NIST Normative Test Process Document: Syndromic Surveillance Test Tool

Test Tool and Test Descriptions to Conduct ONC 2015 Edition Certification
NIST Approved Version 1.0
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Developed by the National Institute of Standards and Technology (NIST) in collaboration with the Center for Disease Control and Prevention (CDC)

National Institute of Standards and Technology

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NIST Normative Test Process Document for §170.315(f)(2) Transmission to public health agencies – syndromic surveillance

This document explains the testing process for which a National Institute of Standards and Technology (NIST) validation test tool is used in evaluating conformance of a health information technology module (Health IT Module) to the certification criterion §170.315(f)(2) Transmission to public health agencies – syndromic surveillance defined in 45 CFR Part 170 of the Office of the National Coordinator for Health Information Technology (ONC), Department of Health and Human Services (HHS) 2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications Final Rule.

For the ONC Approved §170.315(f)(2) Transmission to public health agencies – syndromic surveillance test procedure visit https://www.healthit.gov/policy-researchers-implementers/2015-edition-test-method

For detailed certification criterion verbiage, please consult ONC's 2015 Edition Certification Companion Guide for Syndromic Surveillance https://www.healthit.gov/sites/default/files/2015Ed_CCG_f2-Trans-PHA-syndromic-surveillance.pdf

EXPLANATION OF TERMS

Key for Names and Terms Used Frequently in this Document	
Referenced Names and Terms	**Equivalent Used in Document**
HL7 v2.5.1 PHIN Messaging Guide for Syndromic Surveillance: Emergency Department, Urgent Care, Inpatient and Ambulatory Care Settings, Release 2.0, April 21, 2015, and Erratum to the CDC PHIN 2.0 Implementation Guide, August 20, 2015	**PHIN Messaging Guide and associated Erratum**
International Classification of Diseases, 10th Revision, Clinical Modification (ICD-9-CM)	**"ICD-9-CM" or "ICD-9"**
International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM)	**"ICD-10-CM" or "ICD-10"**
Health IT Module	**"HIT Module" or "Module"**
HL7 v2.5.1 Context-based capability of the NIST Syndromic Surveillance Test Suite	**Tool**

INFORMATIVE TEST DESCRIPTION

This section provides an executive summary describing how the NIST testing process is organized and conducted. The *Understanding Syndromic Surveillance Messaging ONC Certification Testing Edition 2015* document is available via the Documentation tab in the NIST Syndromic Surveillance Test Tool; this document is an additional resource that explains the process of Health IT Module certification testing for HL7 V2 Syndromic Surveillance Messaging.

This document has been developed to be used by the ONC- Accredited Testing Laboratories (ATLs) in certification of Health IT Modules for the ONC. The term 'Tester', when used in this document, refers to a person (such as an ATL employee) acting on behalf of an ATL for certification testing of a Vendor's HIT Module. In addition, a Vendor may use this document to test their own HIT Modules in preparation for certification testing by an ATL.

The test evaluates the capability for a Health IT Module to create messages for electronic transmission of patient syndromic surveillance information that are conformant to

- The HL7 Version 2.5.1 PHIN Messaging Guide for Syndromic Surveillance: Emergency Department, Urgent Care, Inpatient, and Ambulatory Care Settings, Release 2.0, April 21, 2015
- The Erratum to the CDC PHIN 2.0 Implementation Guide, August 20, 2015

During the process of building the Syndromic Surveillance Test Suite, NIST (National Institute of Standards and Technology) discovered conformance requirements that were either conflicting or unclear in the named standards documents as well as additional errata. The "NIST Clarifications and Validation Guidelines for HL7 Version 2.5.1 PHIN MESSAGING GUIDE FOR SYNDROMIC SURVEILLANCE: EMERGENCY DEPARTMENT, URGENT CARE, INPATIENT AND AMBULATORY CARE SETTINGS, Release 2.0, ADT MESSAGES A01, A03, A04 and A08, Optional ORU^R01 Message Notation for Laboratory Data" document clarifies these issues and indicates how they are interpreted in the Tool. This document can be accessed via the "Documentation" tab on the 2015 Edition NIST Syndromic Surveillance Test Suite.

The ONC 2015 Edition Final Rule specifies that only the requirements for **emergency care, urgent care, and inpatient care settings** in the PHIN Messaging Guide are in-scope for ONC certification testing of Health IT Modules.

