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

This document describes the test procedure for evaluating conformance of complete EHRs or EHR modules 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 [available when final]. The test procedures may be updated to reflect on-going feedback received during the certification activities.

The 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 HIT Certification Program[2], is carried out by National Voluntary Laboratory Accreditation Program-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, the 2014 Edition of this Certification Criterion is classified as new from the 2011 Edition. This Certification Criterion meets at least one of the 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.

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 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 Complete EHR 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 Complete EHRs 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 (i.e., 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 Complete EHRs and certified EHR Modules. 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.

This test evaluates the capability for a Complete EHR or EHR Module to electronically generate cancer case information for electronic transmission using the HL7 Clinical Document Architecture (CDA), Release 2.0, Normative Edition, and 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; and the 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.

Test data, verified by the CDC Cancer Surveillance Branch (CSB), are provided for this test procedure.

This test procedure is organized into one section:

- Create – evaluates the capability of the EHR technology to electronically create conformant standard reports for cancer case information
    - 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)

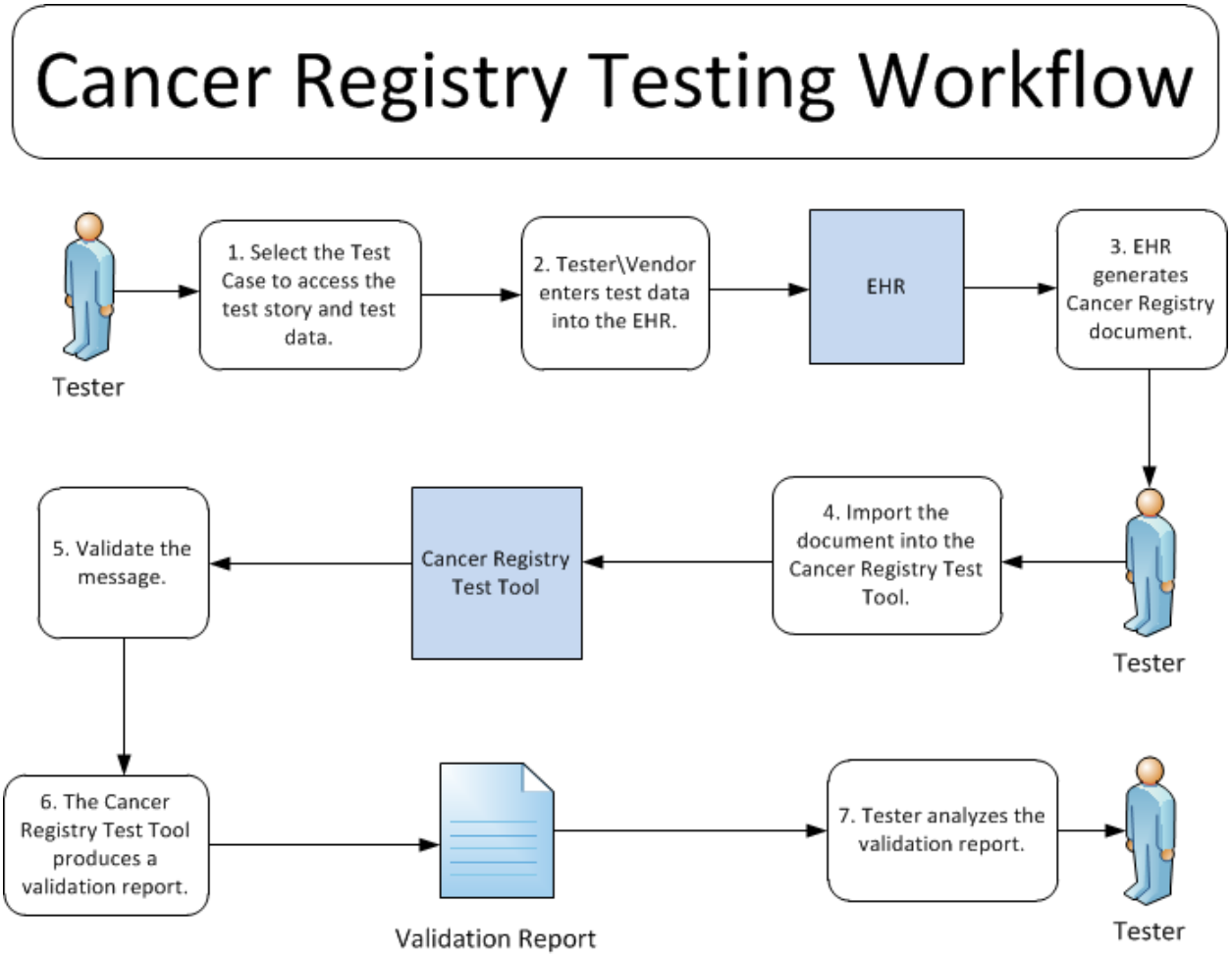
- Using the Vendor-identified EHR function(s) and the provided test data, the Tester causes the EHR to generate the indicated cancer case report using
  - The HL7 Clinical Document Architecture (CDA), Release 2.0, Normative Edition
  - The Implementation Guide for Ambulatory Healthcare Provider Reporting 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 report into the NIST Cancer Registries Conformance Test Tool
- Using the NIST Cancer Registries Conformance Test Tool, the Tester verifies that the cancer case report is conformant to the named standards
- Using the provided test data, the Tester verifies that the cancer case report contains the correct content

