Certification Commission
for Healthcare
Information Technology

Overview of CCHIT: Organization, Process, and Current Status

Presentation to the Healthcare Information Technology Standards Panel (HITSP)

Mark Leavitt, MD, PhD
Chair, CCHIT
HITSP Panel Meeting – May 4, 2006 – Arlington, VA

Topics

- Background
- Organization
- Scope, Timeline, Processes
- Current Status of Work
- Discussion / Q & A

Certification Commission
for Healthcare
Information Technology

Background

History

- July 2004: Certification of HIT products a key action in HHS Strategic Framework
- Sept 2004: AHIMA, HIMSS, and the Alliance fund and launch CCHIT
- June 2005: Eight additional organizations add $325k funding support
- July 2005: HHS issues Health IT RFPs
- Sept 2005: CCHIT awarded 3 year, $7.5M HHS contract to develop compliance criteria and inspection process for EHRs and the networks through which they interoperate

Mission of CCHIT

To accelerate the adoption of robust, interoperable health IT by creating an efficient, credible and sustainable product certification program.

Goals of Product Certification

- Accelerate adoption by reducing the risks of investing in HIT
- Facilitate interoperability of HIT products within the emerging national health information network
- Enhance availability of HIT adoption incentives and relief of regulatory barriers
- Ensure that HIT products and networks always protect the privacy of personal health information

Stakeholders

Private Sector

- Providers
- Vendors
- Payers/purchasers
- Standards Development Organizations
- Quality Improvement Organizations
- Researchers
- Consumers

Public Sector

- HHS/ONC
- HHS Contractors
- Safety Net Providers
- Public Health
- Federal agencies
  - CMS, VHA, NIST, CDC, DoD, DHS, DoC, NSF, GSA, EPA and others

