Leidos AT&E’s ONC Health IT Testing and Certification Program

Our Accredited Testing and Evaluation (AT&E) Lab offers both testing and certification services. It is one of a select few entities that has achieved accreditation as a U.S. Department of Health and Human Services (HHS) ONC Authorized Health IT Testing Laboratory by the National Voluntary Laboratory Accreditation Program (NVLAP Lab Code 200427-0) as well as an ONC-Authorized Certification Body by ANSI.

The Office of the National Coordinator (ONC) Health IT Certification Program was designed to be an iterative process to promote innovation in the health care technology ecosystem to deliver improved information, more conveniently, to patients and clinicians. Since the program’s inception in 2010, the ONC has issued three editions. With the introduction of each new edition, the ONC furthers this objective.

Earlier editions (2011 and 2014) laid the foundation and framework of the program, which include:

- Setting certification criteria
- Establishing technical specifications and standards
- Specifying related standards and implementation specifications required to support Certified EHR Technology (CEHRT) and Health IT (HIT)
  - Meaningful use of EHRs Stage 1 (2011 Edition)
  - Certification specifications for HIT to meet the CEHRT under the Medicare and Medicaid EHR Incentive Programs (2014 Edition)

CURRENT EDITIONS


Building on past rulemakings to facilitate greater interoperability for multiple clinical health information purposes and enable health information exchange through new and enhanced certification criteria, standards, and implementation specifications, the ONC published the 2015 Edition Cures Act Update in 2020 through the 21st Century Cures Act.

The update further supports seamless and secure access, exchange, and use of electronic health information. It also includes a provision requiring that patients have electronic access to all their electronic health information, structured or unstructured, at no cost to the patient.

The new Cures Act Update also changed the existing 2015 Edition Health IT Certification Criteria. The changes focus on but are not limited to standards and new processes.

Standards and Tools

- Inferno Test Tool for Fast Healthcare Interoperability Resources (FHIR) Application Programming Interfaces (APIs)
- Health Level 7 (HL7) Clinical Document Architecture (CDA)
- United States Core Data for Interoperability (USCDI)

New Processes

- Conditions and Maintenance of Certification
- Real World Testing (RWT)
- Standards Version Advancement Process (SVAP)

OUR APPROACH

As one of the few Authorized Testing Labs (ATL) and an Authorized Certification Body (ACB), Leidos offers a comprehensive approach to the ONC Certification Program.

Leidos uses only ONC-approved test methods to test products intended for certification in the ONC Health IT Certification Program, completed through a guided project process by members of our team who have years of ONC experience and practical healthcare experience.
Staff and physicians can be assured that their software meets rigorous ONC Health IT requirements. Implementing an ONC-certified EHR allows a physician’s office to potentially earn more money. Patients’ personal information remains private and secure while readily available to all healthcare providers managing their care through secure APIs and interoperability methods.

***OUR CAPABILITIES***

**Testing and Certification Services**
- Testing through Attestation and Demonstration

**Ongoing Certification Maintenance Services**
- Quarterly Reporting Updates
  - Transparency and Disclosures
- Product Updates including Standards Updates for Cures Edition compliance
- Bi-Annual Certification Maintenance Attestation to Conditions and Maintenance of Certification Requirements – The 21st Century Cures Act (Section 4002) requires the Secretary of HHS to establish Conditions and Maintenance of Certification requirements for the ONC Health IT Certification Program
  - Information Blocking
  - Assurances
  - Communications
  - APIs
  - RWT is a process by which Health IT developers demonstrate interoperability and functionality of their Certified Health IT in real world settings and scenarios
- Criteria Testing Comprehension Support
- Ongoing Compliance and Surveillance – ACBs are required to conduct ongoing surveillance activities to assess whether certified health IT products not only meet the requirements of certification in a controlled testing environment but also continue to do so when implemented and used in a production environment
  - Reactive Surveillance (i.e., complaints investigations)
  - Randomized Surveillance
- SVAP permits health IT developers to voluntarily update health IT products certified under the ONC Health IT Certification Program to newer versions of adopted standards as part of the Real World Testing Condition and Maintenance of Certification requirement

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<th>FEATURES</th>
<th>BENEFITS</th>
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<td>Only EHRs that are secure, trustworthy, or functional receive ONC certification.</td>
<td>Staff and physicians can be assured that their software meets rigorous ONC Health IT requirements.</td>
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<td>Offices can avoid Medicare payment adjustments and receive their respective Medicaid incentive payments.</td>
<td>Implementing an ONC-certified EHR allows a physician’s office to potentially earn more money.</td>
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<td>EHR systems make managing healthcare easier than ever. ONC-certified products are more secure than others.</td>
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**PROVEN SUCCESS**

Building on 20 years of industry experience, Leidos continues our successful contribution through our AT&E Lab as an industry volume leader. Our labs have certified more than 1,000 IT security products across several disciplines.

**WHY PARTNER WITH LEIDOS**

Our Subject Matter Experts intimately understand which standards apply to your product, how to meet the required criteria, and how those requirements fit together. Our personnel combine evaluation expertise with programmatic experience, allowing Leidos to provide a single source for all of your testing and certification needs, decreasing overall cost and timelines, and building a long-term partnership.

**NEXT STEP**

Our testing and certification services provide unparalleled understanding and support. To learn how we can help your organization achieve ONC Certification, contact us today to speak with our team.

**FOR MORE INFORMATION**

ONC-ATL-ACB@leidos.com | leidos.com/capabilities/cyber/accredited-testing-evaluation