

Standards Harmonization

Report to NCVHS

John D. Halamka MD, Chair

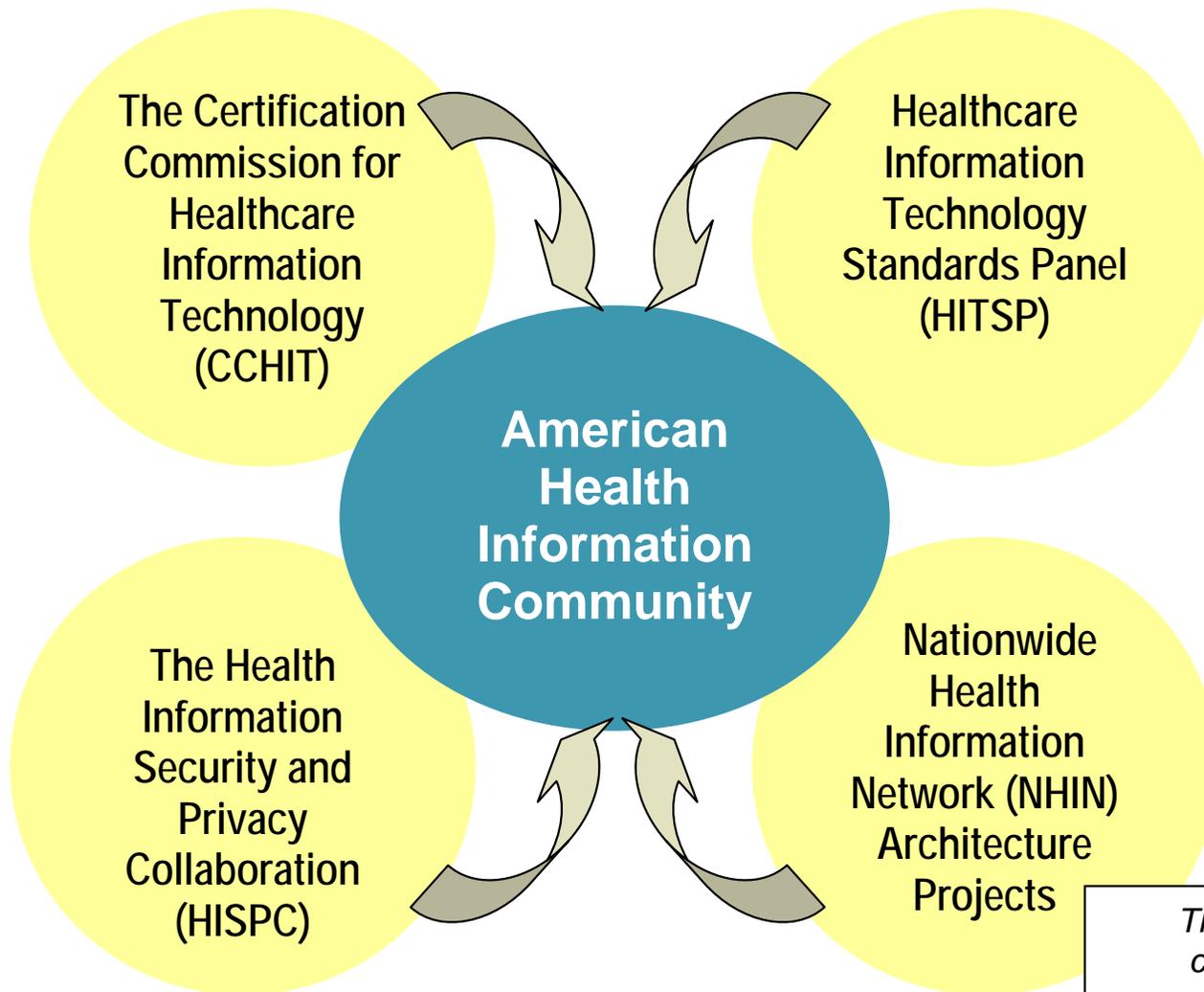
Contract HHSP23320054103EC



September 13, 2006



A public-private “Community” was established to serve as the focal point for America’s health information concerns and drive opportunities for increasing interoperability



