Test Procedure for §170.314(f)(6) Transmission to cancer registries – ambulatory setting only

This document describes the test procedure for evaluating conformance of EHR technology to the certification criteria defined in 45 CFR Part 170 Subpart C of the Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology, Final Rule. The document[1] is organized by test procedure and derived test requirements with traceability to the normative certification criteria as described in the Overview document located at http://www.healthit.gov/certification (navigation: 2014 Edition Test Method). The test procedures may be updated to reflect on-going feedback received during the certification activities.

The Department of Health and Human Services (HHS)/Office of the National Coordinator for Health Information Technology (ONC) has defined the standards, implementation guides and certification criteria used in this test procedure. Applicability and interpretation of the standards, implementation guides and certification criteria to EHR technology is determined by ONC. Testing of EHR technology in the Permanent Certification Program, henceforth referred to as the ONC Health Information Technology (HIT) Certification Program[2], is carried out by National Voluntary Laboratory Accreditation Program (NVLAP)-Accredited Testing Laboratories (ATLs) as set forth in the final rule establishing the Permanent Certification Program (*Establishment of the Permanent Certification Program for Health Information Technology, 45 CFR Part 170; February 7, 2011*).

Questions or concerns regarding the ONC HIT Certification Program should be directed to ONC at ONC.Certification@hhs.gov.

CERTIFICATION CRITERIA

This certification criterion is from the Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology, Final Rule issued by the Department of Health and Human Services (HHS) on September 4, 2012.

§170.314(f)(6) Optional—ambulatory setting only—transmission to cancer registries. EHR technology must be able to electronically create cancer case information for electronic transmission in accordance with:

(i) The standard (and applicable implementation specifications) specified in §170.205(i); and

(ii) At a minimum, the versions of the standards specified in §170.207(a)(3) and (c)(2).

[1] Disclaimer: Certain commercial products may be identified in this document. Such identification does not imply recommendation or endorsement by ONC.

[2] Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology, Final Rule.

Per Section III.A of the preamble of the Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology, Final Rule (September 4, 2012), the 2014 Edition of this certification criterion is classified as new. This certification criterion meets at least one of the two factors of new certification criteria: (1) the certification criterion only specifies capabilities that have never been included in previously adopted certification criteria; or (2) the certification criterion was previously adopted as "mandatory" for a particular setting and subsequently adopted as "mandatory" or "optional" for a different setting.

2014 EDITION PREAMBLE LANGUAGE

Per Section III.A of the preamble of the Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology, Final Rule (September 4, 2012) where the transmission to cancer registries certification criterion is discussed:

- "By designating the certification criteria as optional, EHR technology would not need to be certified to these certification criteria in order to satisfy the EHR technology definition. The optional designation will permit EHR technology developers that support EPs intending to report on the associated MU menu objective and measure to still get certified to these certification criteria, but will alleviate the requirement that all EHR technologies be certified to these certification criteria."
- "To clarify for MU purposes, if an EP seeks to meet the associated MU objective and measure, they will need EHR technology certified to these certification criteria, including the adopted standards and implementation guide, in order to have EHR technology that meets the CEHRT definition."
- "The implementation guide was jointly developed by the CDC and the North American Association of Central Cancer Registries (NAACCR). It is based on many years of harmonized cancer registry reporting across the country. The finalized implementation guide, Implementation Guide for Ambulatory Healthcare Provider Reporting to Central Cancer Registries, Release 1, August 2012, reflects the comments received on the draft and clarifies ambiguities such as minimum data elements required and vocabularies for occupation, stage, and other data elements where none/unknown should be an option. In particular, the use of HL7 null flavor is better described such that it may be used where appropriate to indicate lack of information and clarifications were made to the use case scenarios in response to questions about workflow and triggers."
- "While this implementation guide is based on the CDA, the guide was revised in some aspects to harmonize it with the recently developed Consolidated CDA. The implementation guide was revised to take advantage of the document format used by the Consolidated CDA, including the formatting of the data element tables and conformance statements. The new consensus conformance verbs used in Consolidated CDA (that is, shall, should, may, and should not) were

also adopted in the implementation guide to clarify the optionality of data elements. These improvements resolve the ambiguity on required data elements and vocabularies. Overall, the revisions to the draft implementation guide that have been incorporated into the final (Release 1) improve the ability to test and certify EHR technology to the implementation guide and make it easier for EHR technology developers to implement the guide's requirements based on the corrections and clarifications. Accordingly, we have adopted Release 1 of the implementation guide for the "transmission to cancer registries" certification criterion."