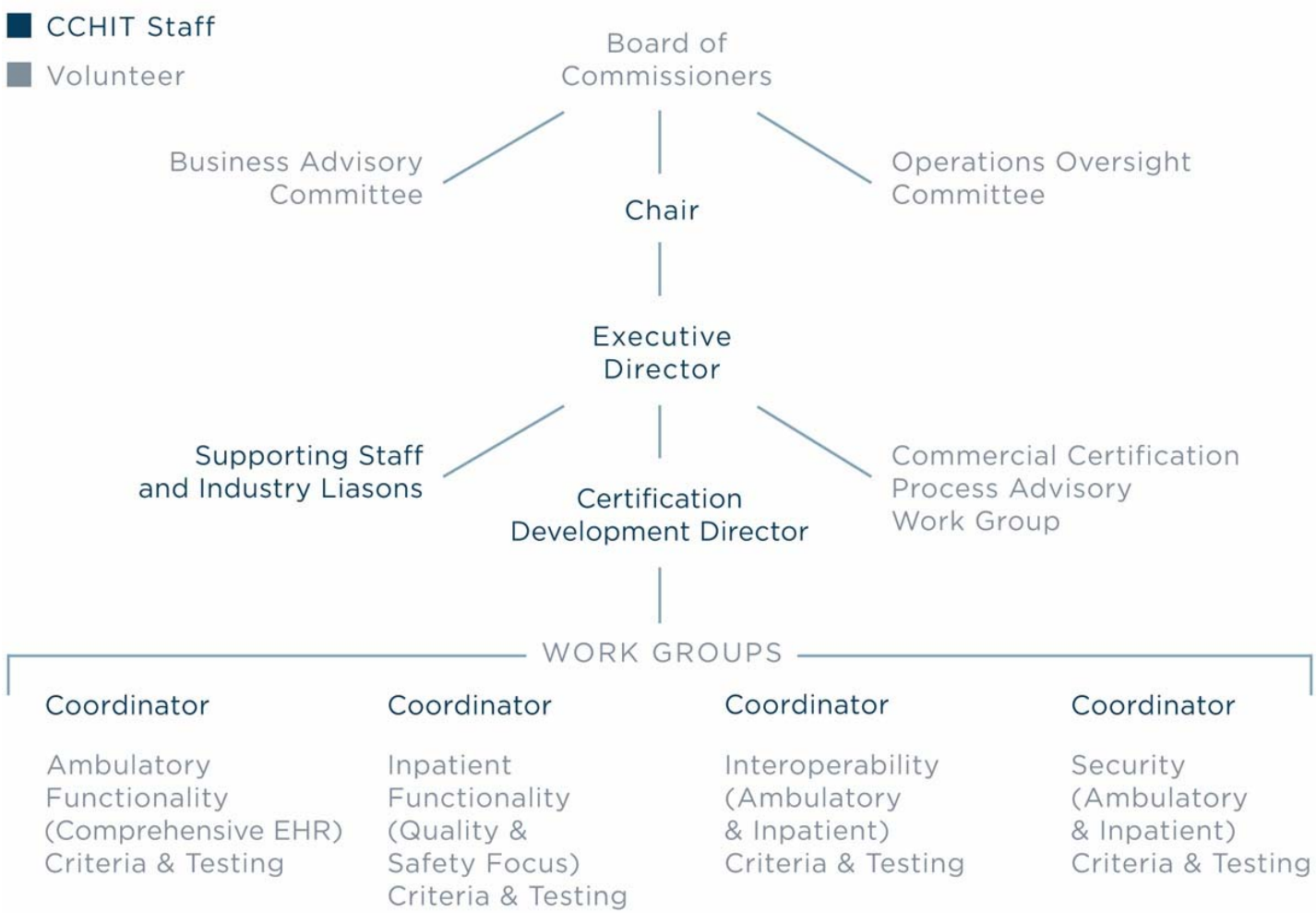
Guiding Principles

- Always protect the privacy of the patient/ consumer's health information
- Need for decisive private-sector action now
- Governance must be credible, objective, and collaborative
- Seek input and deliver compelling value for all key stakeholders
- Inspection process must be objective, fair, reliable, repeatable
- Certification must be efficient, timely, and cost-effective

Certification Commission
for Healthcare
Information Technology

Organization

CCHIT Organization



Ensuring Fairness, Transparency, and Credibility

- Structure
  - Commission
    - Open call for participation
    - At least two from provider, payer, and vendor stakeholder groups
