§170.315(f)(3) Transmission to public health agencies – reportable laboratory tests and value/results

2015 Edition Test Procedure

Version 1.0 Updated on 01-20-2016

Revision History

Version #	Description of Change	Version Date
1.0	Final Test Procedure	01-20-2016

Regulation Text

Regulation Text

§170.315 (f)(3) *Transmission to public health agencies – reportable laboratory tests and value/results—*

Create reportable laboratory tests and values/results for electronic transmission in accordance with:
(i) The standard (and applicable implementation specifications) specified in §170.205(g).
(ii) At a minimum, the versions of the standards specified in §170.207(a)(3) and (c)(2).

Standard(s) Referenced

Paragraph (f)(3)(i)

§ 170.205(g) *Electronic transmission of lab results to public health agencies*. HL7 2.5.1. *Implementation specifications*. HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 (US Realm) with Errata and Clarifications and ELR 2.5.1 Clarification Document for EHR Technology Certification

Paragraph (f)(3)(ii)

§ 170.207(a)(3) International Health Terminology Standards Development Organisation (IHTSDO) Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®) International Release July 2012 and US Extension to SNOMED CT® March 2012 Release

§ 170.207(c)(2) Logical Observation Identifiers Names and Codes (LOINC®) Database version 2.40, Released July 2012, a universal code system for identifying laboratory and clinical observations produced by the Regenstrief Institute, Inc.

Please consult the Final Rule entitled: 2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications for a detailed description of the certification criterion with which these testing steps are associated. We also encourage developers to consult the Certification Companion Guide in tandem with the test procedure as they provide clarifications that may be useful for product development and testing.

Note: The order in which the test steps are listed reflects the sequence of the certification criterion and does not necessarily prescribe the order in which the test should take place.

Testing components

Gap				ONC Supplied Test Data

Paragraph (f)(3)(i)

System Under Test

1. The Health IT Module creates Reportable Lab content using ONC Supplied Test data for each of the test cases under the ONC 2015 Certification Test Plan on the Context-Based Validation Tab of the NIST Electronic Laboratory Reporting (ELR) Test Suite. All test cases are required. Input may be performed using manual or automated processes

Test Lab Verification

Using the Normative Test Description section of the Normative Test Process Document:

1. The tester verifies that the Health IT Module creates the source Reportable Lab content correctly and without omission through visual inspection of the system under test using the test data specification associated with the selected test case.
2. The tester imports the ELR message into the test tool for validation and uses the Validation Report produced by the NIST Electronic Laboratory Reporting (ELR) Test Suite to verify the Health IT module passes without error to confirm that the reportable laboratory tests and values/results message is conformant to the § 170.205(g) HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 and the ELR 2.5.1 Clarification Document for EHR Technology Certification.

Paragraph (f)(3)(ii)

System Under Test

The reportable laboratory tests and values/results used in the messages created in (f)(3)(i), use, at a minimum, the versions of the standards specified in the named § 170.207(a)(3) SNOMED CT® standard and the named § 170.207(c)(2) LOINC® standard.

Test Lab Verification

Using the Normative Test Description section of the Normative Test Process Document, the tester uses the Test Tool Validation Report from (f)(3)(i) test cases and visual inspection of both the Test Tool Validation Report and the Health IT configuration file to verify laboratory tests and values/results are represented using the named § 170.207(a)(3) standard and the named § 170.207(c)(2) standard.

Content last reviewed on September 21, 2018