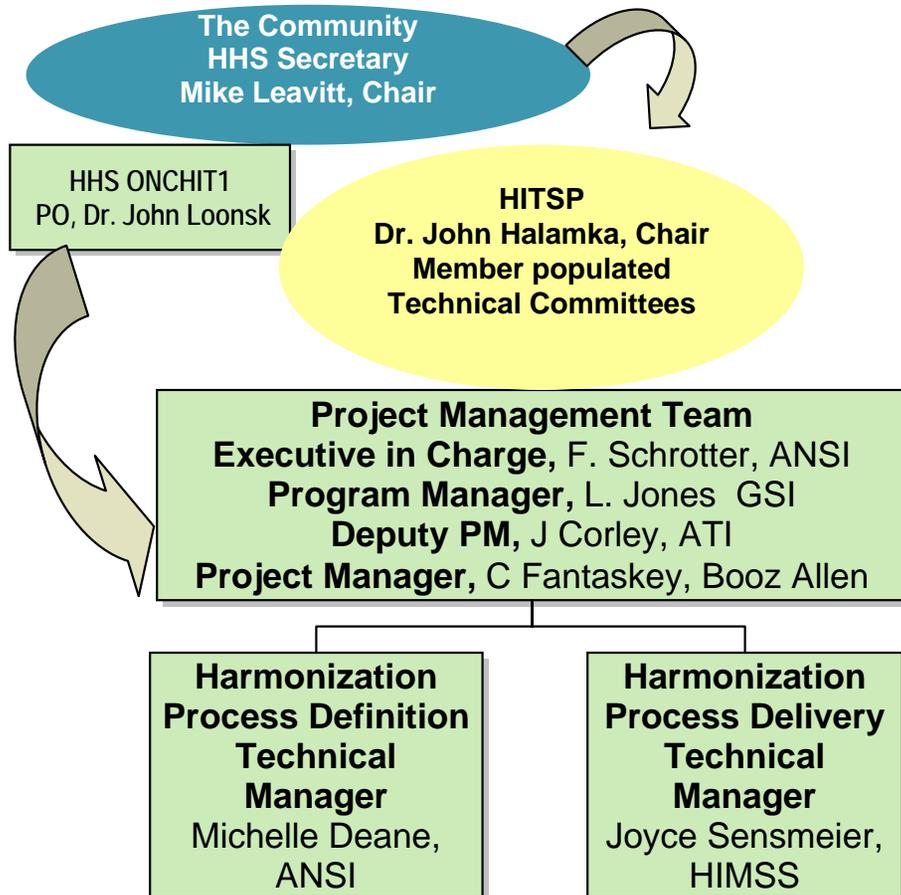
HITSP includes 206 different member organizations and is administered by a Board of Directors

- 17 SDOs (8%)
- 161 Non-SDOs (79%)
- 18 Govt. bodies (8%)
- 10 Consumer groups (5%)

The Community is a federally-chartered commission and will provide input and recommendations to HHS on how to make health records digital and interoperable, and assure that the privacy and security of those records are protected, in a smooth, market-led way.



The HITSP Project Team was charged with completing eleven tasks that focus on developing a harmonization process



Eleven Tasks are included in this contract:

1. Comprehensive Work Plan
2. Conduct a Project Start Up Meeting
3. Deliver Recommended Use-Cases
4. Participate in related meetings and activities, including the AHIC Meetings
5. Develop a Gap Analysis
6. Standards Selection, Evaluations and Testing
7. Define a Harmonization Approach
8. Develop Interoperability Specifications
9. Develop and Evaluate a Business Plan for the self-sustaining processes
10. Submit Monthly Reports – ongoing efforts
11. Assist with communications – ongoing efforts

