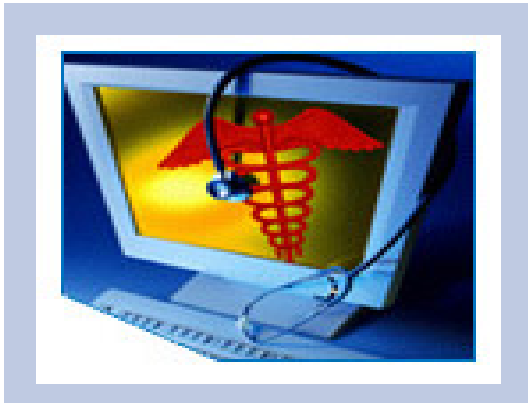


# Evaluation of Standards Harmonization Process for Health Information Technology

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Contract HHSP23320054105EC

## Standards Harmonization Process for Health IT



*Submitted to:*

**Department of Health and Human Services  
Office of the National Coordinator, Health IT**

*Submitted by:*

**American National Standards Institute**  
25 West 43 Street  
4<sup>th</sup> Floor  
New York, New York 10036

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- I. Introduction
- II. Process Overview
- III. Detailed Process Steps
- IV. Planned Process Enhancements

# I. Introduction

- ▶ This document describes a standards harmonization process for health information technology that results in an Interoperability Specification
- ▶ This standards harmonization process document is intended to be a living document that will evolve as the process matures

## The HITSP harmonization process has been evolving since October 2005

- ▶ This document describes the latest refinement for a process to harmonize industry-wide health IT standards development, and a process to maintain and refine the harmonization process over time
- ▶ The standards harmonization process continues to evolve, the team moves forward based on the best approximation of the final process known at any given point in time
- ▶ The historical evolution to date has been:
  - The Request For Proposal (RFP) from the government set the first approximation for the process by identifying a set of deliverables and requirements to be fulfilled by the contractor and Panel
    - ▶ Artifacts are delivered to the government based on this approximation of the process, despite an evolution in our understanding of the requisite process
  - The proposal for fulfillment of the government's RFP served as the second approximation for the process, embellishing on the first approximation with details around various process elements, such as how testing will be performed, and how program management is enjoined. This approximation continues to govern the macro activity of the Panel and contractors

## **The HITSP Harmonization Process will be subject to ongoing review and enhancement**

- ▶ This document represents the team's first approximation of the long term process, developed by defining and vetting the vision for the instantiation of the harmonization process and the Interoperability Specification
- ▶ This process accounts for elements that will not be exercised within the first year contract period, such as reconciliation with previous Interoperability Specifications
- ▶ This process will be adapted to meet the needs and timeframe for this first year, while setting the stage for subsequent iterations of the process
- ▶ A process review board function will be established to formalize the adoption of each process refinement.
- ▶ Therefore, a process will be adopted by HITSP, and it will be frozen for a prescribed period of time for stability, after which the effectiveness of the process will be evaluated, and refinements made if necessary
  - This cycle perpetually recurs