    - At least one from each of seven other stakeholder groups
  - Workgroups
    - Open call for participation
    - Two co-chairs from different stakeholder groups
    - Members represent balance and diversity of stakeholders
- Policies and Processes
    - Rigorous conflict of interest disclosure policy
    - Minutes of all meetings published on CCHIT website
    - Work products published for Public Comment after each step
    - All comments reviewed and responses published
- Communication
    - Town Halls – open forum at major conferences
    - Town Calls – teleconferences with Q & A; open to all
    - Specific outreach to stakeholder groups

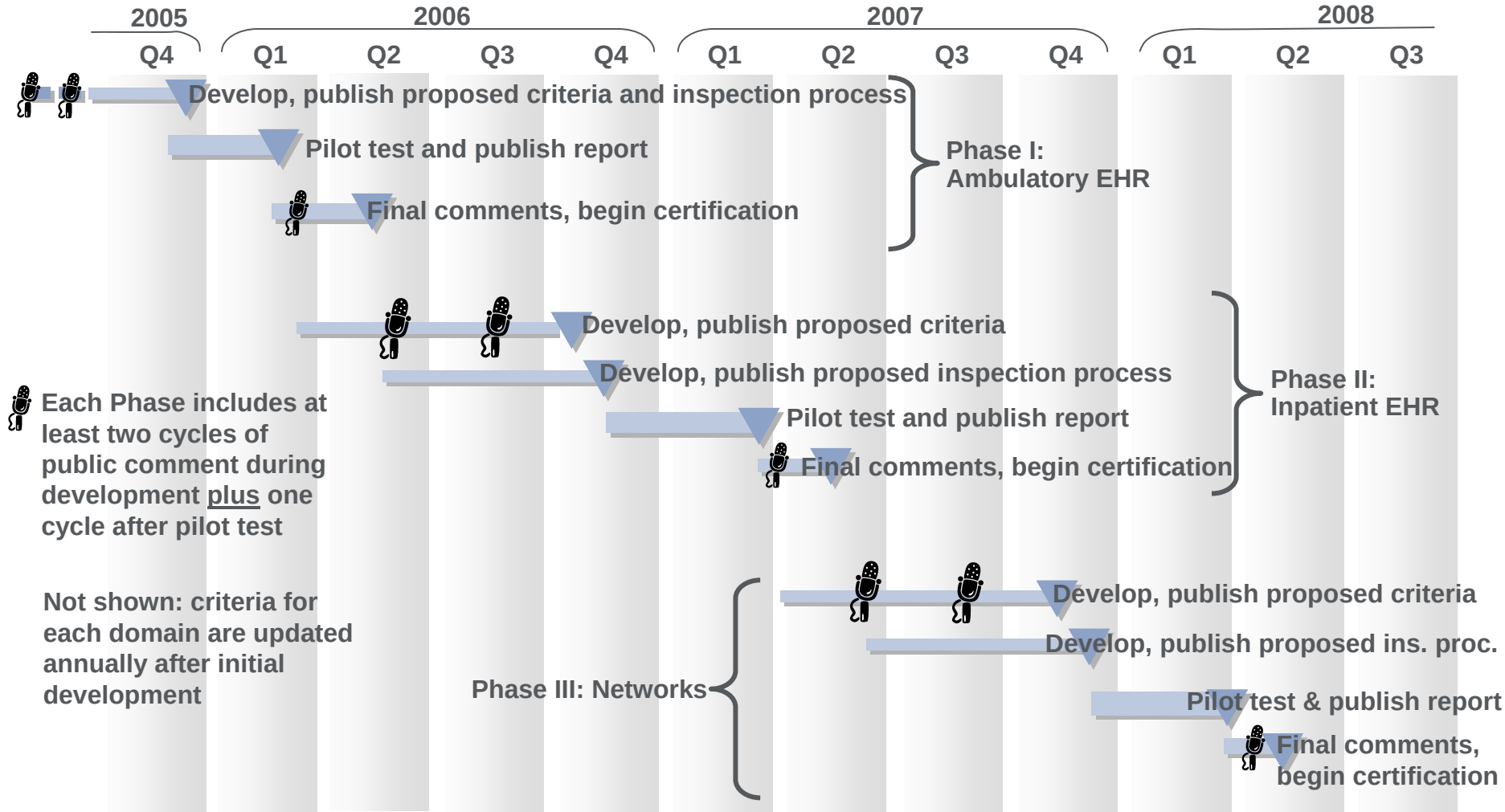
Certification Commission
for Healthcare
Information Technology