Current Project Team Focus



HITSP Technical Committees Overview

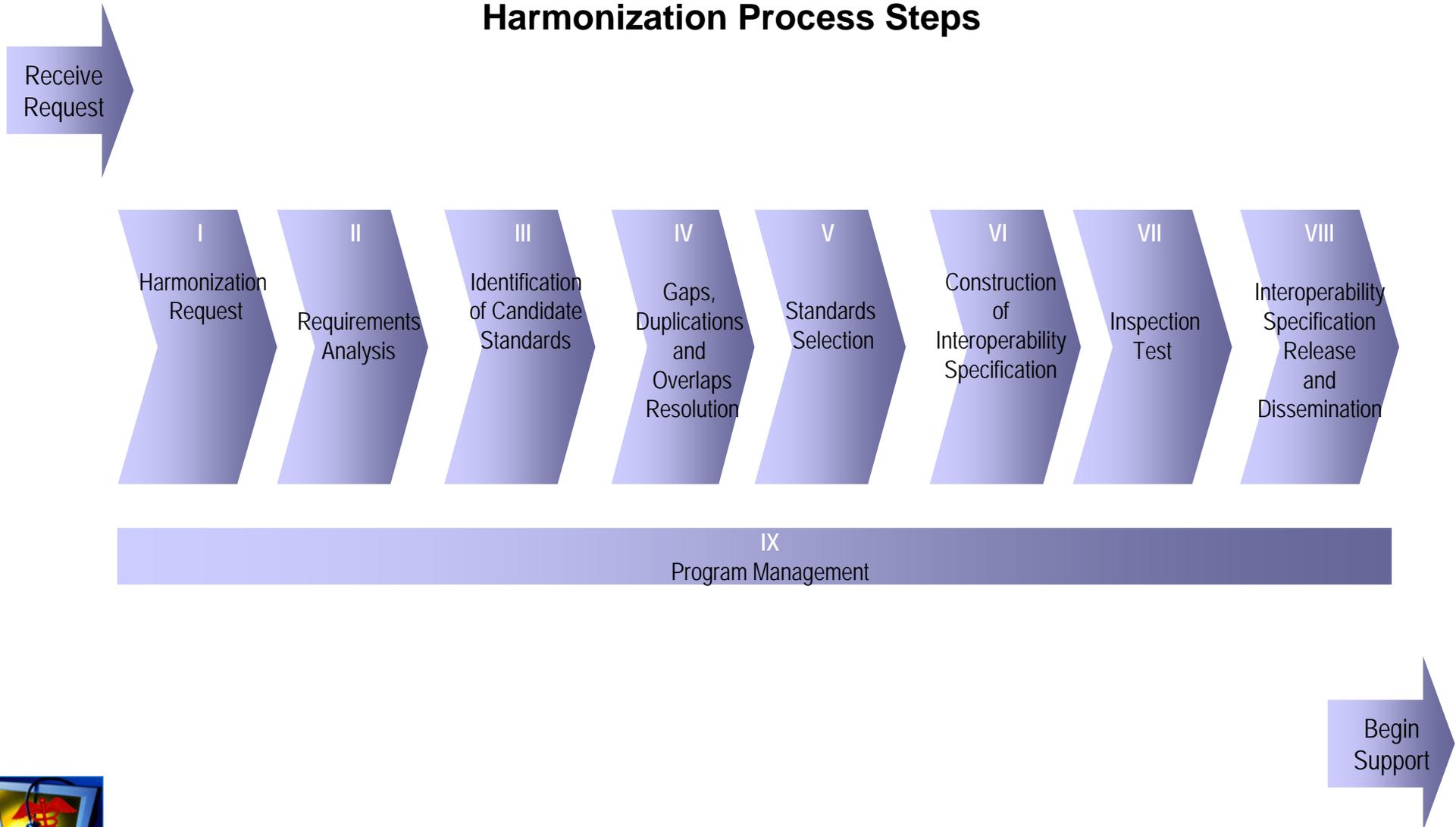
<p>Biosurveillance</p> <p><i>83 members *</i></p>	<p>Transmit essential ambulatory care and emergency department visit, utilization, and lab result data from electronically enabled health care delivery and public health systems in standardized and anonymized format to authorized Public Health Agencies with less than one day lag time.</p>	<ul style="list-style-type: none"> ▪ Floyd P. Eisenberg, MD MPH, SIEMENS Medical Solutions Health Services ▪ Peter L. Elkin MD FACP, Mayo Clinic College of Medicine ▪ Shaun Grannis, MD, The Regenstrief Institute, Indiana University School of Medicine
<p>Consumer Empowerment</p> <p><i>79 members *</i></p>	<p>Allow consumers to establish and manage permissions access rights and informed consent for authorized and secure exchange, viewing, and querying of their linked patient registration summaries and medication histories between designated caregivers and other health professionals.</p>	<ul style="list-style-type: none"> ▪ Elaine A. Blechman PhD, Professor, Univ. of Colorado-Boulder ▪ Charles Parisot, EHR Vendor Association
<p>Electronic Health Record</p> <p><i>98 members *</i></p>	<p>Allow ordering clinicians to electronically access laboratory results, and allow non-ordering authorized clinicians to electronically access historical and other laboratory results for clinical care.</p>	<ul style="list-style-type: none"> ▪ Jamie Ferguson, Kaiser-Permanente ▪ John Madden, MD, PhD, SNOMED Intl ▪ Steve Wagner, Department of Veterans Affairs

***Represents more than 12,000 volunteer hours**



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

Harmonization Process Steps



Tier 1 Standards Readiness Criteria



- ▶ The standards required to support each major Use Case event were organized within an agreed upon standards taxonomy
- ▶ The standards selected for inclusion in the pool were examined using 'HITSP approved' Tier 1 and Tier 2 Harmonization Readiness Criteria



Tier 2 Standards Readiness Criteria

- ▶ Suitability

- The standard is named at a proper level of specificity and meets technical and business criteria of use case

- ▶ 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

- ▶ Preferred Standards Characteristics

- Approved standards, widely used, readily available, technology neutral, supporting uniformity, demonstrating flexibility and international usage are preferred

- ▶ Standards Development Organization and Process

- Meet selected criteria including balance, transparency, developer due process, stewardship and others.

- ▶ Total Costs and Ease of Implementation

- Deferred to future work



HITSP Process

- ▶ HITSP process is open and transparent
- ▶ TC rosters are maintained and posted on ANSI SharePoint Portal
- ▶ Meetings and Conference calls are announced via ANSI list serves
- ▶ Meeting attendance is recorded and posted on ANSI SharePoint Portal
- ▶ List serve messages are archived and posted on ANSI SharePoint Portal
- ▶ Minutes are recorded and posted on ANSI SharePoint Portal
- ▶ Technical documents are version controlled and posted on ANSI SharePoint Portal
- ▶ Deliverables are posted on ANSI SharePoint Portal
- ▶ Consensus process is used to success for majority of TC decisions
- ▶ Voting process is used only when consensus process failed
- ▶ When voting is used, a Quorum is 50% of voting TC members e.g. regularly participating institutional representatives
- ▶ 66% of those casting a vote must agree for a vote to pass
- ▶ One vote is allowed per institutional member “representative on record” or regular participant