The PHIN Messaging Guide for Syndromic Surveillance defines four ADT Message Types that are relevant for certification testing of a Health IT Module:

- ADT^A01 Admit / Visit Notification
- ADT^A03 Discharge / End Visit
- ADT^A04 Register a Patient
- ADT^A08 Update Patient Information[1]

[1] A08 update messages are sent at the time the new or changed information becomes available, whether before or after discharge. The information they contain is cumulative (i.e., **snapshot mode**), presenting all previously sent information that remains correct and adding the new or changed information

The NIST Syndromic Surveillance Messaging Test Tool includes four care setting-specific Test Scenarios with one or more Test Cases, each of which has two or more Test Steps (and specific test data) for each ADT Message Type appropriate for the care setting. For the certification testing, the Tester shall select one Test Case from **each** of the four Test Scenarios. The HIT Module being tested must be able to demonstrate the capabilities included in the four Test Cases in order to pass the certification testing.

The Center for Disease Control and Prevention (CDC), in collaboration with NIST, provided the Test Scenarios and Test Data for this testing process.

Listed in the **Test Data section** of this document are the Test Scenarios, Test Cases, and Test Steps that have been developed for the NIST testing process. Test Data PDF Documents, which are accessible from the NIST Syndromic Surveillance Messaging Test Suite identified in the **Conformance Test Tools section** of this testing process document, contain the test data that are specific to each Test Step. Instructions for use of the provided test data are listed in the **Normative Test Description** and **Test Data sections** of this testing process document.

Note: Regarding messages/capabilities that are out-of-scope for ONC Edition 2015 Health IT certification testing

- The focus of ONC certification is on the ability of the Health IT Module to create conformant Syndromic Surveillance messages and **is not on** the operational aspect of transmitting the messages.
- Batch requirements are not included in the ONC Edition 2015 syndromic certification testing. The NIST Test Tool may support batch processing in the future
- The NIST Test Tool does not support validation of optional message types for ONC certification testing. The PHIN Messaging Guide specifies that HL7 Unsolicited Observation (ORU^R01) Messages that may be sent for submission of laboratory results relevant to syndromic surveillance are O (Optional). ORU^R01 Messages are out-of-scope for the ONC certification testing.
- Public health agency (PHA) Health IT Modules are not included in the ONC Edition 2015 syndromic certification criterion, and Acknowledgement (ACK) messages created by PHA systems are out-of-scope for the ONC certification testing.

