

7001.4350 CERTIFICATION QUALIFICATION.

Subpart 1. **Personnel.** A laboratory must have staff with the education, training, or experience to meet the requirements of certification. At least one staff person must be identified as the laboratory administrator and that person's contact information must be provided with the certification application. The laboratory administrator must notify the agency when there are changes in contact information for the laboratory administrator no later than 30 days after the change occurs.

Subp. 2. **Quality system.** The laboratory must have a quality assurance and quality control program that meets the criteria specified in the agency's Laboratory Certification Program Manual, incorporated by reference under part 7001.4340, subpart 4, that includes:

- A. a quality assurance manual;
- B. standard operating procedures; and
- C. traceability, documentation, record keeping, and reporting.

Subp. 3. **Access to premises.** The laboratory must allow the agency and its members, employees, and agents access to the laboratory for inspection and evaluation purposes and must produce such information and records as the agency requests to determine compliance with this part.

Subp. 4. **Access to records.** The laboratory must maintain all records used to demonstrate the laboratory's compliance with certification requirements. If a laboratory analyzes samples from a client, records that support the client's test results must be made available to the client. Upon request, records must be made available to the agency.

Subp. 5. **Proficiency testing.** A laboratory must conduct proficiency testing as required under part 7001.4390.

Subp. 6. **Subcontracting.** A laboratory that has samples analyzed by another laboratory must use laboratories that have valid agency certification or similar certification.

Subp. 7. **Cease reporting.** A laboratory must not report analytical results after its certification has expired or been discontinued, suspended, or revoked.

Subp. 8. **Fees.** A laboratory must pay the fees required in part 7002.0435 within 30 days of receiving the invoice.

Subp. 9. **Response.** A laboratory must respond in writing to any written communication from the agency.

Statutory Authority: *MS s 115.84*

History: *39 SR 1718*

Published Electronically: *June 25, 2015*