

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology National Voluntary Laboratory Accreditation Program

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LAP: Healthcare IT LAP

LAB BULLETIN

SUBJECT: Amendments to NIST Handbook 150-31, NVLAP Healthcare Information Technology Testing

The purpose of this NVLAP Lab Bulletin is to publish revisions to the Healthcare Information Technology laboratory accreditation program (HIT LAP) handbook to reflect the addition of the 2014 certification criteria for EHR technology to the program. NVLAP is now accrediting testing applicants to the 2014 Edition Test Method. This is in support of the Office of the National Coordinator (ONC) requirements published in the *Federal Register* on September 4, 2012.

The following method has been added to the HIT LAP Test Method Selection List:

Testing based on criteria in 45 CFR Part 170, 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).

Effective immediately, NIST Handbook 150-31, NVLAP Healthcare Information Technology Testing, sections 1.4, 5.2, and 5.3 are amended as follows:

1.4 References

1.4.1 Publications referenced in this handbook

- "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," *Federal Register* (4 September 2012): 54163-54292 (codified at at 45 CFR Part 170); available online http://www.gpo.gov/fdsys/pkg/FR-2012-09-04/pdf/2012-20982.pdf>.
- ONC-Approved 2014 Edition Test Method (effective December 14, 2012); available online at http://www.healthit.gov/policy-researchers-implementers/2014-edition-final-test-method.

5.2 Personnel

5.2.1 The testing laboratory shall maintain responsible personnel and competent technical staff who are knowledgeable of the following (see documents list in 1.4 for complete citations):

— "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," *Federal Register*

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- (4 September 2012): 54163-54292 (codified at at 45 CFR Part 170); available online http://www.gpo.gov/fdsys/pkg/FR-2012-09-04/pdf/2012-20982.pdf>.
- ONC-Approved 2014 Edition Test Method (effective December 14, 2012); available online at http://www.healthit.gov/policy-researchers-implementers/2014-edition-final-test-method.

5.3 Accommodation and environmental conditions

5.3.2 (second paragraph is revised to add the words, "where necessary.")

The testing laboratory shall ensure a secure electronic communication channel exists for remote testing to protect the confidentiality and integrity of the testing process, where necessary.

This bulletin should be maintained with your copy of NIST Handbook 150-31 until the next edition of the handbook is released, at which time these changes will be incorporated into the handbook.

Questions regarding the changes to the HIT program should be directed to Dana S. Leaman, NVLAP Program Manager, at 301-975-4679, or dana.leaman@nist.gov.

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