Nationwide Health Information Network (NHIN) Validation Plan

Version: 2.0

Office of the National Coordinator

May 13, 2010

Version 2.0 replaces Version 1.1, dated April 8, 2010

Nationwide Health Information Network (NHIN) Validation Plan **1**
Purpose and Scope **3**
Background 3
Validation Approach **3**
NHIN Validation 3
NHIN Validation Roles and Responsibilities 4
Validation Process in Context **5**
Validation Criteria **6**
Technical qualification 6
Validation Testing **6**
Conformance Testing 6
Definition 6
Conformance Testing Resources Available for Developmental Purposes (Pre-Application) 7
Conformance Testing within the Validation Process 7
Interoperability Testing 8
Definition 8
The NHIN Validation Testing Process **8**
Plan the Test 8
Define the Test Cases 8
Conduct Tests 9
Report Test Results 9
Validation **9**
Re-Testing **9**
Document History **10**

Purpose and Scope

The NHIN Exchange Validation Plan describes the approach, processes, and requirements for validating that an Applicant has met the requirements for participation in the Nationwide Health Information Network (NHIN) Exchange. This document serves as part of the set of materials in Attachment 2 of the Data Use and Reciprocal Support Agreement (DURSA) called, *NHIN Test Approach and Test Materials.*

Background

The Office of the National Coordinator (ONC) is advancing the Nationwide Health Information Network (NHIN) a set of policies, standards and services that enable the Internet to be used for secure and meaningful exchange of health information to improve health and health care. Work began in 2004 to begin implementing these elements as a network-of-networks (now called the NHIN Exchange) to connect diverse entities needing to exchange health information, such as state and regional health information exchanges (HIEs), integrated delivery networks (IDNs), personally controlled health records (PCHRs), federal and state government agencies, and their component networks.

Validation Approach

The overarching intent of this validation plan is to describe the general principles and processes guiding validation for an Applicant to participate in the NHIN Exchange. The reason a validation process is required is to verify that: (i) Applicants can exchange information securely with other NHIN Participants while maintaining the privacy of the information exchanged, and (ii) the information exchanged over the NHIN is of value and use to Participants.

> The validation approach seeks to confirm, as simply as possible, that an Applicant's technical implementations of NHIN specifications are compliant with the NHIN Performance and Service Specifications and have passed testing;

In order to scale to broader participation, the validation process seeks to employ a repeatable, simple and straightforward process, backed with appropriate rigor, to evaluate that an Applicant meets the testing requirements for participation in the NHIN Exchange.

Validation does not encompass validation of the operations of organizations seeking to participate in the NHIN, and is not an organizational certification, nor a certification of organizations participating in the exchange of health information. Similarly, NHIN conformance validation of products is not product certification and does not circumvent the rules and processes guiding NHIN participation.

NHIN Validation

Participation in the NHIN Exchange, as a trusted community, is predicated on Participants meeting the defined requirements for participation, including organizational (meets the eligibility criteria), technical (employs a technical solution meeting conformance and interoperability testing requirements), and operational (has appropriate administrative, security, and policy qualifications) criteria.

The Data Use and Reciprocal Support Agreement (DURSA) formalizes a Participant's contractual obligation to comply with the NHIN Performance and Service Specifications and demonstrate compliance through testing

63 and validation. The DURSA also incorporates the NHIN Operating Policies and Procedures, which contain
64 Participant eligibility criteria. [Please see the NHIN web site to access this documentation.]

65 NHIN Validation Roles and Responsibilities

66 Currently, ONC supports the validation process. The following describes roles and responsibilities for
67 developing, managing, and conducting validation.