Scope, Timeline, Processes

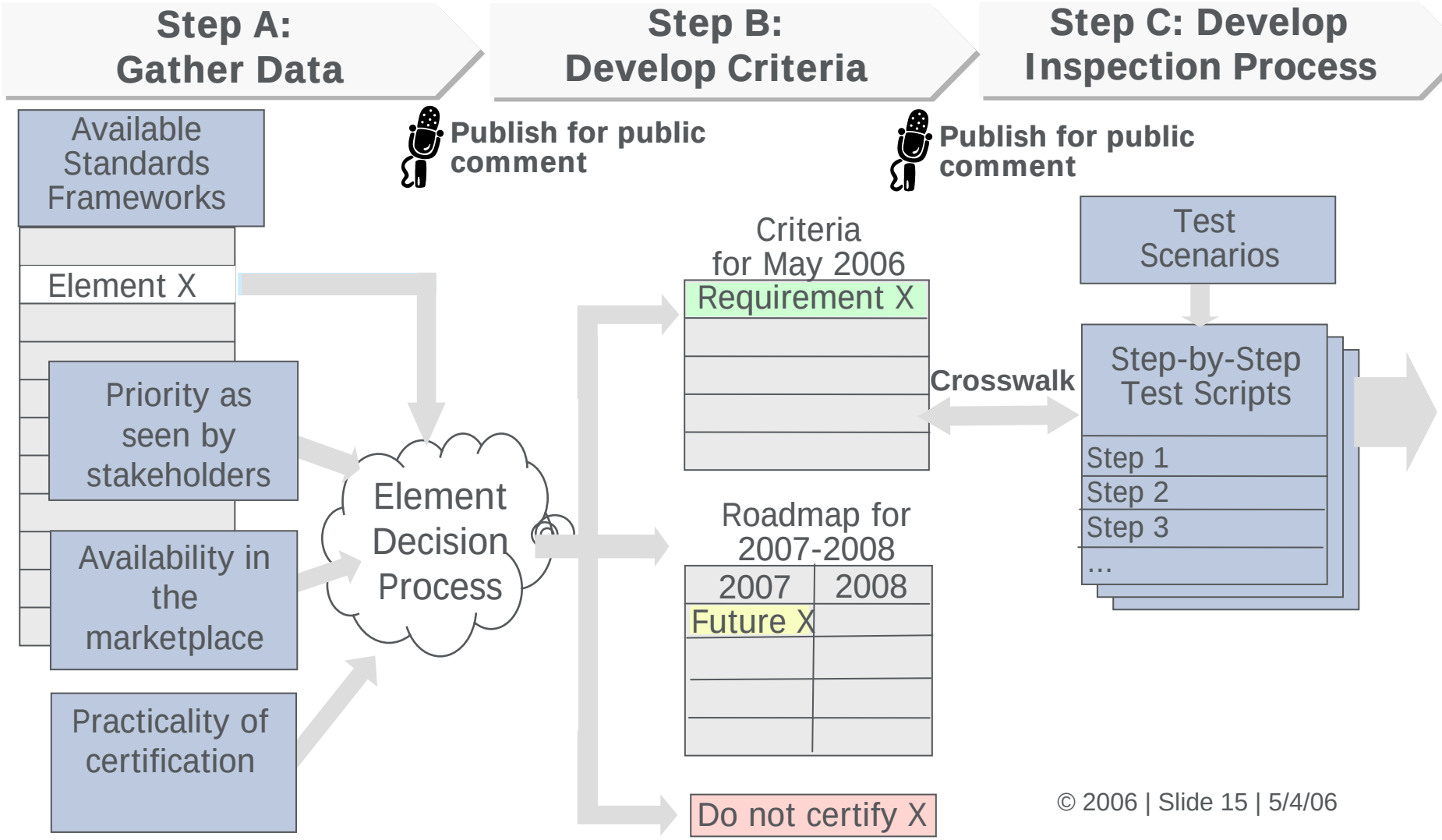
Scope of Work Under HHS Contract

- Phase I (Oct 05 – Sep 06)
  - **Develop, pilot test, and assess certification of EHR products for ambulatory care settings**
- Phase II (Oct 06 – Sep 07)
  - **Develop, pilot test, and assess certification of EHR products for inpatient care settings**
- Phase III (Oct 07 – Sep 08)
  - **Develop, pilot test, and assess certification of infrastructure or network components through which EHRs interoperate**

Timeline of Activities and Deliverables



Development Process



Development Process

Step D: Pilot Test

Step E: Finalization

Launch Certification Program

Call for Pilot Participation

Random Selection of Participants within each Market Segment

Conduct Pilot Tests

Refine Test Process and Scripts as Needed

Publish for public comment

Publish for Comment:

- Pilot Results
- Final Criteria
- Final Test Process
- Final Test Scripts
- Certification Handbook and Agreement

- Respond to New Comments
- Final Adjustments
- Review & Approval by Commission
- Publish Final Version of all Materials

Certification Commission
for Healthcare
Information Technology

Current Status of Work

Functionality Criteria: Recap of the Development Process and Pilot Test Results

- Criteria are all based on HL7 DSTU for Ambulatory EHR
- Criteria vetted and refined through:
  - Two cycles of Public Comment (5/2005, 8/2005)
  - Pilot Testing with six different ambulatory EHR products
  - Final cycle of Public Comment (3/2006)
- Of the **264** Criteria:
  - **245** fully validated by Pilot Test and stable since publication in 11/2005
  - **12** revised with minor wording changes
  - **6** classified Provisional
  - **1** was deleted

Sample Document: **Functionality Criteria**

Final Criteria: FUNCTIONALITY
For 2006 Certification of Ambulatory EHRs
Effective May 1, 2006

Note:
Items highlighted in yellow are Provisional for 2006 (see cover letter)

Original line # Phase I	WG	Category and Description	Specific Criteria	Source or References	Priorities (L,M,H)					Availability			Compliance			
					Providers	Vendors	Payers or Purchasers	Public Health	Patient	2006	2007	2008	Certify in May 2006	Roadmap for May 2007	Roadmap for May 2008 and beyond	
1	F	**Identify and maintain a patient record:** Key identifying information is stored and linked to the patient record. Both static and dynamic data elements will be maintained. A look up function uses this information to uniquely identify the patient.	1. The system shall create a single patient record for each patient.	DC.1.1.1	H	H	H	H	H	H			X			
2			2. The system shall associate (store and link) key identifier information (e.g., system ID, medical record number) with each patient record.	DC.1.1.1	H	H	H	H	H	H			X			Key identifier information must be unique to the patient record but may take any system defined internal or external form.
3			3. The system shall store more than one identifier for each patient record.	DC.1.1.1	H	H	M	H	M	H			X			For interoperability, practices need to be able to store additional patient identifiers. Examples include an ID generated by an Enterprise Master Patient Index, a health plan or insurance subscriber ID, regional and/or national patient identifiers if/when such become available.
4			4. The system shall use key identifying information to identify (look up) the unique patient record.	DC.1.1.1	H	H	H	H	H	H			X			
5			5. The system shall provide more than one means of identifying (looking up) a patient.	DC.1.1.1	H	H	H	H	H	H			X			Examples of identifiers for looking up a patient include date of birth, phone number.
6			6. The system shall provide a field which will identify patients as being exempt from reporting functions.	DC.1.1.1									X			Examples include patients who are deceased, transferred, moved, seen as consults only. Being exempt from reporting is not the same as de-identifying a patient who will be included in reports. De-identifying patients for reporting is addressed in the "Health record output" functionality.
7			7. The system shall provide the ability to merge patient information in a controlled method when appropriate.	DC.1.1.1								X			X	If a duplicate chart is created, information could be merged into one chart.

