



**Nationwide Health Information Network
Exchange**

Validation Plan

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Version 3.0

Document Change History

Version	Date	Items Changed Since Previous Version	Changed By
.1	09/04/2009	Initial draft	Leslie Power
.2	09/11/2009	Added onboarding images after coordination with Nationwide Health Information Network Implementation Team	Leslie Power
.3	09/14/2009	Updated specification sets from conversation with Kevin Puscas and Rich Kernan	Leslie Power
.4	09/23/2009	Updated with feedback from Ginger Price; changed term "certification" to "validation"	Leslie Power
.5	09/28/2009	Incorporated feedback from Amy Olson.	Leslie Power
.6	10/4/2009	Incorporated feedback from Mariann Yeager and Ginger Price	Leslie Power
.7	11/9/2009	Incorporated feedback from Nationwide Health Information Network Testing Team members.	Leslie Power
.8	11/13/09	Incorporated additional Nationwide Health Information Network Testing Team feedback; updated onboarding images	Leslie Power
.9	11/16/09	Incorporated additional Nationwide Health Information Network Testing Team feedback	Leslie Power
1.0	12/17/09	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 NCC on 12/17/09.	Erin Whaley, Steve Gravely, Mariann Yeager and Aaron Seib
2.0-RC1	4/2/10	Modified to allow simpler updating as new specification service sets come online; redefined HIEM service set definition	Leslie Power
2.0-RC2	4/26/10	Additional simplification of process description; reference <i>Nationwide Health Information Network Onboarding Validation Overview</i> document for specifics on	Leslie Power

		automated test tool process	
2.0-RC3	5/5/10	Added information on product conformance	Leslie Power
2.0-RC4	5/6/10	Revised to clarify pre-application validation process	Mariann Yeager
2.0-RC5	5/6/10	Incorporated Mariann Yeager's comments to define methods of pre-application conformance validation process	Leslie Power
2.0-RC6	5/7/10	Incorporated Leslie's comments. Clarified introductory information	Mariann Yeager
3.0-RC1	10/11/10	Revised the document to align with the Nationwide Health Information Network Validation Team's current approach	Leslie Power, Michael Hunter
3.0 – RC2	12/8/10	Revised document – removed logo and references to “NHIN” acronym. Marked “Draft” for TC / CC review.	Mariann Yeager
3.0 – RC3	4/13/2011	Updated process description; removed reference to Technical Committee in roles and responsibilities table; updated “Technical Qualification” system to include Task Group recommendations concerning Participant system expectations.	Leslie Power

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1 Purpose and Scope

The *Nationwide Health Information Network 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 Exchange (herein called Exchange). This document serves as part of the set of materials in Attachment 2 of the Data Use and Reciprocal Support Agreement (DURSA) called, *Nationwide Health Information Network Test Approach and Test Materials*.

1.1 Background

The Office of the National Coordinator for Health Information Technology (ONC) is advancing the Nationwide Health Information Network: 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 started in 2004 to begin implementing these elements as a network-of-networks (now called the 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.

2 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 Exchange. To meet requirements for trust and interoperability in the Exchange, the validation process verifies Applicants can securely exchange information with other Exchange Participants (Participants) while maintaining the privacy of the information exchanged.

The validation approach seeks to confirm, as simply as possible, that an Applicant's technical implementation of Nationwide Health Information Network specifications complies with the Nationwide Health Information Network Performance and Service Specifications and passes testing.

In order to scale to broader participation, the Validation Plan 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 Exchange.

Validation does not encompass validation of the operations of organizations seeking to participate in the Nationwide Health Information Network Exchange, and is not an organizational certification, nor a certification of systems participating in the exchange of health information.

Similarly, Exchange conformance validation of products is not product certification and does not circumvent the rules and processes guiding participation in the Nationwide Health Information Network Exchange.

2.1 Nationwide Health Information Network Validation

Participation in the Exchange, as a trusted community, is predicated on an Applicant meeting the defined requirements for participation, including organizational (meets the eligibility criteria), technical (employs a technical solution meeting validation requirements, which may include both conformance and interoperability testing requirements), and operational (has appropriate administrative, security, and policy qualifications) criteria's.