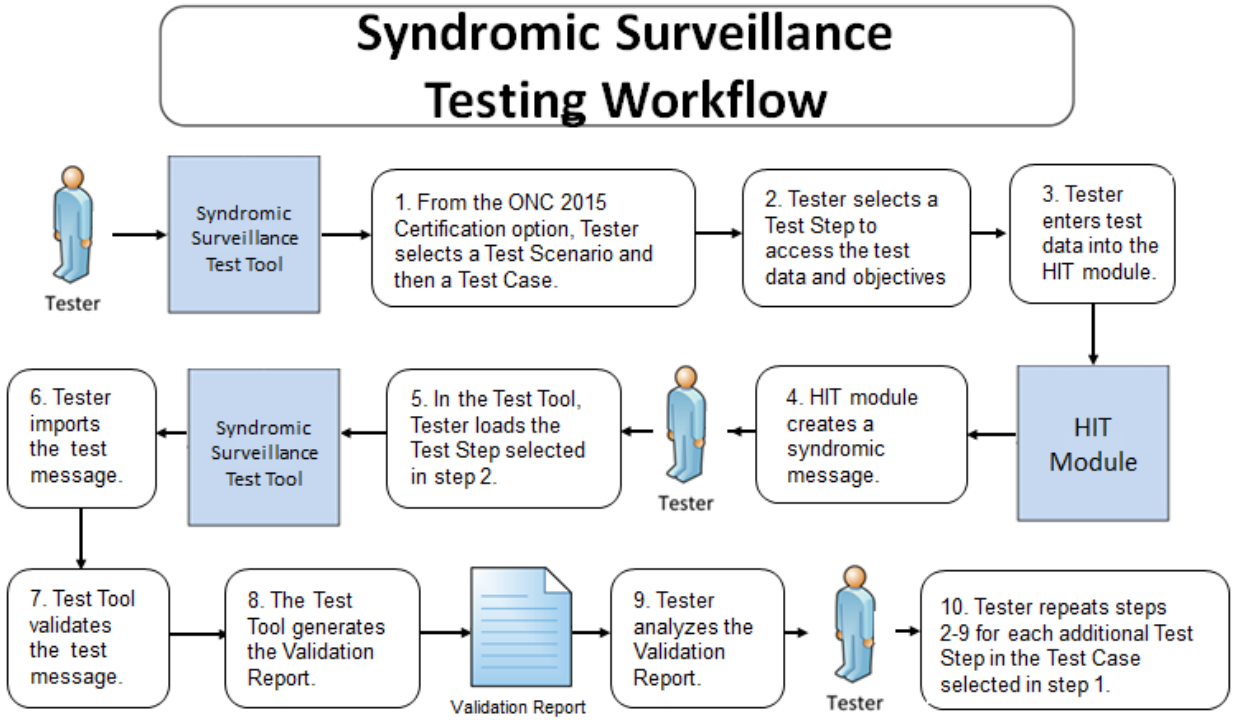
NORMATIVE TEST DESCRIPTION

Derived Test Requirement

SS_DTR - 1: Electronically Create Syndromic Surveillance Messages

SS_DTR - 1: Electronically Create Syndromic Surveillance Messages

Figure 1 Create Syndromic Surveillance Messages



The instructions in the testing process listed below reference the numbered test steps in **Figure 1**.

Required Vendor Information

1. Vendor shall identify the Health IT Module function(s) that are available to 1) create patient records in the Health IT Module and input the test data for the test patients, 2) create syndromic surveillance messages using the test data, and 3) import[2] the syndromic surveillance messages into the NIST Test Tool
2. Vendor shall provide the mechanism necessary to capture and import syndromic surveillance messages into the Tool

[2] During certification testing, the mechanism by which the syndromic surveillance test message is imported (sent) from or to the Health IT Module being tested is not specified. The ATL may have their own utility, they may allow the Module vendor to use a utility created by that vendor, or the message can be cut from the Module and pasted into the NIST Test Tool or cut from the NIST Test Tool and pasted into the Module. For certification testing, the key requirement is for the Module to demonstrate real time/dynamic import.

Required Testing Actions

1. Using the Context-based capability provided in the Tool identified in the **Conformance Test Tools section** of this testing process document, the Tester shall access the **ONC 2015 Certification** test plan and shall select a syndromic surveillance Test Scenario and then a Test Case [Figure 1, Step 1]
2. The Tester shall select the first Test Step in the selected Test Case [Figure 1, Step 2]
3. Using the capabilities in the Health IT Module, the Tester shall
   a) Input the provided syndromic surveillance test data for the selected Test Step using the Test Data Specification in the Tool for the Test Step (input can be performed using a manual or automated process) [Figure 1, Step 3]
   b) Cause the Module to generate the indicated syndromic surveillance message [Figure 1, Step 4]
4. In the NIST Tool, the Tester shall load the selected Test Step and import the syndromic surveillance message generated by the Health IT Module, and the NIST Tool validates the message [Figure 1, Steps 5, 6, & 7]
5. Using the **Inspection Test Guide**, the Tester shall verify that the syndromic surveillance message is conformant to the **Referenced Standards** and that the message includes the specified syndromic surveillance information
6. The Tester shall repeat Required Testing Actions 2 – 5 using the next sequential Test Step until all Test Steps in the selected Test Case are completed [Figure 1, Step 10]