Role	Role Description	Role Validation Responsibilities
ONC NHIN Team	Supporting the development and maintenance of the validation process	The NHIN Implementation Team (internal ONC team) is responsible for managing on-boarding and validation processes in collaboration with NHIN Coordinating Committee, NHIN Technical Committee, and NHIN validation body. The NHIN Technical Team (internal ONC team) provides operational support to the NHIN (service registry management, test and production PKI certificates). The NHIN Test Team (internal ONC team) is responsible for providing the conformance and interoperability test platforms, which are inputs to the validation process.
NHIN Coordinating Committee	Oversees operation of the NHIN Exchange	Responsible for reviewing and approving Applicants, as well as development and maintenance of NHIN operating policies, procedures, legal agreements and approving validation process.
ONC Director of the Office of Standards and Interoperability (OSI)	the ONC Director of OSI is responsible for the overall NHIN program execution on behalf of the HHS ONC for Health IT.	Responsible for reviewing artifacts developed by the NHIN Team, and acceptance of contractually obligated deliverables. Responsible for defining validation process with NHIN Coordinating Committee; responsible for identifying validating body/bodies to carry out validation activities.
NHIN Technical Committee	Delegated with the authority under the DURSA with technical oversight of the NHIN Exchange.	Responsible for reviewing technical components of the NHIN validation process.
NIST (National Institute of Standards and Technology)	A supporting partner organization to HHS/ONC. Works with industry, academia and other government agencies to accelerate the development and adoption of correct, reliable, testable software. NIST develops conformance test tools and improves the implementation of multi-standards environments and the interoperability of standards-based systems.	Develops conformance testing tools. Supports the NHIN Exchange in their validation of the NHIN reference implementation. Provides expert opinion to ONC on testing practices and test results.

Role	Role Description	Role Validation Responsibilities
NHIN Validating Body	An organization identified and approved by the NHIN Program Director to carry out validation activities on behalf of the NHIN Exchange. This role can be performed by several entities.	Responsible for managing validation process, in coordinating with the ONC NHIN Team, NHIN Coordinating Committee, and NHIN Technical Committee. Reports candidate validation status to the NHIN Coordinating Committee as a final step in the validation process.

68

69 # Validation Process in Context

70 Validation testing is stage two of the on boarding process described in the NHIN Operating Policy and
71 Procedure # NHIN-CC-1 document, as below.

72

Stages	Description
Stage 1: Qualification	• After self-qualification, Applicant submits completed Applicant form and signed DURSA • NHIN Implementation Team reviews application package and works with the Applicant as needed to complete the package • NeHC reviews application package and coordinates an eligibility review with the NHINCC • NHINCC reviews application package to ensure candidate meets all eligibility requirements
Stage 2: Validation	• NHIN Implementation Team sends test certificate and validation framework information to Applicant • Applicant configures their test environment and executes conformance/interoperability tests • Applicant submits evidence of successful tests to NHIN Implementation Team • NHIN Implementation Team prepares validation package and submits to NHINCC
Stage 3: NHINCC Review	• NeHC coordinates a review with the NHINCC to evaluate the application and validation results • NHINCC evaluates application and makes a decision on whether to conditionally approve the Applicant or disapprove the Applicant and request remediation (if applicable)
Stage 4: Activation	• NHIN Implementation Team provides production certificate and requests production registry information from the conditional participant • Conditional Participant provides production registry information to NHIN Implementation Team • NeHC facilitates countersigning the DURSA Joinder with the NHINCC • NHIN Implementation Team configures NHIN registry with conditional Participant's information • Conditional Participant is now a Participant on the NHIN and is ready to exchange data over the NHIN

73

74

Validation Criteria

The NHIN Technical Committee approves the technical criteria required for participation in the NHIN Exchange. The NHIN Coordinating Committee approves the policies and legal requirements. Whether an Applicant meets the technical eligibility criteria is determined through validation. ONC identifies the validating bodies that will carry out the validation process.

Technical qualification

The Applicant identifies the service specifications that the Applicant's system will support for its participation in the NHIN Exchange. This will determine which tests must be completed by the Applicant.

As new versions of the specification sets are released, NHIN Participants may be required to re-validate and to pass conformance and interoperability testing when they upgrade. A deprecation grace period (defined by the NHIN Coordinating Committee) will occur prior to obsolescence of prior specification versions, to allow existing Participants to adopt the newer specification versions.

As new specifications or sets of specifications are created, NHIN Participants can opt to add support of those new services in addition to the set(s) they already support; validation testing is required for each new service a Participant opts to support.

Validation Testing

Validation testing focuses on two specific areas: 1) conformance testing - verifying that an Applicant's system conforms to the applicable NHIN specifications, and 2) interoperability testing - verifying that each Applicant's system can interact with the others.

Conformance does not guarantee interoperability; as a result, both elements are essential for the Exchange to function.. The following describes these two processes in more detail.

Conformance Testing

Definition

Conformance testing is focused on validating a particular version of a single system to a specific set of standards and specifications. This testing primarily confirms that a system correctly encodes the syntax and structure of a given data standard in the physical files or transactions that a system produces and receives.