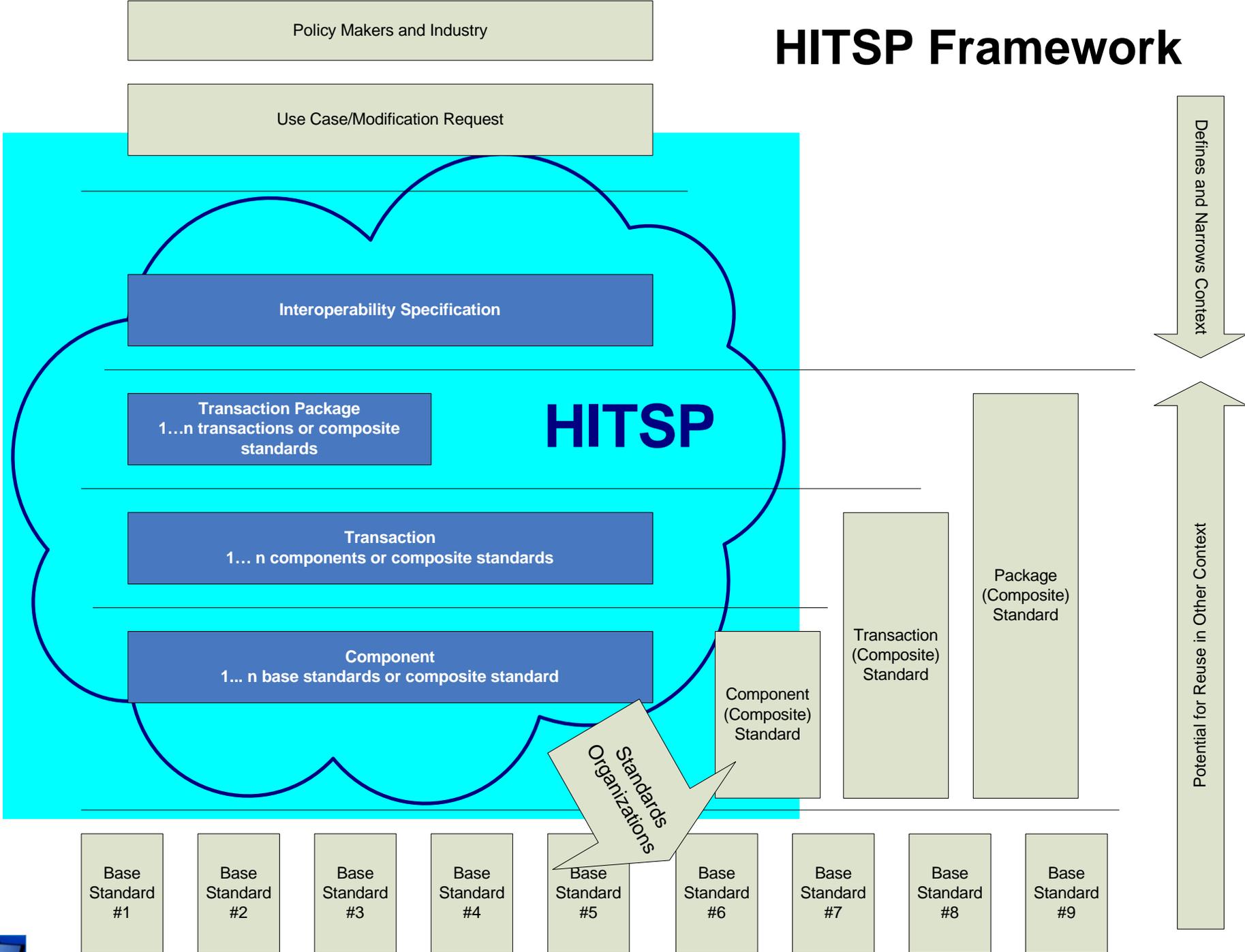


HITSP Deliverables Schedule

Activity	Description of Activity	Responsible	Dates
Draft Interoperability Specifications	Technical Committees meet to finalize the draft IS for inspection testing	TCs & Performance Team	July 5 – August 17 COB August 18 – Project team
Panel Review I: Comment and/or Inspection Test of IS	Interoperability Specification is reviewed and inspection tested by the HITSP Panel and public	Design Team Lead Posts, Performance Team manages comments	August 18 - 30
Update I: Address Comments from Review / Inspection Test	Technical Committees update Interoperability Specifications	TCs & Performance Team	August 31 – September 12
Panel Review II: Review and comment of IS updates	Posted to HITSP.org and review and comment thru the 19 th – comment review period closes the 20 th	Design Team Lead Posts, Performance Team manages comments	September 13 – 19
Panel Approval: Approval IS	HITSP Panel Reviews/Approves IS	Panel	September 20
Update II: TCs Finalize Interoperability Specifications	TC's update IS based on panel comments	TCs & Performance Team	September 21 – 25 COB
Finalize Interoperability Specifications	Project team finalizes IS for delivery to ONC	Project Management Team	September 26 – 28 COB
Deliver Interoperability Specifications	SOW Ref # 9	Project Management Team	Friday, September 29, 2006