Inspection Test Guide

1. Using the Validation Report produced by the NIST Tool**,** the Tester shall analyze the Report and verify that the message created by the Health IT Module meets the conformance requirements in the **Referenced Standards** [Figure 1, Steps 8 & 9]
   a) If the Tester determines that the ICD-9, ICD-10, or SNOMED CT code in a message created by the Module is a **valid code** for a data item (e.g., diagnosis) even though it is different from the ICD-9, ICD-10, or SNOMED CT code provided for that data item in the test data for that message, the Tester shall allow an exception; for example, the Tool may accept five different ICD-9 codes for a given diagnosis (because all five codes are listed in the ICD-9 Value Set in the Tool), but the message created by the Module may be populated with an ICD-9 code that was not included by the subject matter experts who collaborated with NIST on the test data
   b) ICD-9 and ICD-10 codes in the messages are acceptable with or without decimals
   c) The Health IT Module must demonstrate the ability to support ICD-9, ICD-10, and SNOMED CT codes as required in the PHIN Messaging Guide and associated Erratum; for example, Admit/Encounter Reason (PV2-3) and Primary Diagnosis and Additional Diagnoses (DG1-3) are Required data elements that use these codes; where a code from one of these coding systems is provided in the test data for the message associated with a given Test Step, the Module must be capable of supporting the code
2. Once during the certification testing for this criterion, the Tester shall inspect the Health IT Module to verify the capability of the Vendor to support the value sets specified

a) Using the Module's function(s) and the NIST Tool, the Vendor shall demonstrate to the Tester that their Module supports any of the value sets (selected at the Tester's discretion) specified in the PHIN Messaging Guide and associated Erratum

TEST DATA

Test data are provided for the testing process to ensure that the applicable requirements identified in the ONC criteria can be adequately evaluated for conformance, as well as to provide consistency in the testing process across multiple National Voluntary Laboratory Accreditation Program (NVLAP) -Accredited Testing Labs (ATLs). The provided test data focus on evaluating the basic capabilities required of the Health IT Module, rather than exercising the full breadth/depth of capability that installed Health IT Modules might be expected to support. The test data are formatted for ease of use by the Tester during the testing process; the format is not intended to prescribe the design of the display presented to the end-user for viewing the data. No additional requirements should be drawn from the format.

The Tester shall use and apply the provided test data during the testing, without exception, unless one of the following conditions exists:

- The Tester determines that the Health IT Module is sufficiently specialized that the provided test data need to be modified in order to conduct an adequate test. Having made the determination that some modification to the provided test data is necessary, the Tester shall record the modifications made as part of the test documentation.
- The Tester determines that changes to the test data will improve the efficiency of the testing process (for example, using consistent demographic data throughout the testing workflow). The Tester shall ensure that the functional and interoperable requirements identified in the criterion can be adequately evaluated for conformance, and that the modified test data provide a comparable level of robustness.
- The Tester determines that the ICD-9, ICD-10, or SNOMED CT code in a message created by the Health IT Module is a **valid code** for a data item (e.g., diagnosis) even though it is different from the ICD-9, ICD-10, or SNOMED CT code provided for that data item in the test data for that message

Any departure from the provided test data shall focus on meeting the basic capabilities required of the Health IT Module relative to the certification criterion rather than exercising the full breadth/depth of capability that the installed Health IT Module might be expected to support.

The testing process requires that the Tester enter the applicable test data into the Health IT Module being evaluated for conformance. The intent is that the Tester fully controls the process of entering the test data in order to ensure that the data are correctly entered as specified in the testing process. If a situation arises where it is impractical for a Tester to enter the test data directly, the Tester, at the Tester's discretion, may instruct the Vendor to enter the test data, so long as the Tester remains in full control of the testing process,

directly observes the test data being entered by the Vendor, and validates that the test data are entered correctly as specified in the testing process document.

For ONC Health IT Module certification testing, the primary purpose of the provided test data is to assist the Tester in verifying that the vendor's Module is capable of supporting the required functions; verifying the ability to support *specific* content is applicable only when the test data are categorized as, for example, "Value-Profile Fixed" (see How to Interpret the Message Content Data Sheet section below for additional details about the categorization of test data). The clinical test data are relevant for the given Test Stories; however, these data should not be expected to represent standards of practice.

Test data for certification testing related to the §170.315(f)(2) Transmission to public health agencies – syndromic surveillance ONC criterion are available in the NIST Syndromic Surveillance Test Suite (see the Conformance Test Tools section of this testing process document for instructions on how to access the Test Tool).

NAVIGATING A TEST CASE

A Syndromic Surveillance Messaging Test Case contains multiple Test Steps, each consisting of a Test Story, a Test Data Specification, and a Message Content Data Sheet. All of these artifacts are accessible via the NIST Tool.