Conformance tests are based upon a set of resources, including conformance test cases, related criteria, test scripts, supporting processes, and automated testing tools. Currently, ONC, in coordination with NIST and the NHIN Technical Committee and NHIN Coordinating Committee, verifies that all NHIN specifications have corresponding conformance testing resources.

Conformance Testing Resources Available for Developmental Purposes (Pre-Application)

Conformance testing resources are made available to the public to foster development and innovation and may be utilized by entities eligible for participation in the NHIN Exchange, as well as system developers and others that are interested in supporting NHIN standards and services generally.

Applicants can make use of these resources prior to entering the on-boarding process, to test their systems prior to beginning the validation process. For NHIN Applicants, conformance testing is a required component of the validation process.

System developers and others also may make use of these resources. Systems or products that satisfy this basic level of conformance testing are not considered participants in the NHIN Exchange solely based upon conformance testing results. Participation in the NHIN Exchange requires that an entity meet the eligibility criteria and satisfy the participation requirements as defined in the DURSA and NHIN Coordinating Committee operating policies and procedures.

Systems that undergo NHIN conformance testing using the publically-available resources simply demonstrate that a particular version of the system or product conformed to the standard. This in no way means that the system has or will pass testing required for participation in the NHIN Exchange. Further, in no way would such system assure that its use would guarantee that an Applicant that uses the system would pass NHIN validation testing. A system that passes conformance testing in no way guarantees an Applicant will subsequently pass the conformance testing and interoperability testing for the implemented system in Stage 2 of the NHIN Exchange on boarding process.

Conformance testing resources are available on the HHS NHIN web site (www.hhs.gov/healthit - under NHIN Initiatives – NHIN Exchange).

This process is not intended to certify products or interfaces for the NHIN Exchange, but to support a streamlined process to help minimize duplicative conformance tests and scale to meet evolving projects that may need manual test until automated testing tools are available.

Conformance Testing within the Validation Process

Conformance testing is conducted within the NHIN Exchange validation testing process, even if an Applicant, or a system in use by an Applicant, has performed conformance tests using the publically-available resources.

Comformance Testing for Applicants Employing Products or Systems That Have Undergone Conformance Tests

Applicants employing a validated conformant system are still required to perform a reduced set of conformance test cases to ensure that product conformance has not been violated by installation, and to confirm conformance of the complete system seeking NHIN Exchange validation. Just as conformance with NHIN specifications can be affected by the configuration and adaption of edge-systems such as EHRs, it is also possible for non-compliant behaviors to be introduced when installing and configuring a gateway that has already undergone successful conformance tests.

If the Applicant is using a system or product that has undergone conformance testing using the publically-available resources, the Applicant can submit the system's conformance test results. These system conformance testing results may ease conformance testing expectations for Applicants, but do

not forgive it. The ONC NHIN Implementation will use the results, along with discussion of the Applicant's specific system installation, to determine the suite of conformance tests that will be required by the Applicant.

Systems only need to satisfy conformance testing one time for each version of that system. This means that when multiple Applicants use the same version of a system that previously passed conformance testing, the Applicant may rely on those prior test results to satisfy part of the conformance testing requirements for its application to participate in the NHIN Exchange.

Interoperability Testing

Definition

Interoperability testing seeks to validate that multiple systems that implement a particular standard or set of standards can all communicate with one another.

The NHIN Validation Testing Process

This section describes the activities to be performed by the Applicant. Once an Applicant enters the NHIN Exchange on-boarding process, the ONC NHIN Implementation team representative will work with the Applicant to define the tests to be performed for the based on the services identified by the organization in its application. Product vendors seeking conformance validation are not handled within the on-boarding process, nor are they eligible to exchange health information across the NHIN.

Plan the Test

Working with the ONC NHIN Implementation team, the Applicant will create a test plan to describe the timeframe and conduct of the testing. The test plan will also indicate the evidentiary artifacts required to support validation. The ONC NHIN Technical team will review the test plan with the Applicant to confirm that the plan will satisfy testing requirements.

The purpose of testing is to ensure that the system under test is stable, that its messages conform with the specification, and that it is able to exchange information in compliance with the specification.

If the Applicant is using a system or product that has undergone conformance testing using the publically-available resources, the Applicant can submit the system's conformance test results. The ONC NHIN Implementation will use these results, along with discussion of the Applicant's specific system installation, to determine the suite of conformance tests that will be required by the Applicant.