- "We decline to adopt SNODENT for the "transmission to cancer registries" certification criterion for the same reasons we gave when we declined to adopt it for the "problem list" certification criterion…"
- "We have established a process for adopting certain vocabulary standards, including SNOMED CT® and LOINC®, which permits the use of newer versions of those standards than the one adopted in regulation. We refer readers to section IV.B for a discussion of "minimum standards" code sets and our new more flexible approach for their use in certification and upgrading certified EHR technologies. Readers should also review § 170.555, which specifies the certification processes for "minimum standards" code sets."
- "In response to the commenters' suggestion that we permit the use of the "most recent version" of the implementation guide for certification, we refer the commenters to section III.A.5 found earlier in this preamble. This section explains why we cannot take such an approach."
- "This final rule does not create or modify any obligations or choices of EPs to report to disease registries or the operations of those registries. It seeks only to facilitate such reporting through CEHRT."

INFORMATIVE TEST DESCRIPTION

This section provides an informative description of how the test procedure is organized and conducted. It is not intended to provide normative statements of the certification requirements.

The test procedures are developed to be used by the ATLs in certification of EHR technology for the ONC. The term 'Tester', when used in the test procedure, refers to a person (such as an ATL employee) acting on behalf of an ATL for certification testing of a Vendor's EHR technology. In addition, an EHR Vendor may use the test procedures to test their own EHR technology in preparation for certification testing by an ATL.

This test evaluates the capability for an EHR technology to electronically generate cancer case information for electronic transmission using the

- HL7 Clinical Document Architecture (CDA), Release 2.0, Normative Edition;
- Implementation Guide for Ambulatory Healthcare Provider Reporting to Central Cancer Registries, HL7 Clinical Document Architecture (CDA);
- IHTSDO SNOMED CT® International Release July 2012 and US Extension to SNOMED CT® March 2012 Release; and

- Logical Observation Identifiers Names and Codes (LOINC®) Database version 2.40, a universal code system for identifying laboratory and clinical observations produced by the Regenstrief Institute, Inc.

During the process of testing the HL7 CDA Cancer Registry Reporting Validation Tool, conformance requirements that were unclear in the named standards documents were discovered. The "Cancer Reporting Errata and Clarification Document for EHR Technology Certification-Release 1.0" clarifies these requirements and indicates how they are interpreted in the test tool. This document can be accessed via the link under the "Additional Documentation" heading on the HL7 CDA Cancer Registry Reporting Validation Tool.

ONC supplies the test data for this test procedure.

Six Test Case Categories are listed in the Test Data section of this test procedure. Each Test Case Category has three Test Cases composed of a test story written in English and a data sheet that lists (as appropriate):

- A templateID
- Data Element
- Code/Value
- Display Name
- Code System OID
- Code System Name
- Conformance

The test data for the Test Cases are provided in the Test Data PDF documents associated with this test procedure. For the certification test, the Tester shall select one Test Case from **each** of the six Test Case Categories. Additional instructions for use of the provided test data are listed in the Normative Test Procedure and Test Data sections of this test procedure document.

There are several data elements where multiple code systems are allowed according to the Implementation Guide for Ambulatory Healthcare Provider Reporting to Central Cancer Registries, HL7 Clinical Document Architecture (CDA). The EHR Vendor is only required to provide a value from one of the code systems specified in the standard for that particular data element. The test data provide a value for each of the code systems to enable the Tester to validate that the correct value was transmitted for the code system chosen by the Vendor.

This test procedure is organized into one section:

- Create – evaluates the capability of the EHR technology to electronically create conformant standard cancer case information documents for electronic transmission
  - Using the Vendor-identified EHR function(s), the Tester inputs the provided cancer case information test data for the test patients (input can be performed using a manual or automated process)