HITSP Framework



Definitions and Rules

Level	Definition	Example	Rules
Use Case or Harmonization Request	<ul style="list-style-type: none"> ▪ Defines business/functional requirements ▪ Sets Context 	<ul style="list-style-type: none"> ▪ ONC Harmonized EHR Use Case 	
Interoperability Specification	<ul style="list-style-type: none"> ▪ 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 	<ul style="list-style-type: none"> ▪ HITSP EHR Interoperability Specification 	<ul style="list-style-type: none"> ▪ Based on UML diagram to identify technical actors and actions ▪ Sets context ▪ Testable functional requirements ▪ Ids transactions or transaction packages
Transaction Package	<ul style="list-style-type: none"> ▪ Defines how two or more transactions are used to support a stand-alone information interchange within a defined context between two or more systems 	<ul style="list-style-type: none"> ▪ Record Locator Service ▪ Entity Identification Service 	<ul style="list-style-type: none"> ▪ 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	<ul style="list-style-type: none"> ▪ Logical grouping of actions, including necessary content and context, that must all succeed or fail as a group. 	<ul style="list-style-type: none"> ▪ Query lab result ▪ Send lab result 	<ul style="list-style-type: none"> ▪ Fulfills all actions between two or more systems needed to meet one or more interoperability requirements ▪ Testable ▪ May be fulfilled by components or composite standard ▪ Expresses constraints on components or composite standard

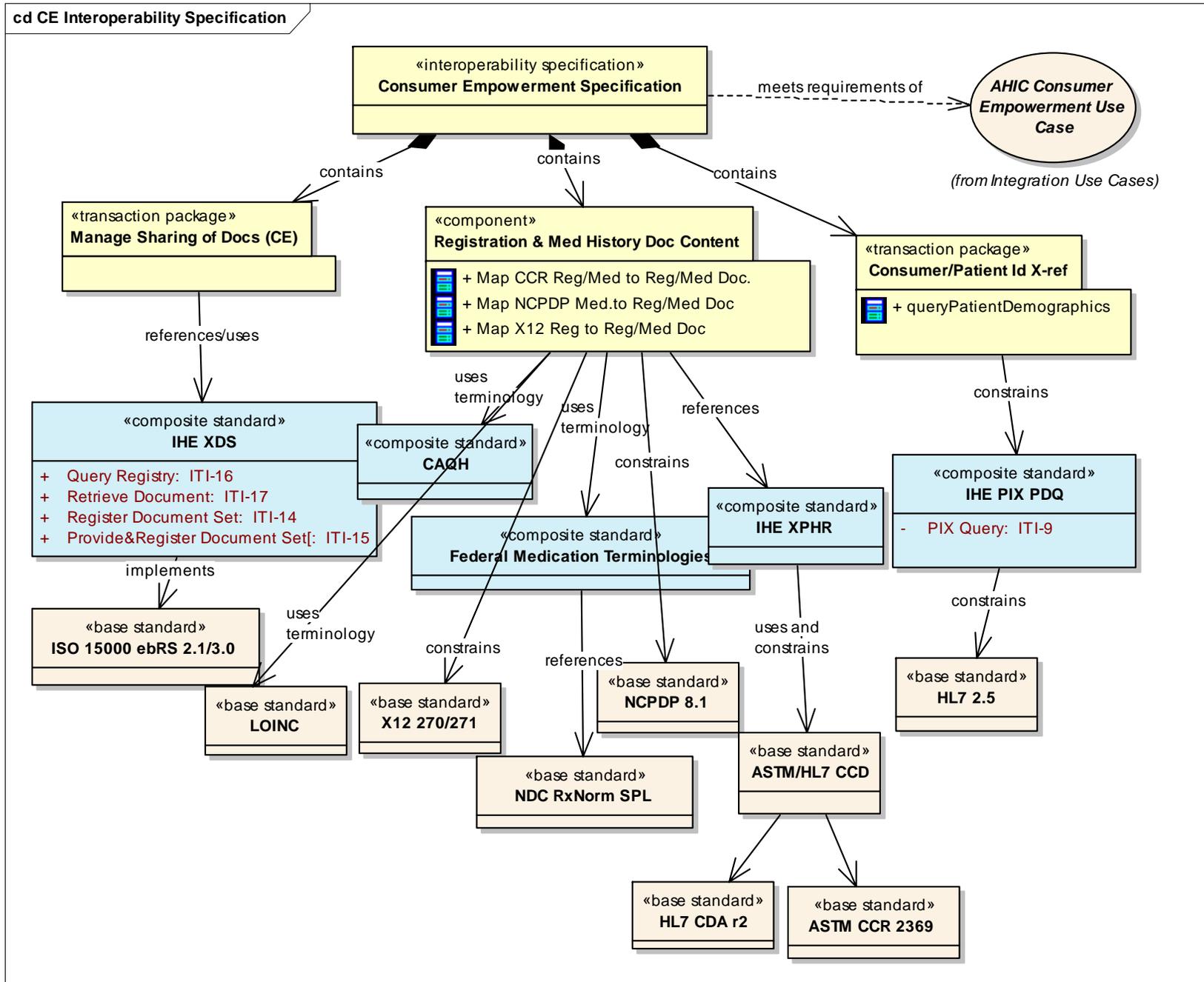


Definitions and Rules (cont.)

