

	<b>DEPARTMENT OF COMMERCE</b> National Institute of Standards and Technology National Voluntary Laboratory Accreditation Program	<b>ISSUE DATE:</b> February 12, 2015
	<b>LAB BULLETIN</b>	<b>NUMBER:</b> LB-84-2015
		<b>LAP:</b> Healthcare IT LAP
<b>SUBJECT:</b> Addition of the 2014 Edition Release 2 Certification Criteria for EHR Technology to the HIT LAP		

On September 11, 2014, the 2014 Edition Release 2 Electronic Health Record (EHR) Certification Criteria and the ONC HIT Certification Program; Regulatory Flexibilities, Improvements, and Enhanced Health Information Exchange; Final Rule was published. As stated by the Office of the National Coordinator (ONC), this rule “introduces regulatory flexibilities and general improvements for certification to the 2014 Edition EHR certification criteria (2014 Edition).” Approved Test Procedures regarding these revisions in criteria were released on January 26, 2015.

Based on this rule and the release of approved test procedures, NVLAP has updated its Healthcare Information Technology (HIT) Laboratory Accreditation Program (LAP) to include the additional 2014 Edition Release 2 EHR certification criteria for testing of EHR technology. For laboratories currently accredited in the NVLAP HIT LAP, addition of these methods to the scope of accreditation must be requested in writing (e-mail is a sufficient form of written request). With the written request, a signed self-declaration regarding implementation of the new test procedures within the laboratory’s management system (attached to this bulletin) is required. (Note: The declaration must be signed by the Laboratory’s Authorized Representative as designated in the NVLAP records.) Each applicant laboratory must also supply a detailed description of how this additional testing has been added into its management system and communicated to its testers.

Once this information is received, NVLAP will proceed with a review of the information and a decision regarding the addition of the new criteria to the scope of accreditation. A revised scope of accreditation will be issued to each applicant that meets the requirements within the HIT program and this bulletin.

Questions should be directed to Dana S. Leaman at 301-975-4679, or [dana.leaman@nist.gov](mailto:dana.leaman@nist.gov).

Attachment:  
Self-Declaration of Implementation



## NVLAP-Accredited Testing Laboratory Healthcare Information Technology Laboratory Accreditation Program

### Self-Declaration of Implementation:

45 CFR 170, Health Information Technology: 2014 Edition Release 2 Electronic Health Record (EHR) Certification Criteria and the ONC HIT Certification Program; Regulatory Flexibilities, Improvements, and Enhanced Health Information Exchange, Final Rule and its associated ONC-approved 2014 R2 Test Procedures, Test Data and Test Tools.

Laboratory Name:	Lab Code:
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As the laboratory's Authorized Representative, I attest that this criteria and its associated test procedures, data and tools have been implemented into our laboratory's quality management system. The appropriate training to conduct this testing to the 2014 R2 criteria has also been performed and documented as required in our system. These statements are correct to the best of my knowledge and are made in good faith.

Signature\_\_\_\_\_

Date\_\_\_\_\_

Printed Name\_\_\_\_\_

2015-02-09

