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National Health Information Center (NHIC)

Enabling Standards-Based eHealth Interoperability

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Saudi Health Information Exchange Testing and Certification Policies

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## Document Revision History

Version	Date	Type of update	Prepared/Revised by
1.0	April 21, 2016	First Release	National Health Information Center

## Policy Approval Process

Subject: Saudi Health Information Exchange Testing and Certification Policies		Approved By:
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# 1. INTRODUCTION

## 1.1 DOCUMENT PURPOSE

The purpose of the policies is to specify the requirements to assure that the interoperability between eHealth products is managed with sufficient rigor and controls to assure that products are conformant with the Saudi eHealth Interoperability Specifications. To achieve this objective three policies are needed:

- Saudi Health Information Exchange Testing Policy
- Saudi Health Information Exchange Certification Policy
- Saudi Health Information Exchange Certification Surveillance Policy

Note: this document aligns with the Saudi e-Government Interoperability Standards (YEFI) to expedite national adoption.

## 1.2 SCOPE

### **In Scope:**

The scope of this document is the specification of testing and certification requirements to verify that products use by Health Information Exchange Nodes (HIE Nodes) are conformant with the Saudi eHealth Interoperability Specifications.

### **Out of Scope:**

The following is a list of content and specifications that are specifically out of scope for this document:

- Operational procedures for the implementation of these policies are to be defined by the operations team that will be performing testing and certification. Such operational procedures are out of scope of this document.

## 1.3 HOW TO READ THIS DOCUMENT

### 1.3.1 Where to Find Information

This document contains six normative sections, as well as informative appendices for the readers' convenience. The document is structured as follows:

**Section 1:** Contains an introduction to the Testing and Certification Policies document. This section contains a summary of the document purpose and scope, as well as other content to help orient the first time reader to the topic of the document and how it relates to other specifications in the Saudi Health Information Exchange (SeHe) Platform.

**Section 2:** Lists the terms used in the document and their official definitions.

**Sections 3 – 5:** Specify the policies as defined for the Saudi Health Information Exchange.

**Section 6:** Lists the Saudi eHealth reference documents, as well as the international standards which underpin the definitions and policies.

### 1.3.2 Document Conventions

Throughout this document the following conventions<sup>1</sup> are used to specify requirement levels:

**SHALL:** the definition is an absolute requirement of the specification.

**(NOTE: "SHALL ..... IF KNOWN" MEANS THAT THE TAG MUST BE SENT. HOWEVER, IF THERE WERE NO INFORMATION, THEN THIS TAG SHOULD BE SENT WITH A <NULLFLAVOR>)**

**SHALL NOT:** the definition is an absolute prohibition of the specification.

**SHOULD:** there may exist valid reasons in particular circumstances to ignore a particular item, but the full implications must be understood and carefully weighed before choosing a different course.

**SHOULD NOT:** there may exist valid reasons in particular circumstances when the particular behavior is acceptable or even useful but the full implications should be understood and the case carefully weighed before implementing any behavior described with this label.

**MAY or OPTIONAL:** means that an item is truly optional. One vendor may choose to include the item because a particular marketplace requires it or because the vendor feels that it enhances the product while another vendor may omit the same item.

## 1.4 METHODOLOGY

These policies have been developed with input from various Saudi stakeholders, collected through workshops and teleconferences.

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<sup>1</sup> Definitions based upon RFC 2119