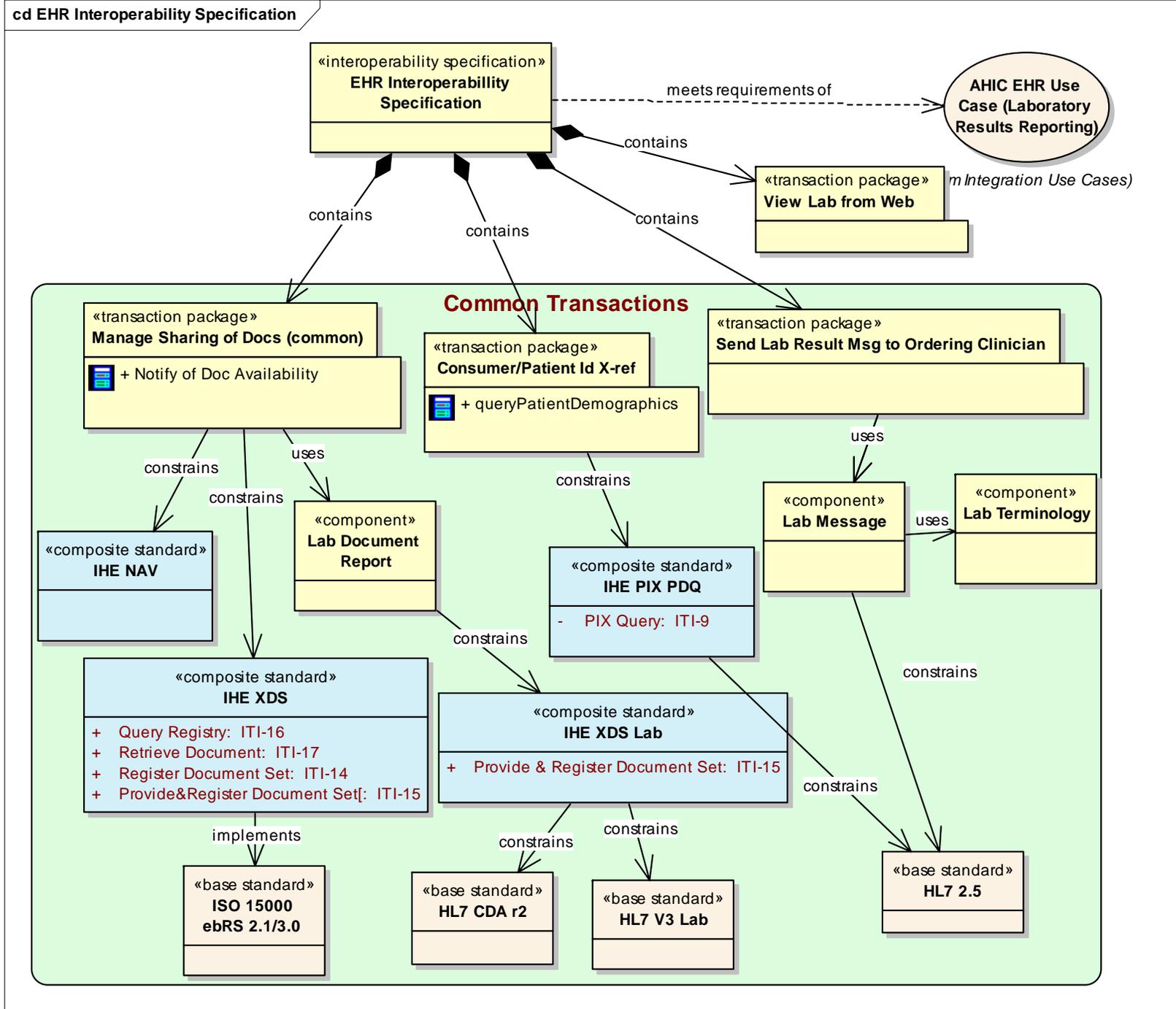
Level	Definition	Example	Rules
Component	<ul style="list-style-type: none"> An atomic construct used to support an information interchange or to meet an infrastructure requirement (e.g., security, logging/audit) 	<ul style="list-style-type: none"> Lab result message Lab result context 	<ul style="list-style-type: none"> Typically will use one “primary” standard and may have other “secondary” standards Expresses constraints on base or composite standards
Base Standard	<ul style="list-style-type: none"> A standard capable of fulfilling a discrete function within a single category produced and maintained by a single standards organization. 	<ul style="list-style-type: none"> Messaging standard Security standard Code set. 	<p>Per HITSP definition the term “standard” refers, but is not limited to,:</p> <ul style="list-style-type: none"> – Specifications – Implementation Guides – Code Sets – Terminologies – Integration Profiles
Composite Standard	<ul style="list-style-type: none"> 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.. 	<ul style="list-style-type: none"> Integration profiles Implementation guides Health transaction services 	<p>Per Definition above</p>