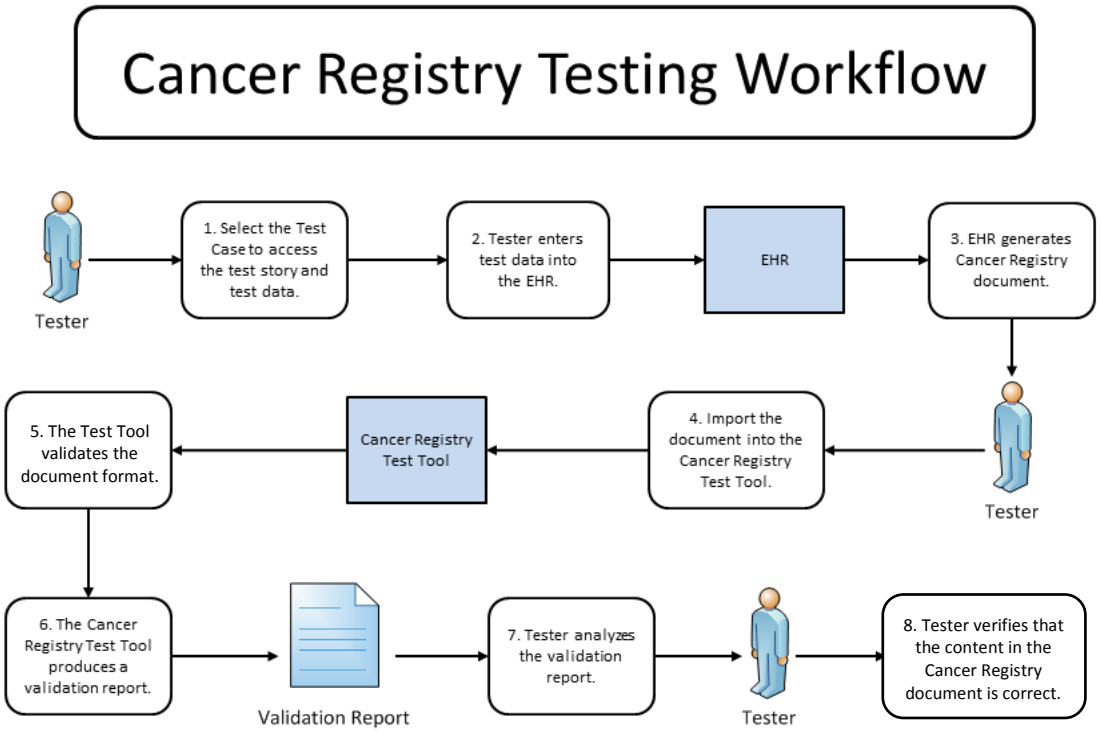
- Using the Vendor-identified EHR function(s) and the provided test data, the Tester causes the EHR to generate the indicated cancer case information document using
  - The HL7 Clinical Document Architecture (CDA), Release 2.0, Normative Edition
  - The Implementation Guide for Ambulatory Healthcare Provider Reporting to Central Cancer Registries, HL7 Clinical Document Architecture (CDA)
  - The IHTSDO SNOMED CT® International Release July 2012 and US Extension to SNOMED CT® March 2012 Release
  - The Logical Observation Identifiers Names and Codes (LOINC®) Database version 2.40
- The Tester imports the cancer case information document into the HL7 CDA Cancer Registry Report Validation tool
- Using the Validation Report produced by the HL7 CDA Cancer Registry Report Validation tool, the Tester verifies that the format of the cancer case information document is conformant to the named standards
- Using the provided test data, the Tester **manually inspects** the cancer case information document and verifies that it contains all of the data elements specified in the provided test data and that the content for these data elements is correct

REFERENCED STANDARDS

§170.205 Content exchange standards and implementation specifications for exchanging electronic health information.	Regulatory Referenced Standard
The Secretary adopts the following content exchange standards and associated implementation specifications:	
(i) Cancer information. Standard. HL7 Clinical Document Architecture (CDA), Release 2.0, Normative Edition (incorporated by reference in §170.299). Implementation specifications. Implementation Guide for Ambulatory Healthcare Provider Reporting to Central Cancer Registries, HL7 Clinical Document Architecture (CDA), (incorporated by reference in §170.299).	
§170.207 Vocabulary standards for representing electronic health information.	**Regulatory Referenced Standard**
The Secretary adopts the following code sets, terminology, and nomenclature as the vocabulary standards for the purpose of representing electronic health information:	
(a)(3) Standard. IHTSDO SNOMED CT® International Release July 2012 (incorporated by reference in §170.299) and US Extension to SNOMED CT® March 2012 Release (incorporated by reference in §170.299).	
(c) Laboratory tests. (2) Standard. Logical Observation Identifiers Names and Codes (LOINC®) Database version 2.40, a universal code system for identifying laboratory and clinical observations produced by the Regenstrief Institute, Inc. (incorporated by reference in §170.299).	

NORMATIVE TEST PROCEDURES

FIGURE 1:



The instructions in the derived test procedure listed below reference the numbered test steps in Figure 1 above.