Roadmap columns forecast future criteria

Provisional Criteria are in yellow

Interoperability Criteria: Recap of the Development Process

- Challenges
  - Workgroup noted existence of conflicting/competing standards, missing implementation guides, and other gaps
- Criteria were developed and vetted:
  - Two cycles of Public Comment (5/2005, 8/2005)
  - Proposed Criteria and Roadmap published Nov 2005
  - Final cycle of Public Comment (3/2006)
- Intervening events:
  - ANSI-HITSP launched Oct 2005
  - AHIC Breakthrough Use Cases released March 2006
- Status
  - ePrescribing and Lab Result Receiving criteria originally on Roadmap for Sept 2006 moved to May 2007 Roadmap
  - Interoperability Workgroup tasked with supporting the AHIC Breakthrough Use Cases
  - Also urgent to include eRx and Lab criteria in Nov/Dec 2006 Pilot Test

Sample Document: **Interoperability Criteria**

Final Criteria: INTEROPERABILITY
For 2006 Certification of Ambulatory EHRs
Effective May 1, 2006

Line #	WG	Category and Description	Specific Criteria	Source or References	Compliance: Certify in May 2006	Compliance: Roadmap for May 2007	Compliance: Roadmap for May 2008 and beyond	Comments
1	I	Laboratory and Imaging	Receive lab results (no specified format) – self attestation		x			
2			Receive general laboratory results using common vocabulary with inbound interface optionality removed	ELINCS 1.0 or later version		x		CCHIT will specify the standard, implementation guide and versions that will be required for interoperability certification requirements. CCHIT will align certification with HITSP standards recommentations.
3			Send orders to lab systems	HL7 V2.5 avail. now; LOINC test naming avail now; Implementation Guide in dev.		x		Complete order must be defined (minimum dataset). There is no good definition for a minimum data set for an order message.
4	I		(1) Create and share sets of digital medical images managed by PACS (2) create and share imaging reports like EKGs (3) web access to digital medical images and reports from EHRs	DICOM avail. Now IHE Cross-Enterprise Image Information Sharing integration profile (Aug 2005)		x		
5	I		Order and schedule radiology tests				x	
6	I	Medications	Transmission of prescriptions	NCPDP SCRIPT 4.2 or later		x		1. Certifying the ability to output a file in a certain format. 2. CCHIT will specify the standard, implementation guide and versions that will be required for interoperability certification requirements. CCHIT will align certification with HITSP standards recommentations.
7	I		**Use Standardized Communication of Sig instructions in e-prescribing.**	Industry SIG Task Group			x	
8	I		Query and receive medication information	NCPDP/RxHub developed*		x		

Security Criteria: Recap of the Development Process and Pilot Test Results

- Criteria drawn from several different sources of standards
- Criteria vetted and refined through:
  - Two cycles of Public Comment (5/2005, 8/2005)
  - Pilot Testing with six different ambulatory EHR products
  - Final cycle of Public Comment (3/2006)
- Of the **51** Criteria:
  - **6** criteria had minor revision
  - **1** criterion moved to 2007 roadmap
  - **1** criterion removed as redundant with another
  - **25** defined as **Assignable**
  - **11** classified as **Provisional**

Sample Document: **Security-Reliability Criteria**

Final Criteria: SECURITY & RELIABILITY
For 2006 Certification of Ambulatory EHRs
Effective May 1, 2006

Note:
Items highlighted in yellow are Provisional for 2006 (see cover letter)

Line #	WG	Category and Description	Specific Criteria	Source or References	Items Assignable* (see below)	Compliance: Certify in May 2006	Compliance: Roadmap for May 2007	Compliance: Roadmap for May 2008 and beyond
S28			The system shall support protection of integrity of all Protected Health Information (PHI) delivered over the Internet or other known open networks via SHA1 hashing and an open protocol such as TLS, SSL, IPSec, XML digital signature, or S/MIME or their successors.	CC SFR: FPT_RCV	Y	X		
S29			The system shall support ensuring the authenticity of remote nodes (mutual node authentication) when communicating Protected Health Information (PHI) over the Internet or other known open networks using open protocol (e.g. TLS, SSL, IPSec, XML sig, S/MIME).	CC SFR: FPT_RCV	Y	X		
R1	SR	Reliability: Backup / Recovery	The system shall generate a backup copy of the application data, security credentials, and log/audit files.	Canadian: Alberta 7.3.16 (Security); CC SFR: FDP_ROL, FPT_RCV; HIPAA: 164.310(d)(1)	Y			
R2			The system restore functionality shall result in a fully operational and secure state. This state shall include the restoration of the application data, security credentials, and log/audit files to their previous state.	Canadian: Alberta 7.3.18.9 (Security); CC SFR: FAU_GEN; SP800-53: AU-2 AUDITABLE EVENTS; HIPAA: 164.310(d)(1)	Y	X		
R3			If the system claims to be available 24x7 then the system shall have ability to run a backup concurrently with the operation of the application.	Canadian: Alberta 7.4.2.5 (Technica+D1l); CC SFR: FDP_ROL; HIPAA: 164.310(d)(1)	Y	X		

If "Y" appears in Assignable column, the function can be assigned to an external component