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:



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 reports for electronic transmission to cancer registries

Required Test Procedure

TE170.314.f.6 – 1.01: The Tester shall select data from the provided cancer case information test data

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)

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 document for the test patients 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 message created in TE170.314.f.6 – 1.03, the Tester shall import the document into the NIST Cancer Registries Conformance Test Tool

TE170.314.f.6 – 1.05: Using the Inspection Test Guide, the Tester shall verify that the cancer case information document is conformant to the named standards, and that the cancer case report contains the correct content

Inspection Test Guide

IN170.314.f.6 – 1.01: Using the NIST Cancer Registries Conformance Test Tool identified in the Conformance Test Tools section of this test procedure**,** the Tester shall verify that the Cancer Registries Implementation Guide conformance requirements tested are met

IN170.314.f.6 – 1.02: Using the provided test data, the Tester shall verify that the information in the cancer information report is correct.

TEST DATA

Test data are provided with the test procedure to ensure that the functional and interoperable 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-Accredited Testing Laboratories (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 is 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-selected report format requires some modification to the test data.

- 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 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 at a freestanding radiation center
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 Cases and Associated Data Sets) lists the six test case categories and identifies three data sets for each category. Details of the test cases (data sets) are provided in PDF and Microsoft Excel Spreadsheet formats.

Table 1: Cancer Registry Test Cases and Associated Data Sets

Cancer Registry Test Cases and Associated Data Sets			
Test Case Category	**Data Set 1**	**Data Set 2**	**Data Set 3**
1. Patient is diagnosed with cancer	Cat1 Case1	To be added	To be added

2. Patient with cancer has a procedure during the encounter	Cat5 Case1	To be added	To be added
3 Patient has medication administered during the encounter	Cat2 Case1	To be added	To be added
4. Patient with cancer has radiation therapy at a freestanding radiation center	Cat4 Case1	To be added	To be added
5. Patient with cancer, contains information over multiple encounters	Cat3 Case1	To be added	To be added
6. Non-reportable cancer diagnosis	Cat6 Case1	To be added	To be added

NAVIGATING A TEST CASE

A test case consists of a test story and a test data specification. The test story gives a real world scenario that provides the context for the test case. The test data specification provides the data associated with the test story and is what is typically available in the clinical setting. Together the test story and the test data specification provide sufficient information that is to be entered into the EHR for a particular test case. Using this data and the EHR functionally a document is to be generated for all categories but category 6, which should not generate a document.

Another artifact called the document content data sheet can be generated using the HL7 CDA tool listed below that is a viewable document instance for the given test case. The document content is organized in a table format that provides the HL7 CDA elements and the data associated with the elements for a given test case. The document content should match the table of test data provided in the test data files for the given test case. The tester will validate that all fields and values are present in the CDA document.

CONFORMANCE TEST TOOLS

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

HL7 Cancer Registry Report – NIST provides an HL7 Cancer Registry Report validation tool designed specifically to support this test procedure. 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. The tool is available in two forms:

- a downloadable package for local installation available at http://hit-testing.nist.gov/cda-validation/muCr.html
- a web-accessible validator which is hosted by NIST available at http://hit-testing.nist.gov/cda-validation/muCr.html

Support for this tool is available by contacting

Andrew McCaffrey
Computer Scientist
National Institute of Standards and Technology (NIST)
Information Technology Laboratory

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 NIST conformance testing tools.

The HL7 CDA/Cancer Registry Report validation tools evaluate individual conformance statements which 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	Date Published
1.0	Released for Public Comment	September 14, 2012