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I. Introduction

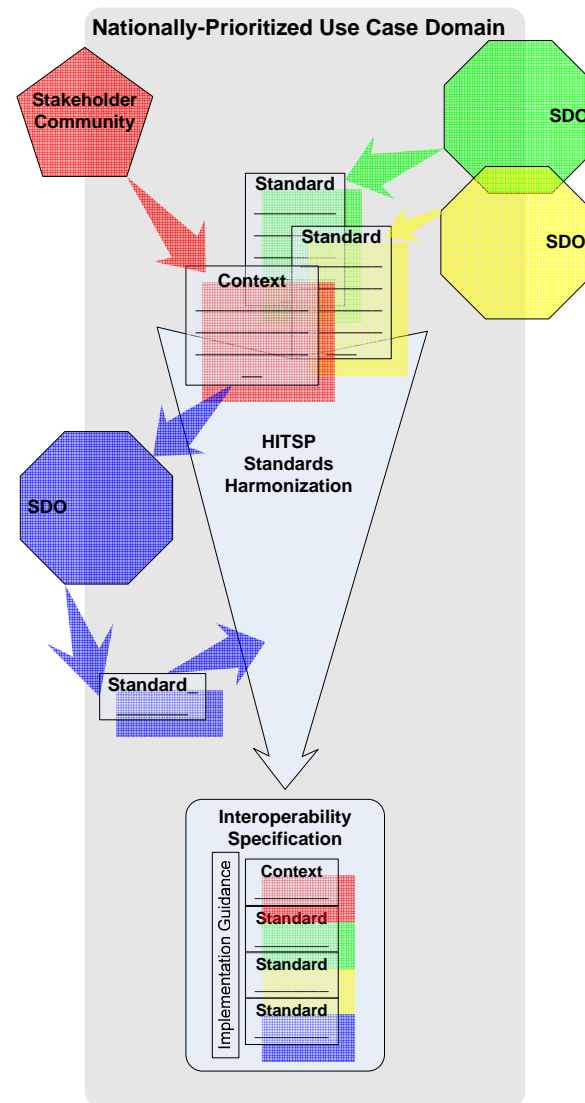
II. Process Overview

III. Detailed Process Steps

IV. Planned Process Enhancements

# A standards harmonization process is used within a context to resolves gaps and overlaps among SDO products

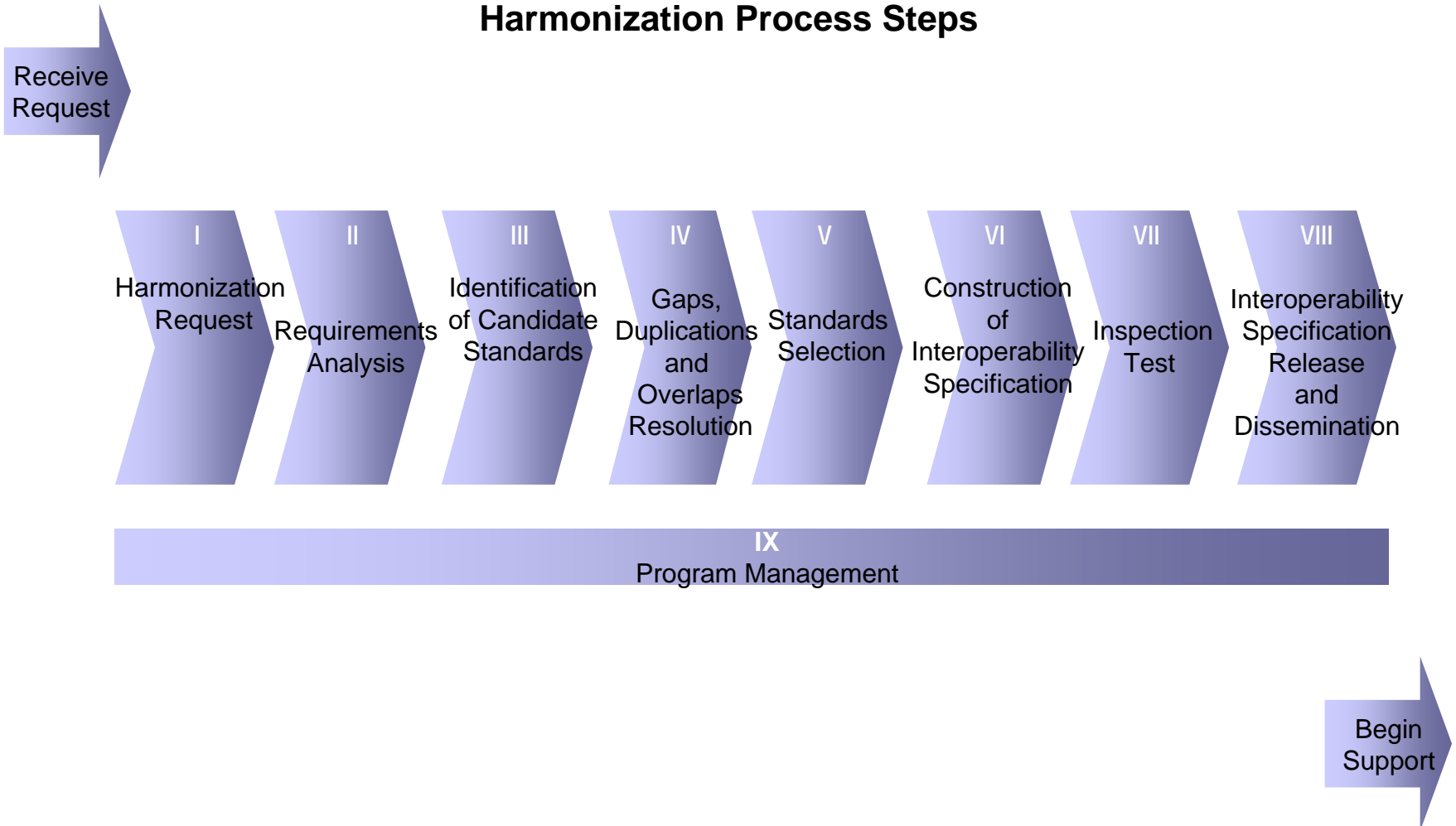
- ▶ **Harmonization** - the selection of standards most ready for use as an interlocking set to implement in support of specific events and actions
- ▶ **Context** – the coupling of an action or event and a specific request for an interoperability specification
- ▶ **Gap** -- missing or incomplete standards that are required for fulfillment of the events in the given Use Case
- ▶ **Overlap** - Overlaps refer to instances where some or all of the requirements are met by multiple standards.
- ▶ **Standards Development Organization** - The term “standards development organization” refers to an organization that produces standards as previously defined



