	DEPARTMENT OF COMMERCE National Institute of Standards and Technology National Voluntary Laboratory Accreditation Program	**ISSUE DATE:** June 17, 2020
	LAB BULLETIN	**NUMBER:** LB-131-2020
		LAP: Healthcare IT LAP

SUBJECT: Addition of the 21st Century Cures Act: Interoperability, Information Blocking and the ONC Health IT Certification Program final rule to the HIT LAP

The 21st Century Cures Act: Interoperability, Information Blocking and the ONC Health IT Certification Program final rule was published in the *Federal Register* on May 1, 2020.

This final rule implements certain provisions of the 21st Century Cures Act, including Conditions and Maintenance of Certification requirements for health information technology (health IT) developers under the ONC Health IT Certification Program (Program), the voluntary certification of health IT for use by pediatric health care providers, and reasonable and necessary activities that do not constitute information blocking. The implementation of these provisions will advance interoperability and support the access, exchange, and use of electronic health information.

The rule also finalizes certain modifications to the 2015 Edition health IT certification criteria and Program in additional ways to advance interoperability, enhance health IT certification, and reduce burden and costs.

The 2015 Edition Cures Update Test Method approved by ONC includes test procedures, test tools and test data and is published on the ONC website at <https://www.healthit.gov/topic/certification-ehrs/2015-edition-cures-update-test-method >.

Based on this rule and the approved test method, NVLAP has updated its Healthcare Information Technology (HIT) laboratory accreditation program (LAP) to include the 2015 Edition Cures Update Test Method. It has been added into the available test methods in the HIT LAP:

- **31/2015-CURES**
  The 2015 Edition Cures Update Test Method based on criteria in 85 FR 25642 of the 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program; Final Rule

For laboratories currently accredited in the NVLAP HIT LAP, addition of testing to the 2015 Edition Cures Update to the scope of accreditation must be requested in writing (an e-mail request is sufficient). With the written request, each applicant must also supply:

- The NVLAP-supplied 2015 Edition Cures Update Self-Declaration of Implementation signed by the laboratory's authorized representative.
- a description of how the 2015 Edition Cures Update ONC-Approved Test Method testing has been added into the management system as well as any updated management system documents to support this incorporation,

- a current list of key staff, including all testers authorized to perform HIT testing in the laboratory,
- a description of how competency of the testers to the 2015 Edition Cures Update Test Method has been evaluated and confirmed, and
- the documented evidence of competence of the testers (e.g. training records).

Once this information is received, NVLAP will proceed with a documentary review. If this information is determined to be incomplete, follow-up information will be requested or a remote assessment (e.g. teleconference call and/or webinar) will be scheduled with the laboratory to assess the competency of the testers approved to conduct testing associated with this scope addition.

Please note that any costs associated with a remote assessment will be billed to the laboratory.

A report of the remote assessment will be issued in accordance with Clauses 3.3.3.1 (a) through (e) of NIST Handbook 150. Any nonconformity cited will require resolution per Clause 3.3.4 of NIST Handbook 150.

Questions should be directed to Brad Moore at 301-975-5740 or bradley.moore@nist.gov.