- The **Test Story** describes a real-world situation that provides the context for the Test Step.
- The **Test Data Specification** provides the data associated with the Test Story and lists the information that would typically be available for a given situation in the specified clinical setting. Together, the Test Story and the Test Data Specification provide sufficient information for the Testers and Health IT Module Vendors to enter into the Module in order to create the Syndromic message for a particular Test Step. The message is to be created using these data and the Health IT Module functions.
- The **Message Content Data Sheet** shows a conformant message instance for the Test Step. The message content is organized in a table format that provides the HL7 v2 message elements and the data associated with the message elements for a given Test Step. The Message Content Data Sheet may provide assistance to the Tester and Health IT Module Vendor for resolving issues discovered during conformance testing. This data sheet can be thought of as the "answer" to the scenario ("question") provided by the Test Story and the Test Data Specification.

For the Syndromic Surveillance ONC certification testing process, the Tester shall select each of the Test Steps for one of the Test Cases in each of the following four Test Scenarios:

1. Urgent Care Visit
2. ED Visit with Mortality
3. ED Visit with Inpatient Admission
4. Inpatient Visit

Table 1 (Syndromic Surveillance Test Scenarios and Associated Test Cases/Test Steps) lists the **four** Test Scenarios and their Test Cases, and identifies **two to four** Test Steps for each Test Case.

Table 1 Syndromic Surveillance Test Scenarios and Associated Test Cases/Test Steps

Test Scenario	Test Case	Test Steps
Urgent Care Visit	TC-1 UC Visit-Influenza_Child	TS-1 Registration-A04
		TS-2 Discharge-A03
ED Visit with Mortality	TC-2 ED Visit-Patient Dies	TS-1 Registration-A04
		TS-2 Update-A08
		TS-3 Discharge-A03
ED Visit with Inpatient Admission	TC-3 ED Visit-Patient Admitted	TS-1 Registration-A04
		TS-2 Update-A08
		TS-3 Discharge-A03
		TS-4 Admission-A01
Inpatient Visit	TC-4 Inpatient Visit_Surgery	TS-1 Admission-A01
		TS-2 Discharge-A03

Details for each Test Step, including the test story, test objectives, test data, and example HL7 message, are provided via the tabs that are displayed when a user selects a Test Step in the Context-based feature of the Test Tool, and also are available in PDF files accessible via the tabs displayed with the Test Step as well as via the Test Tool Documentation tab. The Tester shall follow the instructions in the **Normative Test Description** section of this testing process document to conduct the certification testing.

HOW TO INTERPRET THE MESSAGE CONTENT DATA SHEET

The Message Content Data Sheet indicates the data that are to be included in the ADT message based on the test data entered into the Health IT Module for a particular Test Step. **Table 2** shows a portion of a Message Content Data Sheet.

Table 2 Message Content Data Sheet Excerpt for DG1 Segment in A04 ADT Message Type

Location	Data Element	Data	Categorization
DG1-1	Set ID - DG1	1	Presence-Configuration
DG1-3	Diagnosis Code - DG1		
DG1-3.1	Identifier	4871	Value-Profile Fixed List
DG1-3.2	Text	Influenza with other respiratory manifestations	Presence-Content Indifferent
DG1-3.3	Name of Coding System	I9CDX	Value-Profile Fixed List
DG1-6	Diagnosis Type	W	Value-Profile Fixed List

The information in the ***Location*** column indicates the canonical element location in the HL7 v2 message. For example, DG1-3.1 represents the 1st component in the 3rd field of the DG1 segment. The ***Data Element*** column indicates the name of the data element as specified by the PHIN Messaging Guide and

associated Erratum. The ***Test Data*** column lists the data to be included for each Data Element in the ADT message created by the Health IT Module.

The ***Categorization*** column indicates the type and expected source of the data as well as how the Context-based feature in the NIST Tool will validate the data for the given Data Element in the ADT message. In some cases the test tool validator simply examines the message element for the presence of data, whereas in other cases the validator examines the message element for the presence of data and for exact content. **Table 3** shows the descriptions of the test data Categories and their associated Qualifiers. Additional information about the test data Categories and Qualifiers is available in the *Understanding Syndromic Surveillance Messaging ONC Certification Testing Edition 2015* document, which is accessed via the Documentation tab in the NIST Syndromic Surveillance Test Suite.