Test Scripts: Recap of the Development Process

- Case Scenarios developed by Use Case Workgroup; Test Scripts developed, crosswalked and refined in conjunction with Functionality, Interoperability, and Security WGs
- Case Scenarios and Test Scripts vetted and refined through:
  - First cycle of Public Comment (10/2005)
  - Pilot Testing with six different ambulatory EHR products
  - Final cycle of Public Comment (3/2006)
- Any Test Steps not fully validated by the Pilot Test (i.e. pass rate <83%) were revised and/or made Provisional

Sample Document: **Test Scripts** (Functionality scenario)

Certification Commission for Healthcare Information Technology

Operational Test Scripts – Version 1.0

	Procedure	Expected Result	Actual Result	Pass/Fail		Criteria and Reference		Comments
10	Record reasons for visit: • Vision screening • Hearing screening • Immunization boosters	System accepts reasons for visit		❑ Pass	❑ Fail	F 231	The system shall provide the ability to document encounters by one or more of the following means: direct keyboard entry of text; structured data entry utilizing templates, forms, pick lists or macro substitution; dictation with subsequent transcription of voice to text, either manually or via voice recognition system.	
11	Review required immunization boosters. (If system has already displayed notification of immunizations due, this step may be omitted.)	System displays immunizations due at this visit: • DTaP • IPV • MMR		❑ Pass	❑ Fail	F 180 F 181 F 190 F 192 F 195	The system shall provide the ability to establish criteria for disease management, wellness, and preventive services based on patient demographic data (minimally age and gender). The system shall display alerts based on established guidelines. The system shall identify preventive services, tests or counseling that are due on an individual patient. The system shall provide the ability to identify criteria for disease management, preventive, and wellness services based on patient demographic data (age, gender). The system shall provide the ability to notify the provider that patients are due or are overdue for disease management, preventive, and wellness services.	
12	Retrieve the current immunization record from the EHR.	Report is displayed that shows summary of immunizations. Report includes immunization, date given, patient name, identifier and demographic information.		❑ Pass	❑ Fail	F 217 F 228 F 9	The system shall provide the ability to generate reports consisting of all or part of an individual patient's medical record (e.g. patient summary). The system shall create hardcopy and electronic report summary information (procedures, medications, labs, immunizations, allergies and vital signs). The system shall provide the ability to include demographic information in reports.	
13	Review allergies in chart.	Allergy to penicillin indicated.		❑ Pass	❑ Fail	F 38	The system shall capture and store lists of medications and other agents to which the patient has had an allergic or other adverse reaction.	

Sample Document: **Test Scripts** (Security scenario)

Certification Commission for Healthcare Information Technology

Operational Test Scripts – Version 1.0

	Procedure	Expected Result	Actual Result	Pass/Fail		Criteria and Reference		Assignable	Comments
116	Create one valid clinical user account. This user account will have no administrative rights but will have clinical rights.	User account successfully created as per documentation provided during self-attestation. Appropriate privileges are assigned. If S23 is assigned, see step 181.		❑ Pass	❑ Fail	S 23 S 3	The system shall include documentation that covers: Method used to create, modify, and remove user accounts. The system must be able to associate permissions with a user using one or more of the following access controls: 1) user-based (access rights assigned to each user); 2) role-based (users are grouped and access rights assigned to these groups); or 3) context-based (role-based with additional access rights assigned or restricted based on the context of the transaction such as time-of-day, workstation-location, emergency-mode, etc.)	Y – S 23 N – S 3	
117	Access the directory of users.	Directory of clinical personnel is as in procedure 114 above, and updated with addition of user created in procedure 116.		❑ Pass	❑ Fail	F 213	The system shall allow authorized users to update the directory.	N	
118	Show identifiers required for licensed clinicians to support the practice of medicine.	At a minimum, the system shall mai… of s… DEA, N… number.		❑ Pass	❑ Fail	F 211	The system shall maintain a directory which contains identifiers required for licensed clinicians to support the practice of medicine including at a minimum state medical license, DEA, NPI, and UPIN number.	N	Note – if applicant cannot show this information, they may self-attest to it by providing a table of the directory.
119	Set password strength rules to require 8 characters minimum.	Password strength rules are set to 8 characters minimum. If S13 is assigned, see step 182.		❑ Pass	❑ Fail	S 13	When passwords are used, the system shall support password strength rules that allow for minimum number of characters, and inclusion of alpha-numeric complexity.	Y	

Provisional Step

Assignable Step

Certification Process Diagram (from Certification Handbook)