Define the Test Cases

The NHIN Exchange has a suite of test cases and automated testing tools to provide conformance and interoperability testing for several of specifications, as outlined in the NHIN Exchange Validation Overview document. For emergent and other specifications, the Applicant is responsible for creating appropriate test cases for the specification to be tested, working in consultation with members of the ONC NHIN Technical and Implementation teams.

The focus of test cases is to provide appropriate coverage of the specification to be tested, including negative tests where possible. There are no heuristics on the number of test cases required for this kind of testing, which is why early collaboration with the NHIN Technical and Implementation teams is necessary.

Once the ONC NHIN Technical team approves the test cases and defines the documentation that will be required for validation (logs, screen shots, etc), the Applicant can begin testing.

Conduct Tests

Testing can be conducted using the NHIN automated testing tools that are defined in the NHIN Exchange Validation Overview document, or performed manually by the Applicant.Testing will focus on peer-to-peer testing of the Applicant's system against an implementation using the same version of specifications as those employed by the Applicant (in most cases, both sides of the exchange will be test installations provided by the Applicant). Validation is concerned with confirming that the interactions occur successfully as described by the specification and as defined in the test case.

Testing will be accomplished by performing the tests cases as identified in the test plan, and capturing the evidentiary artifacts defined in the test plan to enable validation review by the NHIN Technical Teams. This process is also supported by validation body(ies) that are contracted by ONC to support this process.

Report Test Results

Although the ONC NHIN team expects to be in close contact with an Applicant during the testing process, the Applicant is required to submit a test report to the ONC NHIN team, to accompany logs, screen shots, and other evidentiary artifacts as identified in the test plan. A template for this report will be provided to Applicants.

Validation

The ONC NHIN Technical team will review the produced evidence, consulting with NIST expert advisors as appropriate, and prepare a summary testing results report.

For NHIN Applicants, this report will be provided to the NHIN Coordinating Committee Secretary and presented to the NHIN Coordinating Committee for consideration. With this step, the technical stage of the on-boarding process is complete.

Re-Testing

If a NHIN Participant's gateway software is modified or upgraded, the NHIN Participant may be required to re-validate (to pass conformance and interoperability testing).

If a NHIN Participant opts to upgrade the version of the specification they support, the NHIN Participant may be required to validate (to pass conformance and interoperability testing) on the new specification version.

If a NHIN Participant opts to add support for a new specification, the NHIN Participant will be required to validate (to pass conformance and interoperability testing) on the specification.

Document History

Date	Version	Description	Name
09/04/2009	.1	Initial draft	Leslie Power
09/11/2009	.2	Added onboarding images after coordination with NHIN Implementation team	Leslie Power
09/14/2009	.3	Updated specification sets from conversation with Kevin Puscas and Rich Kernan	Leslie Power
09/23/2009	.4	Updated with feedback from Ginger Price; changed term “certification” to “validation”	Leslie Power
09/28/2009	.5	Incorporated feedback from Amy Olson.	Leslie Power
10/4/2009	.6	Incorporated feedback from Mariann Yeager and Ginger Price	Leslie Power
11/9/2009	.7	Incorporated feedback from NHIN Testing Team members.	Leslie Power
11/13/09	.8	Incorporated additional NHIN Testing Team feedback; updated onboarding images	Leslie Power
11/16/09	.9	Incorporated additional NHIN Testing Team feedback	Leslie Power
12/17/09	1.0	Aligned language with DURSA and remove the following from the list of required core services, “optional: Access Consent Policies” since this is not a service and is optional. Also changed the term “proscribed” to “prescribed” Approved by NHIN Coordinating Committee on 12/17/09.	Erin Whaley, Steve Gravely, Mariann Yeager and Aaron Seib
4/2/10	2.0-RC1	Modified to allow simpler updating as new specification service sets come online; redefined HIEM service set definition	Leslie Power
4/26/10	2.0-RC2	Additional simplification of process description; reference NHIN Validation Overview document for specifics on automated test tool process	Leslie Power
5/5/10	2.0-RC3	Added information on product conformance	Leslie Power
5/6/10	2.0-RC4	Revised to clarify pre-application validation process	Mariann Yeager
5/6/10	2.0-RC5	Incorporated Mariann Yeager’s comments to define methods of pre-application conformance validation process	Leslie Power
5/7/10	2.0-RC6	Incorporated Leslie’s comments. Clarified introductory information	Mariann Yeager
5/13/10	2.0-RC6	Added effective date, Validation Plan 2.0 was approved by NHIN Coordinating Committee and NTC on 5/13/10, via joint ad-hoc conference call.	Vernette Roberts