## II. Process Overview . . .

The actual harmonization process is a series of steps taken by industry stakeholders within the context of a standards panel -- HITSP

### Harmonization Process Steps





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### III. Detailed Process Steps . . .

## Each of the eight steps of the harmonization process will be described in the following section using a standard template

- ▶ The harmonization process includes 8 process steps:
  1. Harmonization Request
  2. Requirements Analysis
  3. Identification of Candidate Standards
  4. Gaps, Duplications and Overlaps Resolution
  5. Standards Selection
  6. Construction of Interoperability Specification
  7. Inspection Test
  8. Interoperability Specification Release and Dissemination
- ▶ A process element, Program Management, is described here as an overarching activity
- ▶ For each process step the following information is presented
  - Title
  - Objective
  - Major activities
  - Primary actors engaged in the activities
  - Products that result from the step/element

#### Process Step 1: *Harmonization Request*

Objective	<i>This step provide a formal entry point into the harmonization process that will be used by the stakeholder community to identify a need for an interoperability specification. It also provides the analysis required to categorize and prioritize the need and set a schedule to meet the need.</i>	
Actor	Major Activities	Procedures and Artifacts
HITSP	Receive a Harmonization Request for creation of, or change to, an Interoperability Specification	Harmonization Request form and a process for gathering, logging, and tracking them
HITSP TBD	Evaluate the Harmonization Request for completeness and clarity – contact sponsor as necessary	Inspection of Harmonization Request versus model form
HITSP	Stakeholders requested to comment on the Request's completeness, validity and prioritization	Publication of Request
Program Mgt.	Estimate required effort, recommend priority and send to HITSP Board	Evaluation form and metrics to be developed. Artifact: Work Effort estimation Form (TBD)
Program Mgt.	Support and coordinate analysis and documentation of Request actions	
HITSP	Determine whether to authorize a Technical Committee to proceed, defer or decline.	HITSP TBD makes recommendation with rationale for Board decision – confirmed by Panel Artifact: Decision Memorandum (TBD)
HITSP	Advise sponsor of decision, and if accepted, add initiative to public docket of HITSP work	Secretariat advises Artifact: Letter to Sponsor
Requestor/ HITSP	Appeal process	TBD
HITSP	Board assigns approved work item to TC	Artifact: Decision Memorandum
Program Mgt.	Coordinates TC work item and scope within overall project plans and schedules	Artifact: TC recruitment notification and updated Project Plan and Schedule
Result	<i>The HITSP, upon review, will determine the disposition of a Harmonization Request: authorized work item, deferred or declined.</i>	

### III. Detailed Process Steps . . .

## Process Step 1: *Harmonization Request*

Objective	<b><i>This step provides a formal entry point into the harmonization process that will be used by the stakeholder community to identify a need for an interoperability specification. It also provides the analysis required to categorize and prioritize the need and set a schedule to meet the need.</i></b>	
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Program Mgt.	Coordinates TC work item and scope within overall project plans and schedules	Artifact: TC recruitment notification and updated Project Plan and Schedule
Result	<b><i>The HITSP, upon review, will determine the disposition of a Harmonization Request: authorized work item, deferred or declined.</i></b>	

### III. Detailed Process Steps . . .

## Process Step 2: *Requirements Analysis*

Objective	<i>Produce testable Use Case derived requirements</i>	
Actor	Major Activities	Procedures and Artifacts
TC	Enumerate the scenarios of intrinsic diversity within a context for traceability	
TC	Identify Actors and Systems and document their roles, responsibilities, actions, options, and interactions for each context.	Includes specification of preconditions, triggers, primary and secondary flows, successful end condition(s) and fail end condition(s)
TC	Accept work item and schedule	
TC	Develop high level Functional Requirements Specification	Requirements Document listing unambiguous, testable requirements
Program Mgt.	Prepare standard document template and coordinate TC work	Template and standard diagram tools
Result	<i>Complete System Requirements Document to be used in all subsequent steps</i>	

