

§ 1.644 What quality assurance procedures must a third-party certification body have to qualify for accreditation?

A third-party certification body seeking accreditation must demonstrate that it has:

(a) Implemented a written program for monitoring and evaluating the performance of its officers, employees, and other agents involved in auditing and certification activities, including procedures to:

(1) Identify deficiencies in its auditing and certification program or performance; and

(2) Quickly execute corrective actions that effectively address any identified deficiencies; and

(b) The capability to meet the quality assurance requirements of § 1.655, if accredited.

§ 1.645 What records procedures must a third-party certification body have to qualify for accreditation?

A third-party certification body seeking accreditation must demonstrate that it:

(a) Implemented written procedures to establish, control, and retain records (including documents and data) for a period of time necessary to meet its contractual and legal obligations and to provide an adequate basis for evaluating its program and performance; and

(b) Is capable of meeting the reporting, notification, and records requirements of this subpart, if accredited.

REQUIREMENTS FOR THIRD-PARTY CERTIFICATION BODIES THAT HAVE BEEN ACCREDITED UNDER THIS SUBPART

§ 1.650 How must an accredited third-party certification body ensure its audit agents are competent and objective?

(a) An accredited third-party certification body that uses audit agents to conduct food safety audits must ensure that each such audit agent meets the following requirements with respect to the scope of its accreditation under this subpart. If the accredited third-party certification body is an individual, that individual is also subject to the following requirements, as applicable:

(1) Has relevant knowledge and experience that provides an adequate basis for the audit agent to evaluate compliance with applicable food safety requirements of the FD&C Act and FDA regulations and, for consultative audits, also includes conformance with applicable industry standards and practices;

(2) Has been determined by the accredited third-party certification body, through observations of a representative sample of audits, to be competent to conduct food safety audits under this subpart relevant to the audits they will be assigned to perform;

(3) Has completed annual food safety training that is relevant to activities conducted under this subpart;

(4) Is in compliance with the conflict of interest requirements of § 1.657 and has no other conflicts of interest with the eligible entity to be audited that might impair the audit agent's objectivity; and

(5) Agrees to notify its accredited third-party certification body immediately upon discovering, during a food safety audit, any condition that could cause or contribute to a serious risk to the public health.

(b) In assigning an audit agent to conduct a food safety audit at a particular eligible entity, an accredited third-party certification body must determine that the audit agent is qualified to conduct such audit under the criteria established in paragraph (a) of this section and based on the scope and purpose of the audit and the type of facility, its process(es), and food.

(c) An accredited third-party certification body cannot use an audit agent to conduct a regulatory audit at an eligible entity if such audit agent conducted a consultative audit or regulatory audit for the same eligible entity in the preceding 13 months, except that such limitation may be waived if the accredited third-party certification body demonstrates to FDA, under § 1.663, there is insufficient access to audit agents in the country or region where the eligible entity is located. If the accredited third-party certification body is an individual, that individual is also subject to such limitations.