## 2. SAUDI HEALTH INFORMATION EXCHANGE DEFINITIONS

TABLE 2-1 DOCUMENT DEFINITIONS

TERM	DEFINITION
Accreditation	Third-party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks [ISO/IEC 17000]
Accreditation body	Authoritative body that performs accreditation [ISO/IEC 17000] (e.g. of testing laboratories or certification bodies)
Attestation	Issue of a statement, based on a decision following review, that fulfillment of specified requirements has been demonstrated [ISO/IEC 17000]
Audit	Systematic and independent examination of accesses, additions, or alterations to electronic health records to determine whether the activities were conducted, and the data were collected, used, retained or disclosed according to organizational standard operating procedures, policies, good clinical practice, and applicable regulatory requirement(s). [ISO 27789]
Audit Log	Chronological sequence of audit records, each of which contains data about a specific event. [ISO 27789]
Audit Record	Record of a single specific event in the life cycle of an electronic health record. [ISO 27789]
Certificate of Conformity	A document certified by a Certification Body that the supplied good or service meets the required specifications
Certification Body	Third-party conformity assessment body operating certification schemes [ISO/IEC 17065] NOTE: A certification body can be non-governmental or governmental (with or without regulatory authority).
Conformance Criteria	Requirements that are to be fulfilled in order to claim that the tested system is compliant with the specification
Conformance Test Methods	Test procedures, test data, and test tools
Impartiality	Presence of objectivity [ISO/IEC 17065]  NOTE 1: Objectivity is understood to mean that conflicts of interest do not exist, or are resolved so as not to adversely influence the activities of the body.  NOTE 2: Other terms that are useful in conveying the element of impartiality are independence, freedom from conflicts of interest, freedom from bias, freedom from prejudice, neutrality, fairness, open-mindedness, even-handedness, detachment, and balance.
Mark of Conformity	Protected mark issued by a body performing third-party conformity assessment, indicating that an object of conformity assessment (product, process, person, system or body) is in conformity with specified requirements [ISO/IEC 17030]  EXAMPLES Third-party marks of conformity can be: product certification marks, quality/environment management system certification marks, environmental conformity marks, etc.  NOTE 1 A protected mark is a mark legally protected against unauthorized use.  NOTE 2 The specified requirements are generally stated in “normative” documents such as International Standards regional or national standards, regulations and specifications.
May or Optional	Indicates that an item is truly optional. One vendor may choose to include the item because a particular marketplace requires it or because the vendor feels that it enhances the product while another vendor may omit the same item.
Product	A homegrown system or a system that is delivered by a vendor that may be installed in one or more location.

TERM	DEFINITION
Revocation	Cancellation of the statement of conformity [ISO/IEC 17000], Note: initiated by the Certification Body]
Saudi Health Exchange (SeHE)	The Saudi organization known as SeHE that delivers capabilities to enable the electronic sharing of health-related information and health-related services across the country of Saudi Arabia.
Saudi Certification Scheme	The certification scheme is derived and consistent with the Saudi Health Information Exchange Testing and Certification Policies. It operationalizes them at a level which the certification body can use to establish its processes. The certification scheme is used by the accrediting body to accredit the certification body in accordance with ISO/IEC 17065.  Certification system related to specified products, to which the same specified requirements, specific rules and procedures apply [ISO/IEC 17065]
Saudi Testing Scheme	The testing scheme is derived and consistent with the Saudi Health Information Exchange Testing and Certification Policies. It operationalizes them at a level which the testing laboratory can use to establish its processes. The testing scheme is used by the accrediting body to accredit the testing laboratory in accordance with ISO/IEC 17025.  [ISO/IEC 17025] General requirements for the competence of testing and calibration laboratories
Scheme Owner	Person or organization responsible for developing and maintaining a specific certification scheme [ISO/IEC 17065]  NOTE The scheme owner can be the certification body itself, a governmental authority, a trade association, a group of certification bodies or others.
Scope of Certification	Range or characteristics of objects of conformity assessment covered by the certification
Security	Combination of availability, confidentiality, integrity, and accountability. [ENV 13608-1]
Security and Privacy Audit	Audit focused on assuring conformance to security and privacy practices and procedures.
Shall	Whenever occurs in this policy, <b>SHALL</b> means the action must be taken.
Should	Whenever occurs in this policy, <b>SHOULD</b> means it is a recommendation that an action ought to be done, but it is not required.
Suspension	Temporary invalidation of the statement of conformity for all or part of the specified scope of attestation [ISO/IEC 17000]
Test Script	Steps that define the actions and pass/fail criteria.
Testing Laboratory	The organization and physical set of facilities that perform the conformance tests
Vendor	The party responsible for developing a homegrown system or for developing or reselling a commercial product.
Withdrawal	Cancellation of the statement of conformity [ISO/IEC 17000], Note: initiated by the vendor of the Product

### 3. SAUDI HEALTH INFORMATION EXCHANGE TESTING POLICY

#### 3.1 PURPOSE

The purpose of this policy is to specify the requirements to assure that the interoperability between Products that are expected to be used as HIE Nodes is managed with sufficient rigor and controls. The purpose of these controls is to assure that tested products conform to the Saudi eHealth Interoperability Specifications.

#### 3.2 SCOPE/APPLICABILITY

This policy applies to the testing scope, process and methods performed by a testing laboratory that will assess conformance of eHealth Products to the Saudi eHealth Interoperability Specifications. It also applies to any Vendor seeking certification of their Product.