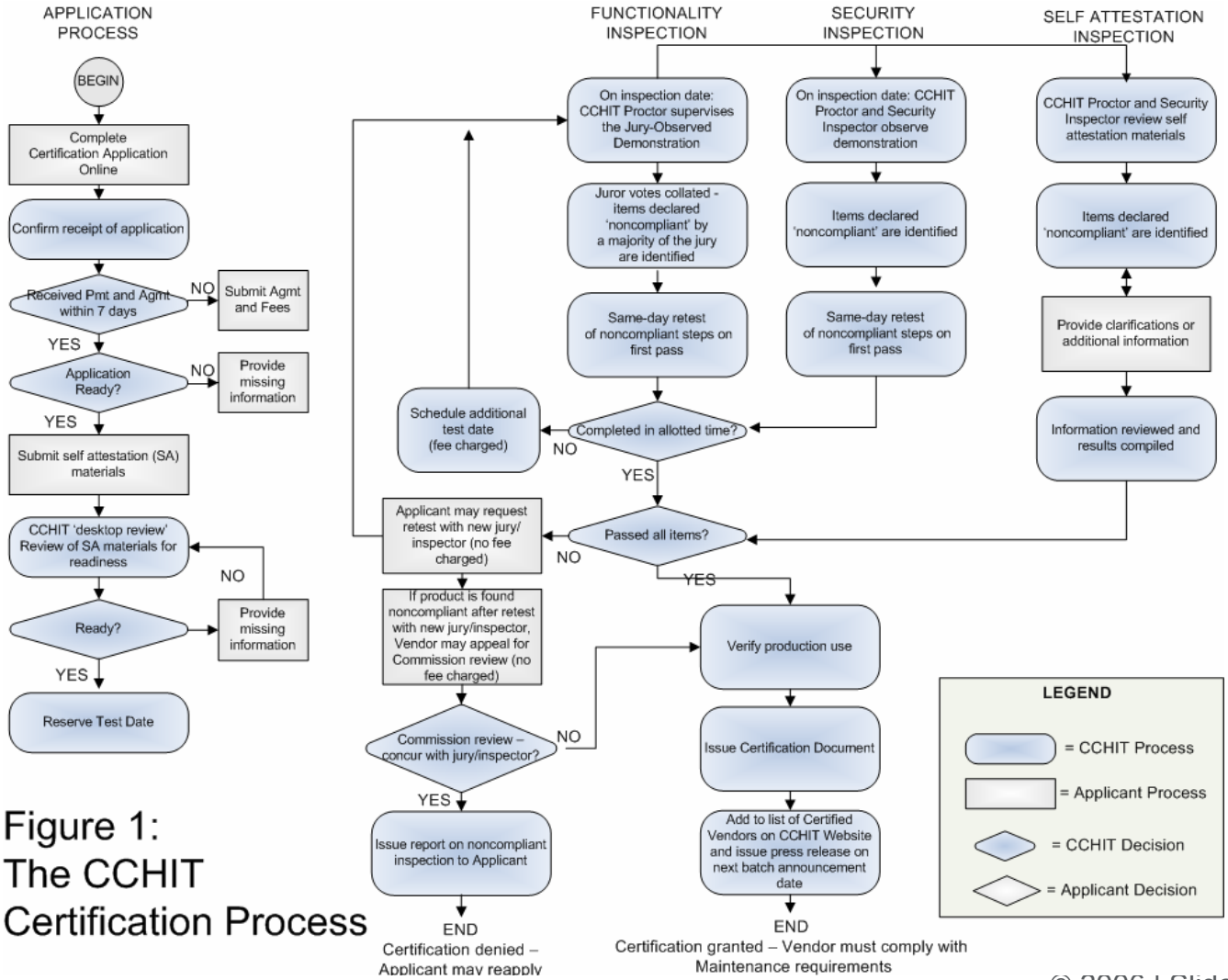
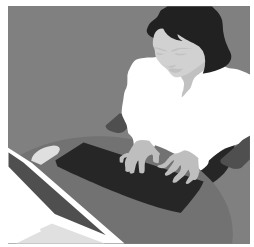


Figure 1:
The CCHIT Certification Process

The Jury-Observed Functionality Demonstration

CCHIT Proctor

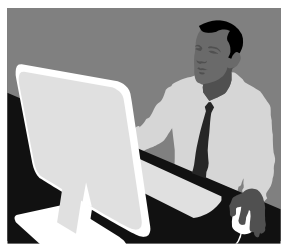


Juror A (Practicing physician)

