

Test Procedure Overview

PURPOSE

This document describes the structure of the test procedure for evaluating conformance of electronic health record (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 as published in the Federal Register on September 4, 2012. Each document is organized by test procedure and derived test requirements with traceability to the normative certification criterion or criteria as described in this document.

The test procedures are intended to provide objective guidance to National Voluntary Laboratory Accreditation Program (NVLAP)-Accredited Testing Laboratories (ATLs) as they conduct EHR technology certification testing in the ONC HIT Certification Program, to provide traceability from certification criterion or criteria to testing activities, and to ensure consistency throughout the certification process.

Tester refers to a person (such as an ATL representative) 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.

DOCUMENT ORGANIZATION

Each test procedure is organized into nine sections including:

- Certification Criterion lists the certification criterion or criteria as published in 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).
- 2014 Edition Preamble Language provides applicable certification criterion or criteria 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).
- 2011 Edition Preamble Language provides applicable certification criterion or criteria language per Section III.D of the preamble of the Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, Final Rule (July 28, 2010).
- Changes from 2011 to 2014 Edition provides language from 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) that lists changes from the 2011 to 2014 Edition of the certification criterion or criteria.

- Informative Test Description 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.
- **Referenced Standards** lists the standards referenced in the certification criterion or criteria. If the standard refers to another source document, such as the Code of Federal Regulations, the appropriate portion of that source document is also included.
- Normative Test Procedure describes the required vendor information and test procedures for verifying conformance to the certification criterion or criteria and standards. This section is divided into sub-sections including derived test requirements, required vendor information, required test procedures and inspection test guides.
 - Derived Test Requirements describes a specific portion of the certification criterion or criteria which will be addressed in a single Required Test Procedure. To provide traceability, each is denoted using the following form:

DTR [FR certification criterion number] – [Sequence number]

 Required Vendor Information – describes the information needed from the Vendor in order to perform the test procedure. To provide traceability, each is denoted using the following form:

VE [FR certification criterion number] – [Sequence number]

Required Test Procedures – describes the test activities required to be performed by the Tester. To provide traceability, each is denoted using the following form:

TE [FR certification criterion number] – [Sequence number]

 Inspection Test Guides – provides additional guidance to the Tester on how to evaluate conformance to the certification criterion or criteria. To provide traceability, each is denoted using the following form:

IN [FR certification criterion number] – [Sequence number]

- **Test Data** provides the test data implementation guidance and links to the associated test data, if applicable.
- **Conformance Test Tools** provides a description and links to the associated conformance test tools, if applicable, to evaluate conformance to the referenced standards.