Table 3 Test Data Categories, Associated Qualifiers, and Descriptions

Test Data Categorization	Description	Qualifier	Description
Indifferent	No content is specified.	***None***	None
Presence	Example content is specified.	***Content Indifferent***	Content is expected to be present in the message, but not a specific value.
		Configuration	Content is expected to be present in the message, but not a specific value. The value is usually determined at installations.
		System Generated	Content is expected to be present in the message, but not a specific value. The value is system generated.
		Test Case Proper	Content is expected to be present in the message, but not a specific value. However, content is expected to be consistent with the clinical test story.
Presence-Length	Example content is specified to a minimum length.	***Same qualifiers as for Presence***	Content of a minimum length is expected to be present in the message, but not a specific value.
Value	Specific content is specified.	***Profile Fixed***	Content is defined as a constant in the conformance profile. The constant is specified in the test data.
		Profile Fixed - List	Content is defined as a set of allowable values in the conformance profile. One value from the allowable set is specified in the test data.
		Test Case Fixed	Content that is defined as a constant in the test case.
		Test Case Fixed - List	Content is defined as a set of allowable values in the test case. One value from the allowable set is specified in the test data.
Non-presence	No content is explicitly specified.	***None***	None

Along with the Test Data Specification, the Message Content Data Sheet can be used to assist the Tester and Health IT Module Vendor in loading the test data into the Module for a given Test Step.

The Test Cases and the Context-based feature in the NIST Test Tool are tightly-coupled. In addition to validating message conformance, the Tool performs selective content validation based on the test data provided, and deviation from the test data may cause the Tool to issue Error notifications. For this reason, the Tester should use the test data as specified.

CONFORMANCE TEST TOOLS

The following testing tools are available to evaluate conformance to the standards referenced in this testing process document:

- NIST HL7 v2 Syndromic Surveillance Test Suite – an HL7v2 messaging validation tool; designed to support the NIST testing process for ONC Health IT Certification testing as well as other Syndromic Surveillance message testing
- The tool is available as a Web Application
- The application can be downloaded for local installation
- The Syndromic Surveillance Test Tool Web Application is available at: http://hl7v2-ss-r2-testing.nist.gov

Support for these tools is available by submitting questions to the following user's group:
http://groups.google.com/d/forum/hl7v2-syndromic-testing

Inquiries may also be sent to this user group via email: hl7v2-syndromic-testing@googlegroups.com.

Several browsers may be used to access the HL7 v2 Immunization Test Suite tool; Firefox, Chrome, or Safari are the supported browsers. The Test Tool uses non-standard ports. If your firewall blocks HTTP traffic on non-standard ports, this tool may not be accessible. Please retry access from a location without a firewall that blocks non-standard ports. Alternatively users may download and run a local version of the tool.

The following information is provided to assist the Tester in interpreting the Validation Reports generated by the HL7v2 Syndromic Surveillance Messaging Test Tool:

The Context-based capability in the HL7v2 Syndromic Surveillance Test Tool evaluates conformance requirements that are specified or have been derived from the standards and implementation guides identified in the 2015 Edition of the ONC Final Rule and the test data provided for this testing process. The Test Suite tool evaluates the submitted HL7 message for each conformance requirement, and then produces a Validation Report.

The Tester should consider a Report that contains only Warning and Alert messages to be indicative of a sufficient level of conformance to the standard and test data expectations. If reported, Errors should be considered significant departures from the standard or test data requirements, and these Errors must be corrected in order to claim conformance. ATLs will need to further analyze each Error to determine if, in the context of meeting the criterion and overall meaningful use objective, the Error results in a failure of the testing process by the Health IT Module.

The NIST context-based testing performs specific content validation depending on the Category/Qualifier combination assigned to the Data Elements in the message (see How to Interpret

the Message Content Data Sheet section for more details). In some cases, in order to perform this type of validation the NIST Tool expects the fields/segments/segment groups in the message to be sequenced in a certain order. The complexity of automatically evaluating specific content necessitates this approach. If the Message Validation Result generated by the NIST Tool indicates content-related errors, the ATL may change the order of the fields/segments/segment groups in the test message to match the Test Case once the message has been loaded into the Message Content window of the Test Tool. These kinds of content-related errors do not imply a failure of the vendor product nor a requirement to create the message with the fields/segments/segment groups in a certain order (beyond the base message structure).

Document History

Version Number	Description of Change	Date Published
1.0	Approved Normative Test Process Document	January 21, 2016