Vendor personnel follow Test Script to demonstrate system at the vendor facility

Web conferencing (gotomeeting.com) and concurrent audio conferencing

Juror B



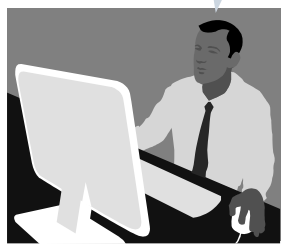
Juror C

The Security Inspection

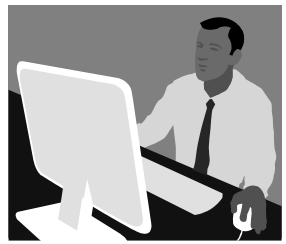
CCHIT Proctor

Vendor personnel follow Test Script to demonstrate system at the vendor facility

Web conferencing (gotomeeting.com) and concurrent audio conferencing

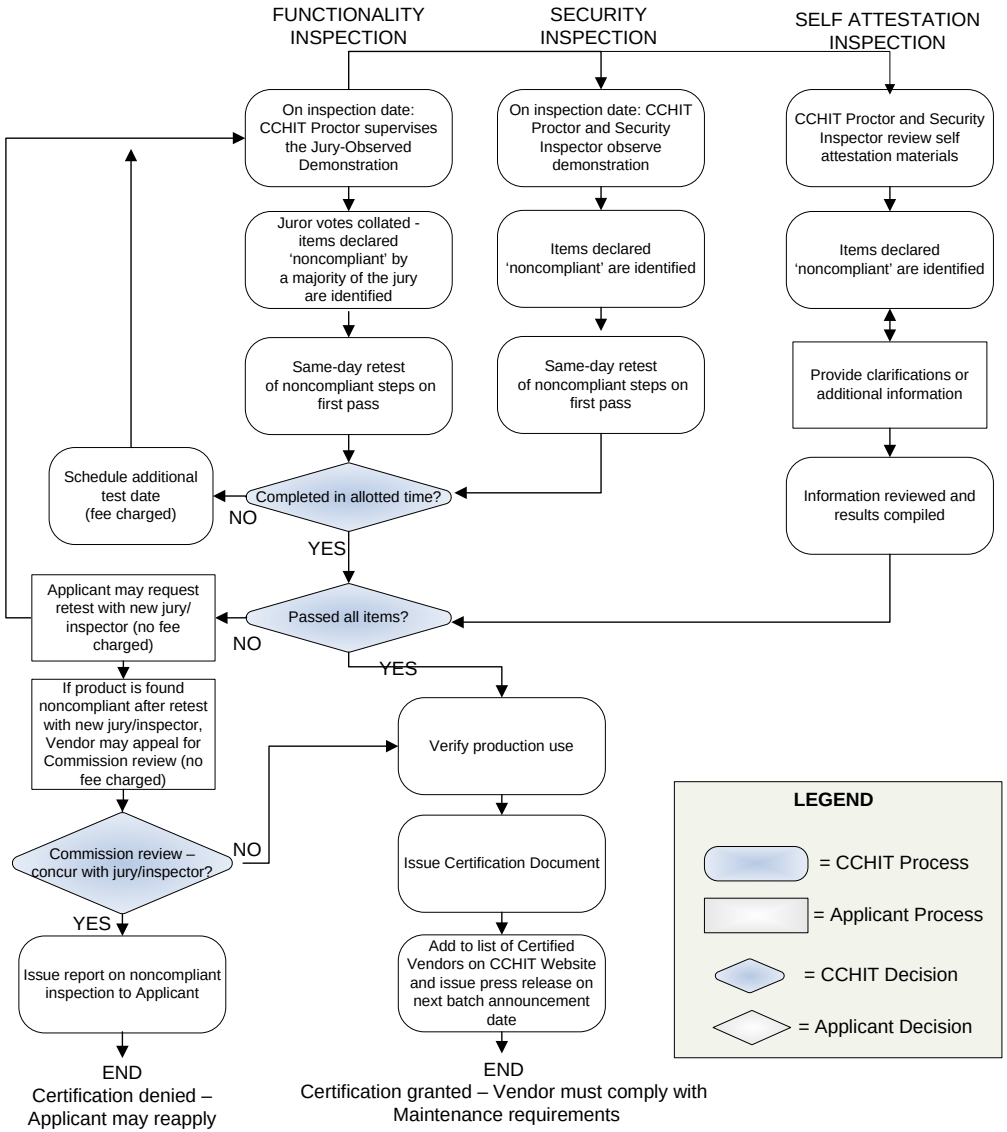


Juror D (IT/Security Expert)



Juror D (IT/Security Expert) also reviews self-attestation material offline, calls or emails vendor as needed for additional documentation

Failsafe Mechanisms: Retests and Appeals



Current Status: Recent and Upcoming Events

- **March 27, 2006**
  Workgroups for Phase II announced
- **May 1, 2006:**
  Final Certification Criteria and Inspection Process for Ambulatory EHR products released
- **May 3, 2006:**
  Certification Program officially launched; applications from vendors being accepted online through May 12
- **Early/Mid-July 2006:**
  Planned announcement of certified products from first quarterly inspection cycle

Thank You!
Discussion / Q & A

For more information:
www.cchit.org