Derived Test Requirements

DTR170.314(f)(6) – 1: Electronically Create Cancer Case Information

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Required Vendor Information

VE170.314(f)(6) – 1.01: The Vendor shall create existing test patient records in the EHR as directed by the Tester

VE170.314(f)(6) – 1.02: The Vendor shall identify the EHR function(s) that are available to electronically generate cancer case information documents for electronic transmission to cancer registries

Required Test Procedure

For each of the **six** Test Case Categories provided in the Test Data section of this test procedure, follow the steps below:

TE170.314(f)(6) – 1.01: The Tester shall select a Test Case from the provided cancer case information test data [Figure 1, Step 1]

TE170.314(f)(6) – 1.02: Using the Vendor-identified inpatient EHR function(s), the Tester shall input the provided cancer case information test data selected in TE170.314(f)(6) – 1.01 (input can be performed using a manual or automated process) [Figure 1, Step 2]

TE170.314(f)(6) – 1.03: Using the Vendor-identified EHR function(s) and the test data input in TE170.314(f)(6) – 1.02, the Tester shall cause the EHR to generate a cancer case information (Cancer Registry) document for the test patients [Figure 1, Step 3] based on

- The HL7 Clinical Document Architecture (CDA), Release 2.0, Normative Edition
- The Implementation Guide for Ambulatory Healthcare Provider Reporting to Central Cancer Registries, HL7 Clinical Document Architecture (CDA)
- The IHTSDO SNOMED CT® International Release July 2012 and US Extension to SNOMED CT® March 2012 Release
- The Logical Observation Identifiers Names and Codes (LOINC®) Database version 2.40

TE170.314(f)(6) – 1.04: Using the Vendor-identified EHR function(s) and the cancer case information document created in TE170.314(f)(6) – 1.03, the Tester shall import the document into the HL7 CDA Cancer Registry Report Validation tool identified in the Conformance Test Tools section of this test procedure [Figure 1, Step 4]

TE170.314(f)(6) – 1.05: Using the Inspection Test Guide, the Tester shall verify that the cancer case information document format is conformant to the named standards [Figure 1, Steps 5, 6, & 7], and that the cancer case information document contains the correct content, as described in detail in IN170.314(f)(6) – 1.02 [Figure 1, Step 8]

Inspection Test Guide

IN170.314(f)(6) – 1.01: Using the Validation Report produced by the HL7 CDA Cancer Registry Report Validation tool**,** the Tester shall verify that the format of the cancer case information document meets the Cancer Registries Implementation Guide conformance requirements being tested [Figure 1, Steps 5, 6, & 7]

IN170.314(f)(6) – 1.02: Using the Implementation Guide for Ambulatory Healthcare Provider Reporting to Central Cancer Registries, the named vocabulary standards (LOINC and SNOMED CT), and the provided test data for the Test Case selected in TE170.314(f)(6) – 1.01, the Tester shall **manually** inspect the cancer case information document, shall verify that all of the data elements specified in the provided test data are included, and shall verify that the content for these data elements is correct [Figure 1, Step 8].

Detailed instructions for **manual** inspection of the cancer case information document:

- For each Section, Entry, and Entry Relationship, the Tester shall verify that the correct template IDs provided in the test data are used
- For each data element, the Tester shall verify that
  1. It has the correct Code System OID if one is provided in the test data
  2. It has the correct "Code/Value" if one is provided in the test data

  Note:
  a. If the provided test data are not used, the Tester shall verify that the Vendor-supplied values are valid in the identified value set
  b. There are several data elements where multiple code systems are allowed according to the Implementation Guide for Ambulatory Healthcare Provider Reporting to Central Cancer Registries, HL7 Clinical Document Architecture (CDA). These data elements include Histologic Type, Primary Site (Target Site Code), Procedures, and Problems. The EHR Vendor is only required to provide a value from one of the code systems specified in the standard for that particular data element. The provided test data reflect this option by listing all possible values for the data element based on the code system implemented by the Vendor. The Tester shall verify that the appropriate value for the data element is provided, based on the code system used by the Vendor.