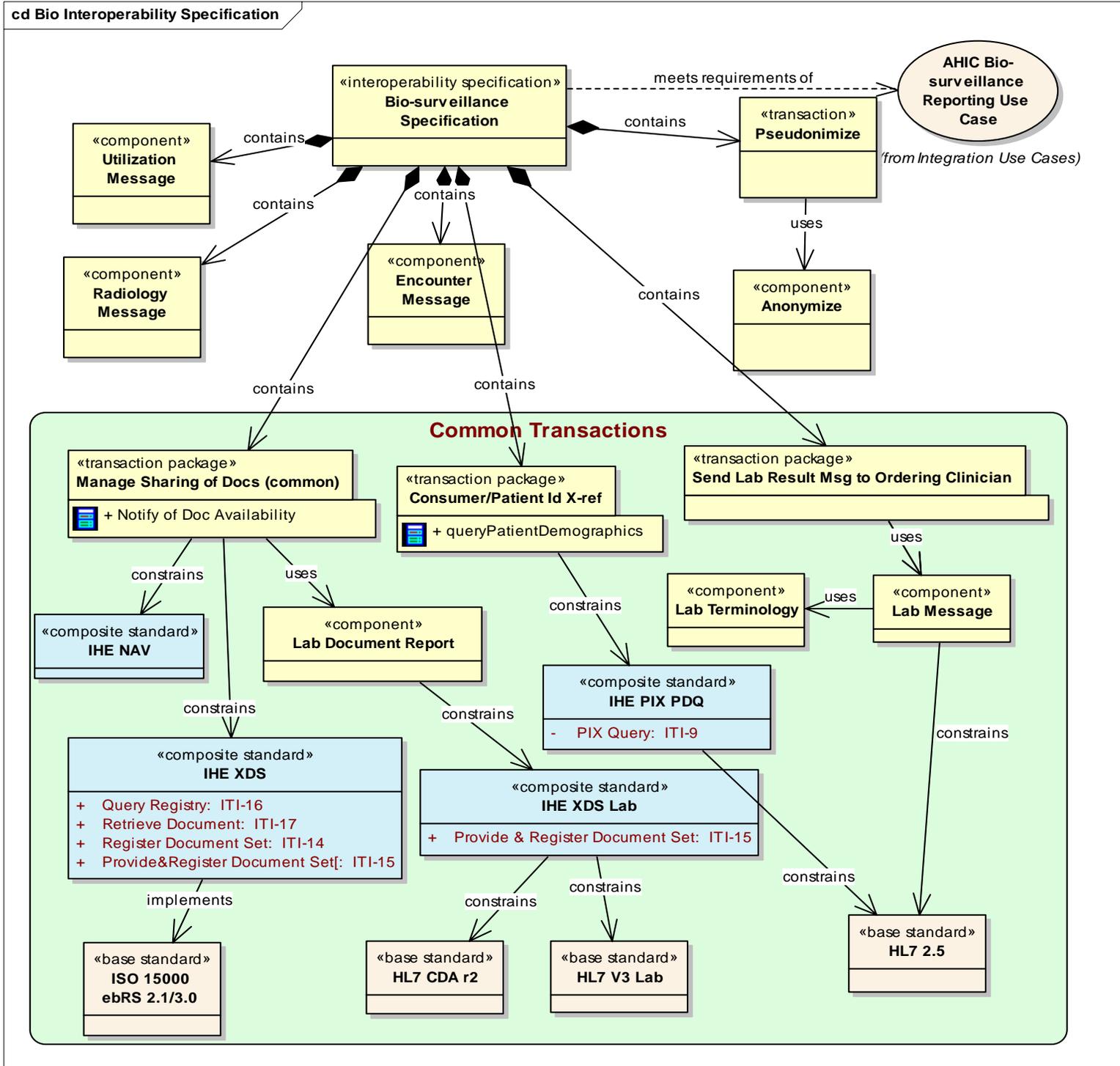
Consumer Empowerment Technical Committee Recommendations



Electronic Health Record Technical Committee Recommendations



Biosurveillance Technical Committee Recommendations



Testing and evaluation schedule

Activities	August											
	18	21	22	23	24	25	26	27	28	29	30	31
Phase 2												
Receive Testing Package	▲											
Testing Period												
Testing Period Kick-off		★										
Mid-Point Telecon					★							
EHR IS Walkthrough Telecon									★			
BIO IS Walkthrough Telecon										★		
CE IS Walkthrough Telecon											★	
End-Point Telecon												★



