate Funding

0 = No Open Governance/No Adequate Funding)

A standards organization should exhibit the flexibility to meet industry needs, within its stated scope and purpose. It is not expected that a standard will solve all the problems of a use case immediately, but its scope of work must have the ability to be enhanced (such as incorporating new business needs, the addition of new code values, new data fields) or the ability to retire items no longer deemed necessary by industry in a timely manner.

(Scoring:

3 = Willingness and Process to Update Exhibited

0 = Willingness and Process to Update Not Exhibited)

6.7 Favorable intellectual property and licensing terms

The standard produced by the organization should be readily available to entities for implementation and usage. The standard should be available to most stakeholders at no or reasonable cost. Code sets or terminologies should have licensing arrangements, which do not

pose a barrier to usage. This availability should include a willingness to share necessary standards with the HITSP and its Technical Committees for use in evaluation and, based on further agreement, in HITSP Interoperability Specifications. When necessary, evaluation of favorable IP and licensing terms may be applied to individual standards if the standards organization maintains different terms for different standards (see 3.0)

(Scoring:

3 = Standards Available

0 = Standards Not Available)

6.8 Willingness to collaborate with other standards developers and the HITSP

The organization must demonstrate examples of past collaborations or intended future collaboration projects.

(Scoring:

3 = Collaboration Demonstrated

0 = Collaboration Not Demonstrated)

The organization must be willing to formally collaborate with the HITSP standards harmonization process.

(Scoring:

3 = Willing to formally collaborate

0 = Not willing to formally collaborate)

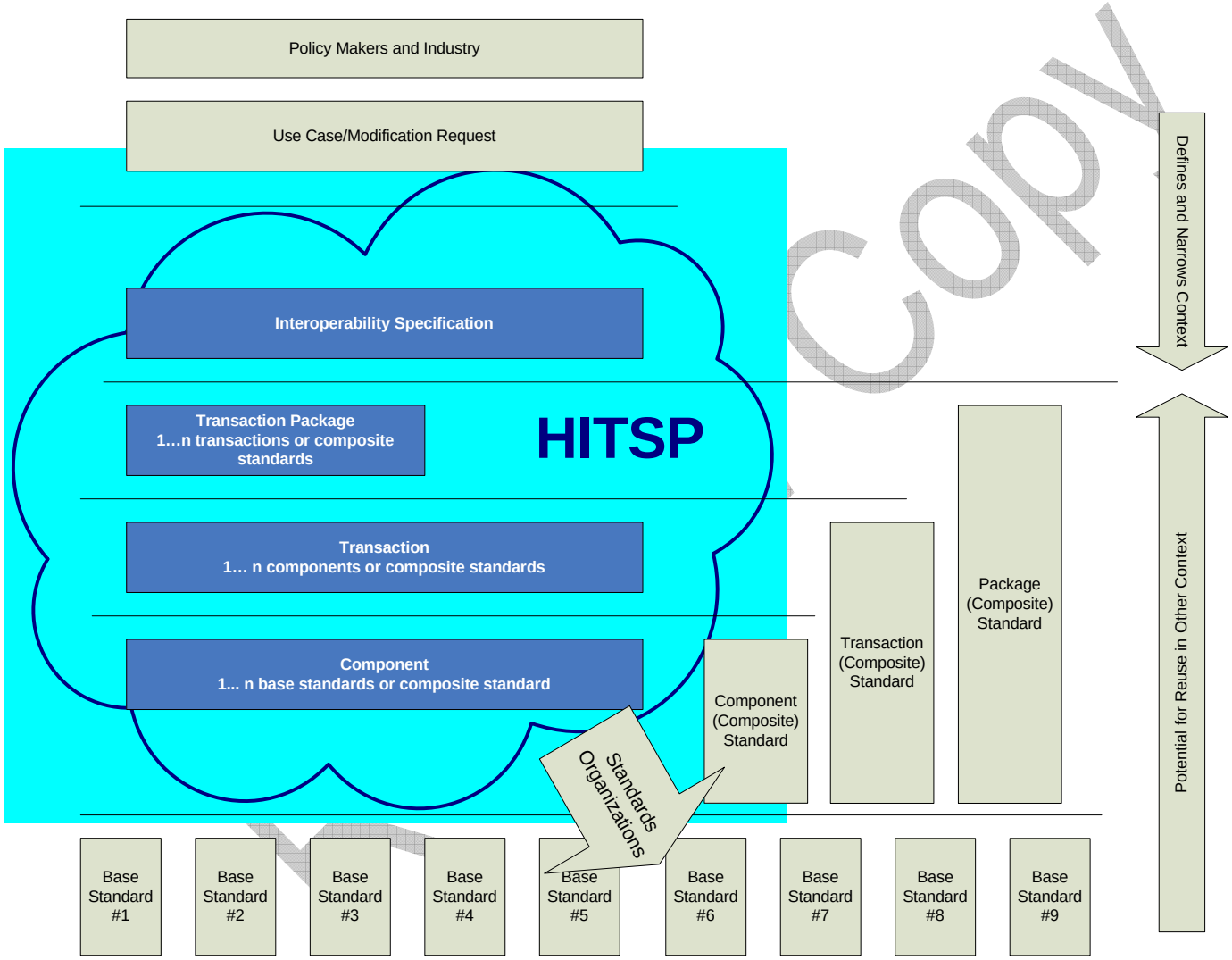
Please note if the organization is a HITSP member.

(Scoring:

3 = Organization is a HITSP member

0 = Organization is not a HITSP member)

7.0 APPENDIX A. HITSP CONSTRUCTS



Definitions and Rules

Level	Definition	Example	Rules
Use Case or Harmonization Request	• Defines business/functional requirements • Sets Context	ONC Harmonized EHR Use Case	
Interoperability Specification	• Models business/functional/interoperability requirements • Identifies technical/system requirements to meet use-case Identifies how to use one or more HITSP constructs to meet use-case requirements	HITSP EHR Interoperability Specification	• Based on UML diagram to identify technical actors and actions • Sets context • Testable functional requirements • Ids transactions or transaction packages
Transaction Package	Defines how two or more transactions are used to support a stand-alone information interchange within a defined context between two or more systems	• Record Locator Service • Entity Identification Service	• Thin context and interoperability requirements • Testable • ·Based on analysis of like technical actors, context and content harmonized across transactions· • May be fulfilled by one or more transactions or composite standard • Expresses constraints on the transactions or composite standard
Transaction	Logical grouping of actions, including necessary content and context, that must all succeed or fail as a group.	• Query lab result • Send lab result	• Fulfills all actions between two or more systems needed to meet one or more interoperability requirements • Testable • May be fulfilled by components or

Level	Definition	Example	Rules
			composite standard • Expresses constraints on components or composite standard
Component	An atomic construct used to support an information interchange or to meet an infrastructure requirement (e.g., security, logging/audit)	• Lab result message • Lab result context	• Typically will use one “primary” standard and may have other “secondary” standards • Expresses constraints on base or composite standards
Base Standard	A standard capable of fulfilling a discrete function within a single category produced and maintained by a single standards organization.	• Messaging standard • Security standard • Code set.	Per HITSP definition the term “standard” refers, but is not limited to,: – Specifications – Implementation Guides – Code Sets – Terminologies – Integration Profiles
Composite Standard	Grouping of coordinated base standards, often from multiple standards organizations, maintained by a single organization. In HITSP, it can serve as a component, transaction or transaction package functional requirements.	• Integration profiles • Implementation guides • Health transaction services	Per Definition above