Examples for **manual** inspection of the cancer case information document:

1. Verify that a data element is present where required (SHALL) and that the value matches the test data. If the test data indicate a value is to be populated for a data element, that data element should NOT have a null flavor. For example, if the test data indicate that the value of "WI" should be provided for the Patient Birth Place data element:

templateID	Data Element	Code/Value	Display Name	Code System OID	Code System Name	Conformance
1.3.6.1.4.1.19376.1.7.3.1.1.14.1	Patient Birth Place	WI	Wisconsin	2.16.840.1.113883.6.92	FIPS 5-2 (State)	SHALL

Then the Valid xml would be:

```
<birthplace>
<place>
        <addr>
        <state>WI</state>
        </addr>
</place>
</birthplace>
```

And the invalid xml would be:

```
<birthplace>
<place>
        <addr nullFlavor="UNK" />
  </place>
</birthplace>
```

2. Verify that the correct Code System OID is used. As indicated in the test data, the valid Code System OIDs for the data element "primary site" are 2.16.840.1.113883.6.103 and 2.16.840.1.113883.6.96.

   a. Valid:

<targetSiteCode xsi:type="CD" code="181422007" **codeSystem="2.16.840.1.113883.6.96"** codeSystemName="SNOMED CT " displayName=" Entire prostate ">

b. Invalid:

<targetSiteCode xsi:type="CD" code="181422007" **codeSystem="2.16.840.1.113883.3.88.12.3221.8.9"** codeSystemName="SNOMED CT" displayName="Entire prostate">

3. Verify that the value is valid for the indicated Code System:

a. Valid: the code provided is the valid ICD-9-CM code, as indicated in the test data:

<targetSiteCode xsi:type="CD" **code="185"** codeSystem="**2.16.840.1.113883.6.103**" ICD-9CM (diagnoses)" displayName="Malignant neoplasm of prostate">

b. Invalid: the code provided is not the ICD-9-CM code indicated in the test data, and is not a valid code in the ICD-9-CM Code System:

<targetSiteCode xsi:type="CD" **code="154573125"** codeSystem="**2.16.840.1.113883.6.96**" codeSystemName="SNOMED CT " displayName=" Malignant neoplasm of prostate">

TEST DATA

ONC supplied test data are provided with the test procedure to ensure that the functional and interoperability requirements identified in the 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 of required EHR technology, rather than exercising the full breadth/depth of capability that installed EHR technology might be expected to support. The test data are formatted for readability of use within the testing process. The format is not prescribing a particular end-user view or rendering. No additional requirements should be drawn from the format

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

- The Tester determines that the Vendor product is sufficiently specialized that the provided test data needs 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; primarily through 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 test data provides a comparable level of robustness.

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

The test procedures require that the Tester enter the test data into the EHR technology 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 test procedure. If a situation arises where it is impractical for a Tester to directly enter the test data, 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 test procedure.

For ONC EHR certification testing, the primary purpose of the provided test data is to assist the Tester in verifying that the vendors' EHR technologies are capable of supporting the required functions; verifying the ability to support the specific content is not the primary purpose of the test data. Such testing and verification is more appropriate for local installations of the EHR

technologies. The provided test data reflect relevant clinical data for the given test stories; however, these data should not be expected to represent standards of practice.

Test data for §170.314(f)(6) Transmission to cancer registries- ambulatory setting only is available through the conformance tool (reference Conformance Tool Section for tool access).

For this test procedure the Tester shall select one Test Case from **each** of the six Categories listed:

1. Patient is diagnosed with cancer
2. Patient with cancer has a procedure during the encounter
3. Patient has medication administered during the encounter
4. Patient with cancer has radiation therapy during the encounter
5. Patient with cancer contains information over multiple encounters
6. Non-reportable cancer diagnosis

The Tester shall follow the normative test procedure to conduct these tests. Table 1 (Cancer Registry Test Case Categories and Associated Test Cases) lists the six test case categories and identifies three test cases for each category. Details of the test cases are provided in PDF and Microsoft Excel Spreadsheet formats.

Table 1: Cancer Registry Test Case Categories and Associated Test Cases

Test Case Categories	Test Case 1	Test Case 2	Test Case 3
Patient is diagnosed with cancer	Cat1 Case1	Cat1 Case2	Cat1 Case3
Patient with cancer has a procedure during the encounter	Cat2 Case1	Cat2 Case2	Cat2 Case3
Patient has medication administered during the encounter	Cat3 Case1	Cat3 Case2	Cat3 Case3
Patient with cancer has radiation therapy during the encounter	Cat4 Case1	Cat4 Case2	Cat4 Case3
Patient with cancer has radiation therapy at a freestanding radiation center	Cat5 Case1	Cat5 Case2	Cat5 Case3
Non-reportable cancer diagnosis	Cat6 Case1	Cat6 Case2	Cat6 Case3

NAVIGATING A TEST CASE

A test case consists of a test story and test data. The test story gives a real world scenario that provides the context for the test case. The test data provide the data associated with the test story and represent the information that typically is available in the clinical setting. Together, the test story and the test data provide sufficient information to be entered into the EHR for a particular test case. Using the provided data and the Vendor-identified EHR function(s), a cancer case information document is to be generated for all of theTest Case Categories except Test Case Category 6, which describes a scenario that does not require generating a cancer case information document for reporting to a Cancer Registry.

