ONC-ATL Authorization Consulting for Health IT Testing Laboratories

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What to have ready

Each item comes from 45 CFR Part 170, Subpart E (eCFR current text read 2 October 2026) or NIST Handbook 150-31, 2021 Edition.

- NVLAP accreditation to the ONC Health IT Certification Program, "including to ISO/IEC 17025," with documentation that confirms it (45 CFR 170.520(b)(3) [https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-D/part-170/subpart-E]).
- A written scope: which certification criteria, or portions of criteria, you will ask to test (45 CFR 170.511).
- A procedure to "Maintain its NVLAP accreditation for the ONC Health IT Certification Program, including accreditation to ISO/IEC 17025" (45 CFR 170.524(a)).
- A training program "that includes documented procedures and training requirements to ensure its personnel are competent to test health IT" (45 CFR 170.524(c)).
- Confirmation that your quality documents work from the November 2021 edition of NIST Handbook 150-31, which "supersedes and replaces the July 2017 edition" (NIST HB 150-31:2021 [https://nvlpubs.nist.gov/nistpubs/hb/2021/NIST.HB.150-31-2021.pdf]; confirmed as the edition NIST's handbook page lists, 2 October 2026).
- Preparation for proficiency testing, which "may include written examinations, oral examinations, and evaluation of artifacts" (NIST HB 150-31:2021, §3.4.1.2).
- A filing plan that allows for ONC's review, which may take "up to 30 days from receipt" for a first application (45 CFR 170.530(a)(2)). If ONC finds deficiencies it issues a deficiency notice and returns the application (170.530(b)(2)). A revised application must be received within 15 days of receipt of the notice unless ONC grants a good-cause extension (170.530(c)(2)). If the revised application still contains deficiencies, ONC issues a denial notice and the applicant cannot reapply for six months (170.530(c)(4)).
- A renewal calendar on the three-year cycle (45 CFR 170.540(c)).