



Nationwide Health Information Network (NHIN) Validation Plan

Version: 1.0

Office of the National Coordinator

November 16, 2009

Purpose and Scope

The NHIN Validation Plan describes the approach, processes, and requirements for validating that an organization has met the requirements for participation in the Nationwide Health Information Network (NHIN).

Background

The Office of the National Coordinator (ONC) is advancing the Nationwide Health Information Network (NHIN) as a “network of networks” that provides the capability to connect diverse entities needing to exchange health information, such as state and regional health information exchanges (HIEs), integrated delivery systems (IDSes), personally controlled health records (PCHRs), federal and state government agencies, and their component networks.

The NHIN’s mission: To achieve better quality, value, and affordability of health and wellness services by establishing the NHIN as a common, secure, nationwide, and easily adopted interoperable network for exchanging health information.

Validation Approach

The overarching intent of the NHIN validation plan is to describe the general principles and processes guiding validation for an Applicant to participate in the NHIN. 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:

- **only Applicants that meet the eligibility requirements established by the NHIN Coordinating Committee become Participants in the NHIN (see NHINCC 1 – Review and Disposition of Applications for Participation and Definitive Plans);**
- **Applicants technical implementations of NHIN specifications are compliant with the NHIN Performance and Service Specifications and have passed testing;**
- **Applicants can meet the organizational requirements of the DURSA with respect to privacy and security; and**
- **Applicants have signed the Data Use and Reciprocal Support Agreement (DURSA).**

Given that NHIN seeks wide adoption and participation, the NHIN validation process seeks to employ a repeatable, simple and straightforward process, backed with appropriate rigor, to evaluate that an Applicant meets the requirements for participation in the NHIN.

NHIN 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.

Flowing from these principles, qualifications for NHIN participation are divided into three components, as described below:



- **organizational**, ensuring that the Applicant meets the organizational eligibility requirements to participate in the NHIN;
- **technical**, verifying that the Applicant's technical solution complies with the NHIN technical specifications; and
- **operational**, verifying that the Applicant has agreed to comply with the security, administrative, operational and policy obligations in the DURSA. (This is not an organizational validation, but requires an organization's attestation that it performs the practices prescribed by the DURSA.)

NHIN validation is not a paper validation process, and requires only candidate attestation of organizational and operational qualifications rather than on-site or paper-based confirmation by a validating body. (Technical testing is performed on an automated system.) Keeping the validation process as simple and automated as possible encourages adoption, and lowers the cost of validation. This automation and simplicity is necessary and important given that Applicants want to participate in the NHIN because NHIN participation provides business and operational value to them.

NHIN Validation

Participation in the NHIN, 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. [Please see the NHIN web site for additional documentation.]

The Data Use and Reciprocal Support Agreement (DURSA) formalizes a Participant's legal obligation to comply with the NHIN Performance and Service Specifications and demonstrate compliance through testing and validation. The DURSA also incorporates the NHIN Operating Policies and Procedures, which contain Participant eligibility criteria.

NHIN Validation Roles and Responsibilities

Many roles within NHIN management and support converge to sustain NHIN validation. These roles identify the participants in the processes of developing, managing, and conducting validation. Within the validation processes each role has a certain set of responsibilities as listed in the table below.

Role	Role Description	Role Validation Responsibilities
NHIN Team	Represents the different workgroups and teams within the NHIN program, and includes members of the NHIN program, the NHIN Cooperative and the FHA program	<p>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.</p> <p>The NHIN Technical Team (internal ONC team, supported by cooperative workgroups such as the Spec Factory and NHIN Testing Team) provides operational support to the NHIN (service registry management, test and production PKI certificates, and operational activity review).</p> <p>The NHIN Test Team (internal ONC team, supported by the cooperative workgroup NHIN Testing Team) is responsible for providing the conformance and interoperability test platforms, which are inputs to the validation process.</p>
NHIN Coordinating Committee	Comprised of one representative from each Participant, one representative from each organization that has an approved Definitive Plan, two elected NHIN Cooperative members, and a representative of ONC. The NHIN Coordinating Committee supports the NHIN operations.	Responsible for reviewing and approving Applicants, as well as development and maintenance of NHIN operating policies, procedures, legal agreements and defining validation process.
NHIN Cooperative	A diverse, representative group of entities, including federal, as well as other entities under contract/grant with HHS to develop technical, policy and legal deliverables using a consensus-based team approach.	Responsible for providing input into the development of the validation process.
NHIN Program Director	NHIN Program Director is responsible for the overall program execution on behalf of the HHS ONC for Health IT.	<p>Responsible for reviewing artifacts developed by the NHIN Team, and acceptance of contractually obligated deliverables.</p> <p>Responsible for defining validation process with NHIN Coordinating Committee; responsible for identifying validating body/bodies to carry out validation activities.</p>
NHIN Technical Committee	Delegated with the authority under the DURSA with technical oversight of the NHIN. Members include representatives from ONC and the NHIN Cooperative.	Responsible for reviewing technical components of the NHIN validation process.