This Policy is intended to be primarily applied to the testing of the interoperability of Products to be deployed as HIE Nodes connected to the Saudi eHealth Exchange (SeHE) Platform.

#### 3.3 POLICY

1. Conformance Criteria and Test Scripts are used for testing:
  - 1.1. Conformance Criteria **SHALL** be derived from one or more Saudi eHealth Core Interoperability Specifications
  - 1.2. Test Scripts **SHALL** be derived from Conformance Criteria
  - 1.3. Both Conformance Criteria and Test Scripts:
    - 1.3.1. **SHALL** be developed, issued for public review, published, and maintained by a body a by the Ministry of Health
    - 1.3.2. **SHOULD** be subject to use in pilot testing prior to authorization for use in operational testing, and
    - 1.3.3. **SHALL** be approved for use in the Saudi eHealth Certification Program as specified by the Certification Policy.
2. Testing may be conducted by (Party seeking testing):
  - 2.1. an independent body (third party (3rd party))
  - 2.2. a purchaser or organization with user interest (second party (2nd party))
  - 2.3. a Vendor (first party (1st party))
3. A party seeking testing of its product **SHALL** select to test for conformance:
  - 3.1. to one or more published Saudi eHealth Core Interoperability Specifications that have been approved for testing, and
  - 3.2. by selecting one or more specific Use Case actors and corresponding options, if any, for each Core Interoperability Specification which the party is seeking testing for one of its Products.
4. Testing **SHALL** follow quality management practices as defined by *ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories*, with additional requirements specified by the Saudi Testing Scheme for:

- 4.1. human factors,
  - 4.2. accommodation and environmental conditions,
  - 4.3. test and calibration methods and method validation,
  - 4.4. equipment,
  - 4.5. measurement traceability,
  - 4.6. sampling,
  - 4.7. the handling of test and calibration items,
  - 4.8. assuring the quality of test and calibration results, and
  - 4.9. reporting the results.
5. The Saudi Testing Scheme used in conjunction with ISO/IEC 17025 **SHALL** be approved by the same entity that is responsible for approving the Interoperability Specifications.
  6. The following types of test laboratory are permissible:
    - 6.1. Testing laboratories **SHALL** be authorized by the Saudi Health Council (SHC).
    - 6.2. The testing laboratory **MAY** conduct all testing activity or **MAY** choose to sub-contract the testing under the *ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories* sub-contracting condition.
  7. Accreditation of Test Laboratories
    - 7.1. Testing **SHALL** be conducted by a testing laboratory accredited under ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories,
    - 7.2. Testing Laboratories **SHALL** be accredited by an accreditation body that is a member in good standing of the International Laboratory Accreditation Cooperation (ILAC),
    - 7.3. Accreditation for test laboratories **SHALL** verify conformance to additional requirements specified by the Saudi Testing Scheme:
  8. Execution of tests:
    - 8.1. **SHALL** use the published Test Scripts related to the Core Interoperability Specification to which conformance is being assessed
    - 8.2. **SHALL** be conducted in-person (product undergoing test collocated with the tester) at a test-laboratory authorized facility in the event that the test lab determines that in-person testing is needed to assure the validity of the test results, and
    - 8.3. **MAY** be conducted remotely (e.g. with tester via a Web Meeting) as determined by the test laboratory.
  9. Detailed Test Results and evidence documentation of testing sessions **SHALL** include all of the following:
    - 9.1. a copy of test messages and/or exchanged documents used to demonstrate conformance,
    - 9.2. screenshots captured during the test session,
    - 9.3. recorded Web Meeting session,
    - 9.4. time stamps associated with all retained messages, documents, screenshots and other evidence,
    - 9.5. record of validator output where test tools include a validation report, and
    - 9.6. communications log that includes the content of exchanges between tester and party seeking testing along with timestamps.

10. Detailed Test Results evidence **SHALL** be archived for at least the duration of the certification validity period by the testing laboratory and communicated to the Certification Body.
11. Tests **SHALL** be verified by at least one test monitor. The test laboratory **MAY** determine that results require verification by multiple monitors.
12. The Test Report Summary **SHALL** include reference to test samples, steps undertaken to demonstrate compliance with a requirement, and the supporting evidence that the testing session was conducted in accordance with specified test scripts. The test report summary **SHALL** use a template approved by the body that publishes the test scripts.
13. The Test Report Summary **SHALL** be made public should the tests be used as the basis for an approved certification.
14. A party seeking testing of its product **SHALL** declare the Product, name, and version that will be tested.
15. A party seeking testing of its product **MAY** distinguish modules within its Product. In this case, the party seeking testing of its product **SHALL** declare the name and version of each of the modules that will be tested.
16. A testing laboratory **MAY** offer incremental testing for compliance to conformance criteria with requirements that overlap those for which the party seeking testing has already demonstrated conformance. The test laboratory **SHALL** apply the necessary level of rigor (e.g. selective re-testing) based upon the design evidence provided by the party seeking testing of its product.