### III. Detailed Process Steps . . .

## Process Step 3: *Identification of Candidate Standards*

<b>Objective</b>	<b><i>Identify Candidate standards to meet Use Case Requirements</i></b>	
<b>Actor</b>	<b>Major Activities</b>	<b>Procedures and Artifacts</b>
TC	Review UML process model with data flows and Functional Requirements	
TC	Based upon TC membership expertise and standard overview descriptions, develop list of Candidate Standards	List of Candidate Standards
Program Mgt.	Coordinate with appropriate SDOs for TC access to Candidate Standards	Letter to SDO(s) requesting access to standards.
Program Mgt.	Review Standard's SDO evaluation form	Request SDO update self evaluation if out of date (2 yrs old) (Ref TIER 2 SOP)
Program Mgt.	Provide TC access to Candidate Standards	Make available through SharePoint
<b>Result</b>	<b><i>Candidate Standards available for TC review</i></b>	

### III. Detailed Process Steps . . .

## Process Step 4: *Gaps and Overlaps Resolution*

<b>Objective</b>	<i>Identify standards that duplicate or overlap among candidate standards and identify gaps in standards</i>	
<b>Actor</b>	<b>Major Activities</b>	<b>Procedures and Artifacts</b>
TC	Develop an Evaluation Criteria Checklist	Using the UML Process model with data flows and the requirements specification, complete the HITSP evaluation criteria checklist. Artifact: Evaluation Criteria Checklist
TC	Evaluate candidate standards	Using the Candidate Standards fill out the Evaluation Criteria Checklist Artifact: Completed Evaluation Criteria Checklist
TC	Identify Gaps, Overlaps among Candidate Standards	Identified through analysis of the Evaluation Criteria Checklist
TC	Enter into discussion with SDOs about plans to resolve Gaps in standards or to integrate standards with other SDOs	MOU with and/or between SDOs
<b>Result</b>	<i>Agreements or process to reach agreement with SDOs to fill gaps and reduce and overlaps</i>	

### III. Detailed Process Steps . . .

## Process Step 5: *Standards Selection*

<b>Objective</b>	<i>Identify the best available standards to support the use case</i>	
<b>Actor</b>	<b>Major Activities</b>	<b>Procedures and Artifacts</b>
TC	Develop list of recommended standards that meet best meet selection criteria	Artifact: List of Recommended Standards
Program Mgt.	Submit List of Recommended Standards to HITSP Board	Artifact: Memorandum forwarding list to HITSP Board
<b>Result</b>	<i>A list of best available standards forwarded to HITSP for consideration/approval</i>	

### III. Detailed Process Steps . . .

## Process Step 6: *Construction of Interoperability Specification*

<b>Objective</b>	<i>Develop a specification identifying 'best practice' processes for consistent and efficient workflow (Process Interoperability)</i>	
<b>Actor</b>	<b>Major Activities</b>	<b>Procedures and Artifacts</b>
TC	Completes Interoperability Specification Template to document the problem, requirements, proposed solution and describes a roadmap for filling identified gaps in recommended standards. Document should identify processes for consistent and efficient workflow and if applicable addresses standards for secure reliable system connectivity.	Artifact: Interoperability Specification
Program Mgt.	Uses checklist to assure completeness of specification. Edits specification as appropriate.	
Program Mgt.	Coordinates production of the Interoperability Specification	
HITSP Board	Calls for pre-release peer review (Inspection Testing) from Panel Members	Artifact: HITSP Board Memorandum
<b>Result</b>	<i>An Interoperability Specification is produced for the Use Case</i>	