The DURSA formalizes an Applicant's contractual obligation to comply with the Nationwide Health Information Network Exchange Performance and Service Specifications and to demonstrate compliance through testing and validation. Also, the DURSA incorporates a set of Exchange Operating Policies and Procedures, which contain Applicant eligibility criteria. To access the DURSA and related information, refer to the Nationwide Health Information Network Exchange web site at:

http://healthit.hhs.gov/portal/server.pt/community/healthit_hhs_gov_nhin_resources/1194

2.2 Nationwide Health Information Network Validation Roles and Responsibilities

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

Table 1. Validation Roles and Responsibilities

Entity or Team	Role Description	Validation Responsibilities
ONC. Office of Standards and Interoperability (OSI). Office of Policy and Planning (OPP).	The ONC OSI is responsible for the overall execution of the Standards and Interoperability initiatives within ONC, including those related to the Nationwide Health Information Network. OSI also provides program support for the Exchange for the on boarding and validation process. The ONC OPP is responsible for the overall execution of policy and governance within ONC, including those related to the Nationwide Health Information Network.	ONC issued a set of contracts to support the validation activities for the Exchange. For more details, see the Standards and Interoperability Framework Contractor responsibilities below.
Standards and Interoperability (S&I) Framework Contractors to ONC, including: <ul style="list-style-type: none"> • Testing 	Supporting the development and maintenance of the validation process.	This ONC contractor is responsible for the following tasks: Managing onboarding processes in accordance with the Exchange operating policies, DURSA, in coordination with the Exchange

Entity or Team	Role Description	Validation Responsibilities
<p>Infrastructure Team.</p> <ul style="list-style-type: none"> • Operations Team. • Spec Factory Team. 		<p>Technical Committee (TC) and Exchange Coordinating Committee (CC).</p> <p>Providing operational support to the Exchange (service registry management, test and production PKI certificates).</p> <p>Providing conformance and interoperability test infrastructure that provides the inputs to the Exchange validation process.</p> <p>Publishing technical specifications, which are to be tested against when validating organizational candidates for Exchange participation.</p>
<p>Nationwide Health Information Network Exchange Coordinating Committee (CC).</p>	<p>Oversees operation of the Exchange, including participation, suspension and termination decisions related to the Exchange. This Committee also sets Exchange operating policies and procedures and fulfills the duties set forth in the DURSA.</p>	<p>Responsible for reviewing and approving Applicants, including acceptance of validation results for participation in the Exchange.</p> <p>Oversees development and maintenance of the Exchange operating policies, procedures, legal agreements, and approval of the validation process, including the validation plan and test cases.</p>
<p>National Institute of Standards and Technology (NIST).</p>	<p>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.</p>	<p>Develops Conformance Testing tools.</p> <p>Supports the Exchange in their validation of the Nationwide Health Information Network Exchange reference implementation.</p> <p>Provides expert opinion to ONC on testing practices and test results.</p>
<p>Nationwide Health Information Network Exchange Validating</p>	<p>An organization identified by ONC to carry out validation activities in support of the Exchange.</p>	<p>Responsible for managing validation process, in coordinating with ONC, the Exchange Technical Committee and CC.</p>

Entity or Team	Role Description	Validation Responsibilities
Body.	This role can be performed by several entities. At present, the S&I Framework Testing Infrastructure Team fulfills this role.	Prepares the validation results and reports candidate validation status to the CC as a final step in the validation process.

3 Validation Process in Context

Validation Testing (hereafter referred to as ‘Validation’) is stage two of the onboarding process as described in the Nationwide Health Information Network Operating Policy and Procedure # NHIN-CC-1 document, outlined below.