Role	Role Description	Role Validation Responsibilities
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 such as the NHIN.	<p>Develops conformance testing tools.</p> <p>Supports the NHIN Cooperative in their validation of the NHIN reference implementation.</p> <p>Provides expert opinion to the NHIN Cooperative on testing practices and test results.</p>
NHIN Validating Body	An organization identified and approved by the NHIN Program Director to carry out validation activities on behalf of the NHIN. This role can be performed by several entities.	<p>Responsible for managing validation process, in coordinating with the NHIN Team, NHIN Coordinating Committee, and NHIN Technical Committee.</p> <p>Reports candidate validation status to the NHIN Coordinating Committee as a final step in the validation process; the Coordinating Committee then approves (or rejects) NHIN participation.</p>

The operation of the NHIN intersects and interplays with the validation process; the governance process and the validation process interact and depend on one another. This process is described below.

Validation Process from the Candidate's Perspective

This high-level view includes fewer details of the validation process while covering the relevant interactions.

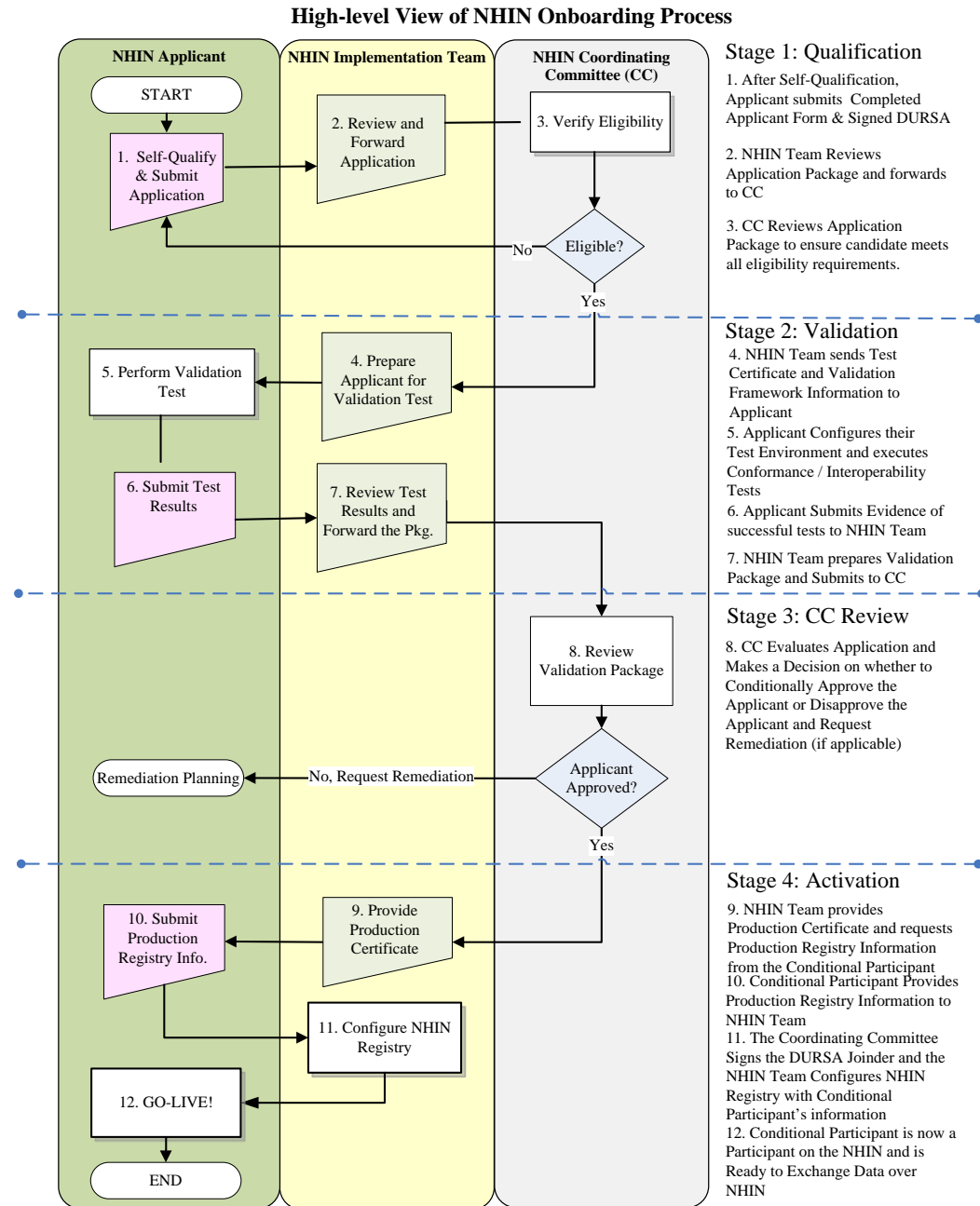


Figure 1 - This figure provides a higher-level view of the touch points and interactions to achieve NHIN validation.