### **3.4 POLICY MAINTENANCE**

The Saudi Health Council (SHC) is responsible for monitoring and maintenance of this policy.

## 4. SAUDI HEALTH INFORMATION EXCHANGE CERTIFICATION POLICY

### 4.1 PURPOSE

The purpose of this policy is to specify the requirements for issuing an authoritative Certificate of Conformity attesting that the Products that are expected to be used as HIE Nodes conform to the Saudi eHealth Interoperability Specifications.

### 4.2 SCOPE/APPLICABILITY

This policy applies to the Certification Body that will be used as a source for certification attestation of Products performing eHealth information exchange and to any party seeking certification under the Saudi eHealth Testing and Certification Policy.

This Policy is intended to be first applied to the interoperability of products connected to the Saudi eHealth Exchange (SeHE) Platform.

### 4.3 POLICY

1. The Saudi eHealth Certification Body meets the following criteria:
  - 1.1. It **SHALL** be a single national entity.
  - 1.2. It **SHALL** be authorized by CHS.
  - 1.3. It **MAY** be governmental, commercial, not-for-profit, or subcontracted to one of these.
2. Products that **MAY** be certified include:
  - 2.1. Any IT Product – irrespective of care setting – that needs to exchange health information in conformance with the Saudi eHealth Interoperability Specifications.
  - 2.2. Any Product that will be installed on systems performing eHealth information exchange with the Saudi eHealth Exchange (SeHE) Platform.
3. The Scope of Certification **SHALL** be determined by CHS by identifying (1) one or more Core Interoperability Specifications and for each Core Interoperability Specification (2) the specific Use Case Actors that are within the scope of certification. This is published in the Saudi eHealth Certification Scheme.
4. The Saudi eHealth Certification Scheme **SHALL** be developed and maintained by the same body as the one designated by CHS to develop and maintain the Saudi Testing Scheme.
5. A party seeking certification of its products **SHALL** select within the currently published Scope of Certification:
  - 5.1. to one or more published Saudi eHealth Core Interoperability Specifications that have been approved for testing, and,
  - 5.2. by selecting one or more specific Use Case actors and corresponding options, if any, for each Core Interoperability Specification for which the party is seeking testing for one of its Products.

6. The Saudi eHealth Certification Body **SHALL** process the testing reports provided by any of the testing laboratories authorized per the Testing Policy and validate their content to issue or not the Certificate of Conformity.
7. The certification **SHALL** be carried out by a person who has not been involved in the determination testing activities.
8. The Certificate of Conformity **SHALL** be provided to the party seeking certification by the designated Saudi eHealth Certification Body.
9. The Certificate of Conformity **SHALL** be valid for a period of four (4) years from the date of issue.
10. A Mark of Conformity **MAY** be used by the party having received the Certificate of Conformity in its literature, promotional material, and product packaging according to the constraints established by the Certification Scheme.
11. Accreditation for the Certification Body **SHALL**:
  - 11.1. be based on ISO/IEC 17065 Conformity assessment — Requirements for bodies certifying products, processes and services, with additional requirements specified by the Saudi eHealth Certification Scheme, and
  - 11.2. be conducted by an accreditation body designated by CHS.
12. The accreditation process **SHALL** begin with an initial assessment based upon operational plans prior to beginning certification operations, followed by a follow-up assessment to be delivered within Six (6) months of beginning certification operations.

#### **4.4 POLICY MAINTENANCE**

The Saudi Health Council (CHS) is responsible for monitoring and maintenance of this policy.

## 5. SAUDI HEALTH INFORMATION EXCHANGE CERTIFICATION SURVEILLANCE POLICY

### 5.1 PURPOSE

The purpose of this policy is to specify the requirements for monitoring and reassessment of certified Products to assure continued validity of their conformance to the Saudi eHealth Interoperability Specifications.

### 5.2 SCOPE/APPLICABILITY

This policy applies to the Certification Body that will be used as a source for monitoring and reassessment of certification of Products performing eHealth information exchange and for any party that has products certified under the Saudi eHealth Testing and Certification Policy.