CONFORMANCE TEST TOOLS

The following testing tools are available to evaluate conformance to the standards referenced in this test procedure:

- HL7 CDA Cancer Registry Report Validation tool – the HL7 CDA validation tool is designed specifically to support this test procedure by evaluating whether the generated cancer case information document conforms to the **format** requirements listed in the HL7 Clinical Document Architecture and the Implementation Guide for Ambulatory Healthcare Provider Reporting to Central Cancer Registries
- The tool is available as a Web Application
- The application can be downloaded for local installation
- The web application validation service is available at:

  http://cda-cancer-testing.nist.gov

Support for these tools is available by submitting questions to the following user's group: https://groups.google.com/d/forum/cancer-reg-testing-tool.

Inquiries may also be sent to this user group via email: cancer-reg-testing-tool@googlegroups.com.

Multiple browsers may be used to access this tool; if the tool does not load completely using Internet Explorer 8 or Internet Explorer 9, alternative browsers such as Firefox, Google Chrome, or Safari are recommended. HL7 CDA Cancer Registry Reporting Validation 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.

HL7 CDA style sheet – HL7 provides a style sheet to render HL7 CDA structured documents as part of the CDA specifications package. Contact HL7 directly for the specification package.

The following information is provided to assist the Tester in interpreting the conformance reports generated by the HL7 CDA Cancer Registry Reporting Validation Tool.

The HL7 CDA Cancer Registry Reporting Validation Tool evaluates individual conformance statements that have been derived from the standards and implementation guides identified in the Final Rule and the test data provided in this test procedure. The validation tools evaluate the submitted CDA instance for each conformance statement, and then produce a conformance report. The Tester should consider that a report containing only Affirmative and Warning messages indicates general conformance to the standard and test data expectations. If reported, Errors should be considered as significant departures from the standard or test data requirements which need to 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 test procedure by the EHR technology. The Tester may need to inspection-test data values derived from required vocabularies and code sets.

Document History

Version Number	Description of Change	Date Published
1.0	Released for public comment	November 19, 2012
1.1	Delivered for National Coordinator Approval	December 3, 2012
1.2	Posted Approved Test Procedure	December 14, 2012
1.3	Posted Updates to Approved Test Procedure Updates: • Clarified instructions regarding the Implementation Guide for Ambulatory Healthcare Provider Reporting to Central Cancer Registries, HL7 Clinical Document Architecture in the Informative Test Description, the Inspection Test Guide step IN170.314(f)(6) – 1.02, and the Test Data section.	June 10, 2013

1.4	Posted Updates to Approved Test Procedure
	• Informative Test Description section
	  ○ Clarified instructions regarding verification of the cancer case information document format using the Message Validation Report generated by the HL7 CDA Cancer Registry Report Validation Tool
	  ○ Clarified instructions regarding the manual inspection of the cancer case information document content using the provided test data
	• Normative Test Procedure section
	  ○ In Figure 1, clarified the verbiage in Steps 5 & 8
	  ○ In the Required Test Procedure step TE170.314(f)(6) – 1.05, clarified the process of verifying the format versus the content of the cancer case information document
	  ○ In the Inspection Test Guide, clarified the instructions in step IN170.314(f)(6) – 1.01 regarding verification of the cancer case information document format using the Message Validation Report generated by the HL7 CDA Cancer Registry Report Validation Tool
	  ○ In the Inspection Test Guide, clarified the instructions in step IN170.314(f)(6) – 1.02 regarding manual inspection of the cancer case information document content using the Implementation Guide for Ambulatory Healthcare Provider Reporting to Central Cancer Registries, the named vocabulary standards, and the provided test data
	  ○ Added detailed instructions for manual inspection of the cancer case information document, and added examples for manual inspection of the cancer case information document
	• Test Data section
	  ○ Removed the reference to and instructions for the document content data sheet
	• Conformance Test Tools section
	  ○ Clarified the purpose of the HL7 CDA Cancer Registry Report Validation Tool
		July 15, 2014