Validation Criteria

The NHIN Coordinating Committee approves the eligibility criteria that will be used to determine membership for participation in the NHIN. Whether an Applicant meets the eligibility criteria is determined through validation. ONC identifies the validating bodies that will carry out the validation process. Criteria for NHIN eligibility are listed below.

Organizational and Operational criteria

The candidate organization must meet the eligibility criteria defined in the NHIN Coordinating Committees Operating Policy and Procedure 1. The Coordinating Committee initially determines if an applicant meets these eligibility criteria during the Qualification Stage of the NHIN Onboarding process.

Technical qualification

A minimum set of NHIN specifications must be supported by all NHIN candidates. These core services, which must be implemented as the basis of the technical validation sets, are defined below.

Core NHIN Services


The set of services below must be supported by all Applicants for NHIN validation.

- Messaging Platform Service
- Authorization Framework Service
- Service Registry Service

To validate as a NHIN participant, a candidate must support Core NHIN Services and either NHIN Patient & Document Services, the NHIN Health Information Event Messaging Service, or both.


NHIN Patient & Document Services

In addition to the base NHIN services, Applicants can support NHIN patient and document services, as a service initiator, a service responder, or preferably both.

 <p>Figure 2 – In addition to the base NHIN services, Applicants can support the NHIN Patient & Document Service Set, as a service initiator, a service responder, or preferably both.</p>	<p>NHIN Patient & Document Services Initiator (core NHIN services plus the below)</p> <ul style="list-style-type: none"> • Patient Discovery Service • Query for Document Service • Retrieve Document Service 	<p>NHIN Patient & Document Services Responder (core NHIN services plus the below)</p> <ul style="list-style-type: none"> • Patient Discovery Service • Query for Document Service • Retrieve Document Service
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NHIN Health Information Event Messaging Service

In addition to the base NHIN services, Applicants can support the NHIN health information event service, as a service initiator, a service responder, or preferably both.

 <p>Figure 3 – In addition to the base NHIN services, Applicants can support the NHIN Health Information Event Messaging Service Set, as a service initiator, a service responder, or preferably both</p>	<p>Health Information Event Service Initiator (core NHIN services plus the below)</p> <ul style="list-style-type: none"> • HIEM Service 	<p>Health Information Event Service Responder (core NHIN services plus the below)</p> <ul style="list-style-type: none"> • HIEM Service
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Service Set Combinations and Versioning

Applicants can be validated in either or both NHIN Patient & Document Services and NHIN Health Information Event Service, as pictured below.

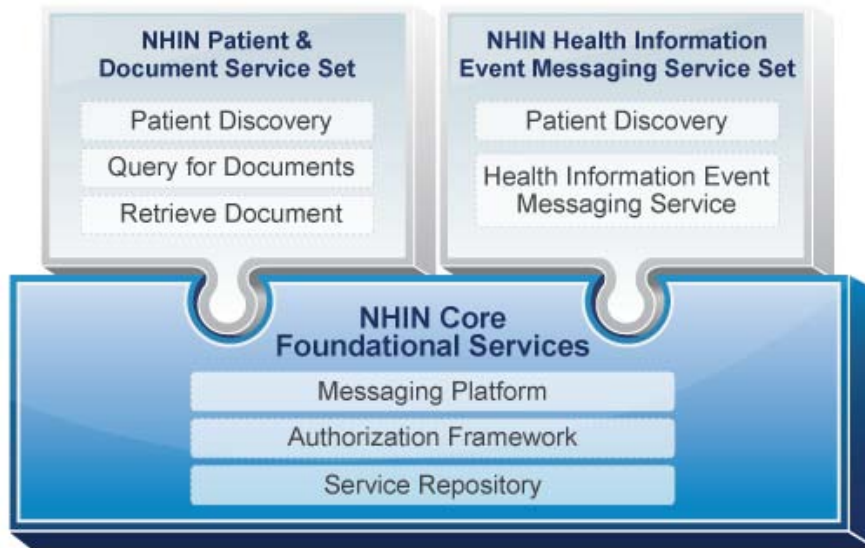


Figure 4 – Applicants can be validated in either or both NHIN Patient & Document Services and in NHIN Health Information Event Service.

As new versions of the specification sets are released, NHIN Participants will be required to re-validate on the technical track (to pass conformance and interoperability testing) when they upgrade. A deprecation grace period 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; technical validation is required for each new service a Participant opts to support.

Testing

The Applicant must comply with the following testing requirements:

- Passing NHIN conformance tests, and
- Passing NHIN interoperability tests.

Both conformance and interoperability testing are automated processes built upon test cases created by the NHIN Testing Team.

Validating Body(ies)

In keeping with its focus on simplicity and ease, NHIN validation can be performed by a validating body or bodies authorized to validate an Applicant’s ability to meet the criteria defined by the NHIN Coordinating Committee. We anticipate that a well-defined, simple qualification process can be



performed by multiple qualified organizations, which will promote participation in the NHIN for a diverse group of entities. As the network grows, so will the value of the network.

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