### III. Detailed Process Steps . . .

## Process Step 7: *Inspection Test*

Objective	<b><i>Conduct an Inspection/Test of the Interoperability Specification</i></b>	
Actor	Major Activities	Procedures and Artifacts
HITSP (Self Selected Reviewers SSR)	Reviewers separately inspect the Interoperability Specification to insure that each required event or action is fulfilled with a fully specified and unambiguously constrained standard.	Artifact: Test Form (check list)
HITSP (SSR)	Each reviewer submits test form results which are disseminated to the TC and all other reviewers	
SSR with TC	Meeting with TC to review findings	
TC	TC modifies Interoperability Specification as agreed with reviewers	Artifact: Modified Interoperability Specification
Program Mgt.	Facilitates review meeting(s) and performs final edit of document	Cross team edits for consistency
Program Mgt.	Coordinates production of revised Interoperability Specification	
HITSP Board	Directs release of the Interoperability Specification	Artifact: Release Memorandum
Result	<b><i>Critically peer inspected Interoperability Specification ready for release</i></b>	

### III. Detailed Process Steps . . .

## Process Step 8: *Interoperability Specification Release and Dissemination*

Objective	<i>Release Interoperability Specification for general use</i>	
Actor	Major Activities	Procedures and Artifacts
HITSP	Final review and approval of Interoperability Specification	
HITSP	Releases Interoperability Specification and makes available on Web Site	Interoperability Specification (electronic format)
HITSP	Prepares press releases announcing availability, scope or use and importance	
HITSP	Begin process of support	Open Issue: how will TC or staff will provide support, respond to questions?
HITSP	Begin process of maintenance and change management	Receive Harmonization Requests for modification
HITSP TBD	Triage requests (priority fix, planned enhancement or deferred)	
Program Mgt.	Coordinate release and support processes and documentation	
Result	<i>Interoperability Specification released for general use with ongoing support by HITSP</i>	

### III. Detailed Process Steps . . .

## Process Element 9: *Program Management*

<b>Objective</b>	<i>To manage program and staff to insure successful operation and support of HITSP</i>	
<b>Actor</b>	<b>Major Activities</b>	<b>Procedures and Artifacts</b>
Program Mgmt.	Manage HITSP operations and processes	HITSP Charter
Program Mgmt.	Cross TC Coordination	Joint TC Leadership Working Group
Program Mgmt.	Maintain HITSP artifacts and references	HITSP.org website
Program Mgmt.	Facilitate SDOs agreeing to work with HITSP to resolve gaps, overlaps and duplications	HITSP SDO agreements
Program Mgmt.	Manage interactions with external groups, such as the American Health Information Community, or the Certification Commission for Health Information Technology	Memoranda of Understanding
Program Mgmt.	Manage schedules, interim deliverables, status updates, issue triage, and other project management functions	Project Plans
Program Mgmt.	Solicit organizations to participate in the HITSP process as appropriate	
<b>Result</b>		

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## Planned Process Enhancements to the HITSP Harmonization Process

- ▶ The Project Management Team has identified other processes and artifacts for future development:
  - Process Review Board
  - Inspection Tests
  - Test Program
  - Configuration Change Management
  - Revise and Finalize Readiness Criteria
  - Interoperability Specification Fan-Out from Request
  - Unit of Analysis
  - SDO Agreements
  - Outsourcing or Franchising the HITSP Process

## Develop a Process Review Board

- ▶ A **Process Review Board** will be formed to manage change to the HITSP process
  - The Process Review Board will act as a decision body charged with the responsibility of maintaining and enhancing the HITSP process
  - The Process Review Board will develop methods to formally evaluate the HITSP process and its effectiveness
  - The Process Review Board will adopt a methodology for ratifying the process
- ▶ The Process Review Board's change management responsibilities are separate from the functions of Configuration Change Management, which is the maintenance and management of change to Interoperability Specifications

## Develop Inspection Tests

- ▶ **Inspection Tests** will be conducted by HITSP Stakeholders to evaluate an Interoperability Specification
  - The Inspection Test is a formal test by the HITSP stakeholders
  - The Inspection Test is structured in such a way that it will address specific topics, such as how well an Interoperability Specification meets technical and business requirements, selection criteria, completeness and unambiguous constraints for designated standards
  - The Inspection Test will result in a detailed reports from the stakeholders to the Technical Committees, the Technical Committees will evaluate the test results and make any necessary modifications to the Interoperability Specification(s) prior to release

## Develop a Test Program

- ▶ A **Test Program** will be implemented for external testing and feedback to the HITSP
  - Current planning is based on the premise that actual testing of instances of the implementations will not be conducted by, but coordinated with HITSP
  - The HITSP Harmonization Request specifies that the requesting organization must have a means to participate in an initial implementation of the resulting Interoperability Specification(s), which will provide a further test and validation
  - HITSP test coordination includes the development of test plans, test tools and test suites
  - HITSP envisions reaching agreements with testing organizations, such as NIST, IHE, CCHIT or others, to conduct tests of initial implementations, demonstrations and certifications
  - HITSP intends to provide self and third-party testing guidance as part of Interoperability Specification releases
  - HITSP will establish formal feedback channels for testing partners