### 5.3 POLICY

1. Certified eHealth products **SHALL** be re-certified:
  - 1.1. following every major product version update,
  - 1.2. following every product minor version update or release, based upon assessment conducted by the Certification Body and as advised by the testing laboratory to determine if functionality is assessed to have been sufficiently changed from the previous version or release, and
  - 1.3. following major updates to a Core Interoperability Specification, based upon assessment conducted by the Certification Body and as advised by the testing laboratory.
2. The party seeking testing **MAY** apply for a re-testing waiver with documented justification as to how the Product updates do not impact the aspects of the product that have been certified.
3. A Certificate of Conformity issued to specific version of a product remains valid for four (4) years. Upon request of the Party seeking certification, a surveillance **MAY** be conducted by the Certification Body, and if approved, **MAY** result in extending the validity for another four (4) years.
4. Suspension/Withdrawal
  - 4.1. In the event that a request for certification withdrawal is made by the vendor of the certified product, certification **SHALL** remain valid for installed products only for the remaining certificate validity.
  - 4.2. In the event that a request for certification withdrawal is due to cause, the organization or individual initiating the request **SHALL** submit the evidence with explicit reference to a specific test case.
  - 4.3. Once a request for certification withdrawal is received by the Certification Body, the Certification Body **SHALL** either accept or reject the validity of the problem identified in the request within one month of the date of receipt.
  - 4.4. Once a Certification Body has accepted the validity of a problem identified in a request for certification withdrawal, the decision to suspend or withdraw the

- certificate **SHALL** be communicated to the supplier within three (3) months of the date the problem was determined to be valid.
- 4.5. The maximum time for a suspension **SHALL** be six (6) months. During this time, the supplier **SHALL** either be re-certified, or the certificate **SHALL** be withdrawn.
5. A problem report **MAY** be filed by a party that has acquired or plans to acquire the product, by another vendor, or by a third party.
6. A Problem Report **SHALL** be handled according to the following criteria:
- 6.1.1. Investigation of validity **SHALL** be made by the Certification Body.
  - 6.1.2. Per laws, legal action against abuse of the problem reporting process **MAY** be taken.
  - 6.1.3. Suppliers **SHALL** be notified of any report that is under investigation regarding their product.
  - 6.1.4. The source of the report **SHALL** be kept confidential until the validity of the report is confirmed.
  - 6.2. Once the validity of a report is confirmed, the source of the report and vendor impacted **SHALL** be notified and **SHALL** be engaged in the investigation.
  - 6.3. If the validity of a report is not confirmed, the source of the report and vendor impacted **SHALL** be notified.
  - 6.4. Based on the conclusion of the investigation, a determination **SHALL** be made by the Certification Body on the basis of the Saudi eHealth Certification Scheme, if the problem justifies:
    - 6.4.1. A suspension (e.g., non-intentional error introduced in the product that needs to be fixed)
    - 6.4.2. A revocation (e.g., test falsified).
    - 6.4.3. No impact on the status of the Certificate of Conformity but an advice to the supplier (e.g., correction to the product), or to the entity responsible for the Conformance Test Methods.
  - 6.5. If a decision is made by the Certification Body to suspend or to revoke the certification, the source of the report and the vendor impacted **SHALL** be notified Sixty (60) days prior to public notice.
  - 6.6. Revocation or suspensions of Certificates of Conformity **SHALL** be published.

#### **5.4 POLICY MAINTENANCE**

The Saudi Health Council (CHS) is responsible for monitoring and maintenance of this policy.

## 6. REFERENCED DOCUMENTS

TABLE 6-1 EXTERNAL REFERENCES

DOCUMENT NAME/ STANDARD	DOCUMENT DESCRIPTION
ISO/IEC 17000 Conformity assessment — Vocabulary and general principles	Specifies general terms and definitions relating to conformity assessment, including the accreditation of conformity assessment bodies, and to the use of conformity assessment to facilitate trade
ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories	Specifies the general requirements for the competence to carry out tests and/or calibrations, including sampling. It covers testing and calibration performed using standard methods, non-standard methods, and laboratory-developed methods.
ISO/IEC 17030 - Conformity assessment — General requirements for third-party marks of conformity	Provides general requirements for third-party marks of conformity, including their issue and use
ISO/IEC 17065 Conformity assessment — Requirements for bodies certifying products, processes and services	Specifies the requirements for the competence, consistent operation and impartiality of product, process and service certification bodies.