Table 2. Onboarding Stages

Stages	Description
Stage 1: Qualification	<ul style="list-style-type: none"> After self-qualification, Applicant submits completed Applicant form and signed DURSA. Application package is reviewed, and clarifications obtained, if necessary, to complete the package. The CC reviews application package to verify whether the candidate meets all eligibility requirements. If approved, the Applicant is able to begin Validation.
Stage 2: Validation	<ul style="list-style-type: none"> S&I Operations Team sends test certificate and validation framework information to Applicant. Applicant configures its test environment (a production-ready system, see section 4.1) and executes required conformance and/or interoperability tests. Applicant submits evidence of successful tests to the S&I Testing Infrastructure Team. S&I Testing Infrastructure Team prepares validation results and submits the Applicant’s validation summary report to the CC Secretary.
Stage 3: Coordinating Committee (CC) Review	<ul style="list-style-type: none"> The CC evaluates the test results and makes a decision on whether to conditionally approve the Applicant or disapprove the Applicant and request remediation (if applicable). The CC communicates the decision to the Applicant.

Stages	Description
Stage 4: Activation	<ul style="list-style-type: none"> • If approved, the S&I Operations Team provides production certificate and requests production registry information from the conditional participant. • Applicant provides production registry information to S&I Operations Team. • National eHealth Collaborative (NeHC) facilitates countersigning the DURSA Joinder with the CC Chair. • Operations contractor configures Exchange registry with conditional Participant's information. • Conditional Participant is now a Participant on the Nationwide Health Information Network Exchange and is ready to exchange data with other Participants.

4 Validation Criteria

The CC approves the policies, legal requirements, and technical criteria for participating in the Exchange, and evaluates the impact of changes to specifications and validation plans adopted for the Exchange. The validation process determines whether an Applicant meets the technical requirements. ONC identifies the validating bodies that carry out the validation process.

The Exchange validation process tests adherence to the specifications and technical criteria for participating in the Exchange. Testing of policies, rules, and laws as well as business partner-specific requirements are outside the scope of Exchange validation.

4.1 Technical Qualification and Expectations

In its application, the Applicant identifies the service specifications that the Applicant's system will support for its participation in the Exchange. This determines which tests the Applicant must complete.

Applicants and Exchange Participants are expected to:

- * Bring forth a production-ready system for validation. "Production-ready" assumes that development and testing of the system is complete, and that the validation system is deployed on a tier that replicates, as closely as possible, the production environment.
- * Identify the system components that are relevant to validation, including those components used to create or modify Nationwide Health Information Network messages in accordance with the Performance and Service Specifications in effect for the Exchange. The Applicant does not need to provide evidence to the Validating Body (which is currently the S&I Testing Infrastructure team), unless relevant to planning the Applicant's tests.
- * Identify when to bring forward its system for retesting when it makes system changes that impact its compliance with the Performance and Service Specifications. The ability to exchange

messages can be affected, or adversely impacted, by modifications to components involved in creating or modifying Exchange messages. Therefore, Applicants and Participants should retest in order to confirm that system modifications have not introduced non-compliant behaviors. To request retesting or revalidation, the Applicant and/or Participant should contact the S&I Testing Infrastructure Team.

As new versions of the specifications are adopted for Exchange, Participants may be required to re-validate and to pass Conformance and Interoperability Testing when they upgrade. A deprecation grace period (defined by the CC) occurs before obsolescence of prior specification versions, to allow existing Participants to adopt the newer specification versions.

As new specifications or sets of specifications are adopted for Exchange, Participants can opt to add support of those new services in addition to the set(s) they already support; Participants shall complete Validation Testing for each new service added.

4.2 Changes to Test Artifacts and Criteria

Major changes to test artifacts are subject to CC review, as described in the *Nationwide Health Information Network Validation Change Management* document.

5 Aspects of Validation Testing

Validation Testing focuses on two specific areas:

- (i) Conformance Testing – verifying that an Applicant’s system conforms to the applicable Nationwide Health Information Network specifications adopted for the Exchange, and
- (ii) Interoperability Testing – verifying that each Applicant’s system can interact with other Participants.

Conformance does not guarantee interoperability; as a result, both elements are essential for the Exchange to function. Many conformance tests confirm interoperability (that a system can exchange a message with another system), but some specifications require interoperability testing, which involves a more complex exchange of messages to simulate actual business scenarios. The following sections describe these two processes in more detail.