## **Develop Change Management Processes to support and maintain Interoperability Specifications**

- ▶ **Change Management Processes** will be instituted to support and maintain Interoperability Specifications
  - Harmonization Requests act as the change request mechanisms for stakeholders to request modifications to or the replacement of an Interoperability Specification
  - Request for change may come from HITSP counterparts such as the Certification Commission for Health Information Technology as a result of their experiences with a HITPS product
- ▶ The Change Management Process will be further refined in the several months with the release of HITSP's first set of Interoperability Specifications test and release
  - Traditional change management techniques will be used such as capturing defects, enhancements, and methods for whole scale replacement Interoperability Specifications

## Revise and finalize Readiness Criteria

- ▶ Apply readiness criteria to candidate standards
  - First, and currently underway, the Technical Committees will evaluate the candidate standards for suitability, compatibility and preferred characteristics
  - Second, evaluate the standards development organization sponsoring the individual standards. The Readiness Committee will recommend that each standards development organization conduct a self evaluation against HITSP criteria.
  - Finally, it is recommended that the HITSP Board appoint a special committee to evaluate responses from SDOs and make recommendations to the Board and Panel concerning acceptability as a HITSP standards development partner

## **Develop a methodology for determining the number of Interoperability Specifications per Harmonization Request**

- ▶ Currently, there are multiple schools of thought regarding the level of granularity of an interoperability specification relative to the granularity of a harmonization request
  - One thought is to have an atomic unit of an inter-system transaction be the basis for a single Interoperability Specification
  - Another line of thinking advocates for a logical aggregation of such transactions to meet business objectives as a better approach to defining the scope of a single interoperability specification

## **Develop a Unit of Analysis that allows for the reuse of elements and a method for comparison for Interoperability Specifications**

- ▶ Technical Committees have identified methodologies for bundling actions that are used repeatedly in a specification or across specifications
  - Building Blocks or Integration Profiles have emerged as the preferred method for bundling like actions
  - While the Building Block provides a method for identifying and grouping like actions, there is a tension between specifying a unit of analysis generically enough to be reusable across contexts, versus making them specific or able to be tailored to a precise context
  - The requisite level of granularity is also at issue, for instance, what is the heuristic to consistently apply a prescribed level of granularity, and can it be universally applied and tested

## Develop an SDO Agreement

- ▶ One aspect of an SDO Agreement will be to provide HITSP with access to SDO material in support of various activities in the process lifecycle, but HITSP agreements with SDOs more generally will need to encompass aspects of the entire HITSP process lifecycle, as needed
  - Items requiring agreement/policy regarding SDO participation in the HITSP process are:
    - ▶ Access to standards
    - ▶ Balanced participation in Technical Committees
    - ▶ Agreement to resolve gaps
    - ▶ Joint standards development for overlap resolution
    - ▶ Adoption of HITSP constructs (e.g. – implementation guidance) to be maintained within SDO
    - ▶ Participation in HITSP change management
    - ▶ Incorporation of SDO intellectual property into HITSP artifacts
    - ▶ Configuration management coordination with HITSP

## Develop a plan for outsourcing or franchising the HITSP process

- ▶ Outsourcing or franchising the HITSP Process will increase HITSP's bandwidth and base of expertise
- ▶ Several discussions have been had about other groups taking on some tasks on behalf of HITSP for subsequent submission to HITSP for ratification. Some possible scenarios include:
  - The Federal Health Architecture initiative with HHS may perform the HITSP process across all agencies of the federal government to allow for federal priorities to move forward without conflicting with private-sector priorities
  - Credible industry associations or other entities may be commissioned to handle harmonization requests within their domain to hasten resolution
  - Organizations and initiatives, such as the ELINCS initiative, may augment its previous works to conform to HITSP specifications in order to submit such augmented work to HITSP for ratification as a formal Interoperability Specification
  - During the HITSP formative years, key organizations depending on the output of HITSP (e.g. – CCHIT) may advance some work for HITSP in order to meet their own objectives, and to help HITSP learn further lessons about the harmonization activity
- ▶ The mechanism of this kind of delegation of activity and the due diligence associated with ratification have yet to be detailed

**Thank you for your attention.**

- ▶ Discussion welcome.