

	DEPARTMENT OF COMMERCE National Institute of Standards and Technology National Voluntary Laboratory Accreditation Program	ISSUE DATE: November 22, 2013
	LAB BULLETIN	NUMBER: LB-79-2013
		LAP: Healthcare IT LAP
SUBJECT: Addition of Test Reporting Requirements to the HIT LAP		

The purpose of this bulletin is to publish a minor revision to NIST Handbook 150-31 for the subclause noted below. This bulletin becomes a part of NIST Handbook 150-31, *NVLAP Healthcare Information Technology Testing*, until such time as the next edition of the handbook is published.

Overview and background

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. Under Section 170.523(f)(8), publication of the test results used to make the certification decision is required. To ensure consistency among the Accredited Test Laboratories (ATLs), NVLAP, with input from the ATLs, supplied information to the Office of the National Coordinator (ONC) on a test report summary template.

In September 2013, ONC released the 2014 EHR Test Results Summary Template for immediate implementation and use. Based on the release of this template, NVLAP has updated its Healthcare Information Technology (HIT) Laboratory Accreditation Program (LAP) to include the required use of the ONC-approved template for reporting test results.

Implementation of changes

Effective upon the issuance of this bulletin, the first paragraph of NIST Handbook 150-31, subclause 5.10.3 is revised as shown in the italicized text:

5.10.3 *For test report information that is being generated by the testing laboratory for use by the certification body to make the certification decision, the laboratory shall use the ONC-approved test report summary template. The testing laboratory shall may also create an additional test report template for its own use that includes other information necessary for reporting to describe the system/module being certified and shall ensure policies and procedures exist to meet the requirements of the vendor, the certification body, or the ONC.*

The second paragraph of subclause 5.10.3 is deleted.

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