- ▲ Key Deliverable
- ★ Key Meeting

The purpose of the inspection test was to ensure that Interoperability Specifications meet the following objectives

✓ Conforms to Style and Editorial Guidelines	<ul style="list-style-type: none">➤ Ensure the integrity of document pieces – that all the cascading documents are present➤ Validate grammar, spelling, and consistency of terminology➤ Validate that it follows the style guide for text and graphics
✓ Contains Accurate References and Data	<ul style="list-style-type: none">➤ Validate the references to other documents and data sources are valid and that data in tables is accurate.
✓ Meets Use Case Requirements	<ul style="list-style-type: none">➤ Validate that the IS when implemented will meet the specific requirements as defined in the use case
✓ Is Technically Valid	<ul style="list-style-type: none">➤ Check the specification to determine the existence of the following:<ul style="list-style-type: none">• Ambiguities/ lack of specificity• Inconsistencies• Gaps and overlaps• Testability• Completeness• Internal consistency• Ability to implement



Test results indicate an overall positive response

IS	# Testers	Worksheet	# Responses*	# Y (and %)	# N	# Comments**
EHR	10	▶ Technical Validity	337	201 (60%)	90	78
		▶ Interoperability Requirements	132	118 (89%)	3	26
		▶ Editorial Comments	105			49
BIO	8	▶ Technical Validity	138	84 (61%)	37	68
		▶ Interoperability Requirements	64	49 (77%)	13	41
		▶ Editorial Comments	341			75
CE	8	▶ Technical Validity	72	26 (36%)	42	53
		▶ Interoperability Requirements	123	89 (72%)	29	52
		▶ Editorial Comments	105			34

*Note: # Y and # N do not add up to the # Responses because in some cases the test result field (Y or N) for a question was left blank.

**Note: The testers were asked to enter a comment for each N answer, however # Comments does not match up to the #N.

- In some cases testers did not provide comments for N
- In some cases testers provided comments for Y
- In some cases testers provided comments for blank



Test results indicate an overall positive response (continued)

Shared documents

Document	# Testers	# Responses*	# Y (and %)	# N	# Comments**
▶ ISTP-13 Manage Sharing of Docs	14	63	50 (79%)	6	22
▶ ISTP-14 Send Lab Result Message	12	55	45 (82%)	7	16
▶ IST-22 Patient ID Cross Referencing	14	97	47 (48%)	29	60
▶ IST-23 Patient Demographics Query	14	71	50 (70%)	7	35
▶ IST-29 Notification of Lab Report Availability	11	44	40 (91%)	4	7
▶ ISC-35 EHR Lab Terminology	12	29	17 (59%)	10	14
▶ ISC-36 Lab Report Message	13	41	20 (49%)	17	23
▶ ISC-37 Lab Report Document Structure	14	34	21 (62%)	12	14
▶ ISC-39 Encounter Message	5	10	9 (90%)	1	2
▶ ISC-45 Acknowledgements	11	24	22 (92%)	1	7

*Note: # Y and # N do not add up to the # Responses because in some cases the test result field (Y or N) for a question was left blank.

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The team received 704 informal comments from 45 members of the Panel or public at large

- ▶ Inspection Test drafts were posted to the public website to encourage review prior to the formal public comment period
- ▶ Comments were reviewed and categorized
- ▶ Technical Committees were provided with all the public comments
 - Many mapped to the defects identified during Inspection Testing
 - All were used to inform the Technical Committees as they addressed defects

Type of Comment	Number	Description
▶ Mechanics	300	Mechanics of presenting the technical content – from typos to overall document organization
▶ Content	200	Pertaining to the selection of standards and other technical content
▶ Approach, Choice of Standards, Process	200	Of the 200 – 120 are “barriers to adoption” including <ul style="list-style-type: none"> – Excludes someone - small organizations, non-providers, etc (12) – Something already exists/is in place; cost of change (36) – Assumes what's not available/balloted (37) – Process is flawed (2) – Various - bad fit, architecture, optionality, CLIA, etc (23)



Summary

- ▶ We had over 50 volunteers to inspection test the three Interoperability Specifications
- ▶ We had a series of 5 teleconference/Netspoke sessions
- ▶ HITSP has collated the test results into three spreadsheets (technical validity, interoperability requirements met and editorial) for each Technical Committee
- ▶ They were reviewed by the Technical Committees at face to face meetings September 6 – 9 in Washington
- ▶ The TCs made necessary corrections and the revised documents have been posted for the Panel's formal comments (September 13 – 20)
- ▶ The HITSP project team will reconcile disposition by TC to the test worksheets and post results for testers
- ▶ The HITSP will be asked to approve the Interoperability Specifications at its September 20 meeting in Washington
- ▶ Any final revisions based on the Panel's instructions will be made prior to formal release and delivery to ONC on September 29

