ONC-ACB Authorization Consulting for Health IT Certification Bodies

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What to have ready

Each item comes from 45 CFR Part 170, Subpart E, current eCFR text read 2 October 2026, unless another source is named.

- ISO/IEC 17065 accreditation documentation "with an appropriate scope," from an accreditation body that is an IAF MLA signatory (45 CFR 170.520(a)(3) [https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-D/part-170/subpart-E]).
- An agreement, executed by your authorized representative, to adhere to the Principles of Proper Conduct for ONC-ACBs (170.520(a)(4)).
- A decision on scope under section 170.510: Health IT Module certification, other types of health IT with adopted criteria, or both.
- A procedure to "Maintain its accreditation in good standing to ISO/IEC 17065" (170.523(a)).
- A way to track attendance at "all mandatory ONC training and program update sessions" (170.523(b)).
- A procedure to report "within 15 days any changes that materially affect" legal, organizational, personnel or policy status (170.523(d)).
- Readiness to "Allow ONC, or its authorized agent(s), to periodically observe on site (unannounced or scheduled), during normal business hours, any certifications performed" (170.523(e)).
- Surveillance procedures, since ONC-ACBs must "ensure continued conformity of the certified health IT, which may include surveillance activities" (HealthIT.gov [https://healthit.gov/certification-health-it/certification-process/onc-authorized-certification-bodies-onc-acbs/]).
- A renewal calendar that puts the renewal request 60 days before status expires (170.540(c)).