5.1 Conformance Testing

5.1.1 Definition

Conformance testing focuses 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 testing is performed based on a set of resources, including test cases and data, testing guidance documents, supporting processes, and manual or automated test tools and capabilities.

All Applicants must perform conformance tests to validate their system's compliance to a specification.

5.1.2 Full, or Product, Conformance Testing

Each Applicant is expected to perform full, or product, conformance testing, using the entire suite of applicable conformance test cases, unless the product used by the Applicant has already undergone and passed conformance testing, in which case a smaller subset of test cases may apply (see "Installation Conformance Testing," below).

Developers of systems or products that implement the Performance and Service Specifications adopted for Exchange may undergo conformance testing to demonstrate that a particular version of the system or product conforms to the specifications.

This process is not intended to certify products or interfaces for the Exchange, and systems or products that satisfy this basic level of conformance testing are not considered participants in the Exchange solely based upon conformance testing results. (Participation in the Exchange requires that an entity meet the eligibility criteria and satisfy the participation requirements as defined in the DURSA and CC operating policies and procedures.)

5.1.3 Conformance Testing for Applicants Employing Products or Systems That Have Undergone Conformance Tests – Installation Conformance Testing

When multiple Applicants use the a product 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 Exchange. Applicants must employ a validated conformant product or system 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 Exchange validation. Just as conformance with Exchange Performance and Service Specifications can be affected by the configuration and adaption of edge-systems such as Electronic Health Records (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 full, or product conformance testing, 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 S&I Testing Infrastructure Team uses the results, along with discussion of the Applicant's specific system installation, to determine the suite of conformance tests required for validation by the Applicant.

5.2 Interoperability Testing

5.2.1 Definition

Interoperability Testing seeks to validate that multiple systems implementing a particular standard or set of standards can all communicate with one another. Some conformance tests also confirm interoperability, but interoperability testing can also involve a more complex exchange of messages to simulate actual business scenarios.

Interoperability testing is performed based upon a set of resources, including interoperability test cases and scenarios, related criteria, test scripts, supporting processes, and automated testing tools.

6 Nationwide Health Information Network Validation Testing Process

This section describes the activities to be performed by the Applicant. Once an Applicant enters the Exchange onboarding process, the S&I Framework Testing Team representative will share validation artifacts, including test guides and test cases, which define how the tests will be conducted for the Applicant.

6.1 Plan the Test

Working with the S&I Framework Operations Onboarding Team representative, the Applicant creates a test schedule to describe the timeframe and conduct of the testing.

The purpose of testing is to ensure the system under test is stable, its messages conform to the specification, and it is able to exchange information in compliance with the specification. Test guides, cases, and data are provided for each specification, which describe the test process in detail.

6.2 Review the Test Documentation

There is a suite of test cases and automated testing tools to provide conformance and interoperability testing for the Exchange Performance and Service Specifications, as outlined in the *Nationwide Health Information Network Onboarding Validation Overview* document. These testing requirements are outlined in specification test guides that are provided to Applicants. These guides define the cases, data, process, and evidentiary artifacts required for each specification. (For emergent and other specifications, the Applicant may be asked to work in consultation with members of the S&I Testing Infrastructure Team to create appropriate test cases for the specification to be tested).

6.3 Conduct Tests

Testing should be conducted using the Exchange testing methods and tools defined in the *Nationwide Health Information Network Onboarding Validation Overview* document. Validation is concerned with confirming the interactions occur successfully as described by the specification and as defined in the test guides and test cases.

Applicants accomplish testing by performing the test cases as identified in the test guide, and capturing the evidentiary artifacts defined therein to enable validation review by the Nationwide Health Information Network Exchange Validating Body.

6.4 Submit Test Evidence

The Applicant must submit, to the Nationwide Health Information Network Exchange Validating Body, the logs, screen shots, and other evidentiary artifacts identified in the relevant test guide.

7 Validation

The Validating Body reviews the produced evidence, consulting with NIST expert advisors as appropriate, and prepares a summary testing results report (Validation Summary Report).

The Validating Body provides the Validation Summary report to the CC Secretary who presents it to the CC for consideration. With this step, the validation stage of the onboarding process is complete.