

	DEPARTMENT OF COMMERCE National Institute of Standards and Technology National Voluntary Laboratory Accreditation Program	ISSUE DATE: December 3, 2012
	LAB BULLETIN	NUMBER: LB-70-2012
		LAP: Healthcare IT LAP
SUBJECT: Addition of the 2014 Certification Criteria for EHR Technology to the HIT LAP		

On September 4, 2012, the 2014 Edition Standards and Certification Criteria (S&CC) final rule was published outlining the Stage 2 of the Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs, updates to Stage 1, and other program modifications. As stated by the Office of the National Coordinator (ONC), this “2014 Edition S&CC final rule reflects ONC’s commitment to reduce regulatory burden; promote patient safety and patient engagement; enhance EHR technology’s interoperability, electronic health information exchange capacity, public health reporting, and security; enable clinical quality measure data capture, calculation, and electronic submission to CMS or states; and introduce greater transparency and efficiency to the certification process.”

Based on this rule, NVLAP has updated its Healthcare Information Technology (HIT) Laboratory Accreditation Program (LAP) to include the new 2014 criteria testing for 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, each applicant must also supply the following supporting information:

- An implementation plan outlining how the 2014 criteria will be incorporated into the laboratory’s management system. This plan must not exceed 30 days from the publication of the approved test procedures, test tools, and test data. The plan shall also address how any further training activities or anticipated changes in the laboratory’s system will be addressed with the associated laboratory personnel once the approved procedures are released.
- Per Section 5.2.3 of NIST Handbook 150-31, the laboratory shall supply a current list of key staff, including all testers performing HIT testing in the laboratory.
- The laboratory shall supply all current training records for those involved in the HIT testing. These records should reflect those staff that attended the October 2012 tool webinars and the November 2012 ONC Workshop. Also, for personnel not in attendance at these training events, it would be expected that the laboratory demonstrate what materials, mechanisms, etc. were used to disseminate the appropriate training to its remaining testing personnel.
- Per Section 5.10.3 of NIST Handbook 150-31, the laboratory shall supply a copy of the revised 2014 test report template.

The first review wave will be conducted from December 16-28, 2012. All requests received by COB on December 14, 2012, will be reviewed in this first review wave. From this review wave, those successfully demonstrating the incorporation of the 2014 criteria testing into their systems will be announced on January 2, 2013.

Those laboratory requests for addition of the new methods to the scope of accreditation received after December 14, 2012, will be reviewed after the first review wave process has been completed.

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