

## Food and Drug Administration, HHS

## § 1.620

from, or accredited by, such accreditation body; and

(b) The capability to meet the applicable conflict of interest requirements of this subpart, if recognized.

### **§ 1.614 What quality assurance procedures must an accreditation body have to qualify for recognition?**

An accreditation body seeking recognition must demonstrate that it has:

(a) Implemented a written program for monitoring and evaluating the performance of its officers, employees, and other agents and its accreditation program, including procedures to:

(1) Identify areas in its accreditation program or performance where deficiencies exist; and

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

(b) The capability to meet the applicable quality assurance requirements of this subpart, if recognized.

### **§ 1.615 What records procedures must an accreditation body have to qualify for recognition?**

An accreditation body seeking recognition must demonstrate that it has:

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

(b) The capability to meet the applicable reporting and notification requirements of this subpart, if recognized.

## **REQUIREMENTS FOR ACCREDITATION BODIES THAT HAVE BEEN RECOGNIZED UNDER THIS SUBPART**

### **§ 1.620 How must a recognized accreditation body evaluate third-party certification bodies seeking accreditation?**

(a) Prior to accrediting a third-party certification body under this subpart, a recognized accreditation body must perform, at a minimum, the following:

(1) In the case of a foreign government or an agency of a foreign government, such reviews and audits of the

government's or agency's food safety programs, systems, and standards as are necessary to determine that it meets the eligibility requirements of § 1.640(b).

(2) In the case of a foreign cooperative or any other third-party seeking accreditation as a third-party certification body, such reviews and audits of the training and qualifications of agents conducting audits for such cooperative or other third party (or in the case of a third-party certification body that is an individual, such individual) and such reviews of internal systems and any other investigation of the cooperative or other third party necessary to determine that it meets the eligibility requirements of § 1.640(c).

(3) In conducting a review and audit under paragraph (a)(1) or (2) of this section, an observation of a representative sample of onsite audits examining compliance with the applicable food safety requirements of the FD&C Act and FDA regulations as conducted by the third-party certification body or its agents (or, in the case of a third-party certification body that is an individual, such individual).

(b) A recognized accreditation body must require a third-party certification body, as a condition of accreditation under this subpart, to comply with the reports and notification requirements of §§ 1.652 and 1.656 and to agree to submit to FDA, electronically and in English, any food or facility certifications it issues for purposes of sections 801(q) or 806 of the FD&C Act.

(c) A recognized accreditation body must maintain records on any denial of accreditation (in whole or in part) and on any withdrawal, suspension, or reduction in scope of accreditation of a third-party certification body under this subpart. The records must include the name and contact information for the third-party certification body; the date of the action; the scope of accreditation denied, withdrawn, suspended, or reduced; and the basis for such action.

(d) A recognized accreditation body must notify any third-party certification body of an adverse decision associated with its accreditation under

## § 1.621

this subpart, including denial of accreditation or the withdrawal, suspension, or reduction in the scope of its accreditation. The recognized accreditation body must establish and implement written procedures for receiving and addressing appeals from any third-party certification body challenging such an adverse decision and for investigating and deciding on appeals in a fair and meaningful manner. The appeals procedures must provide similar protections to those offered by FDA under §§ 1.692 and 1.693, and include requirements to:

(1) Make the appeals procedures publicly available;

(2) Use competent persons, who may or may not be external to the recognized accreditation body, who are free from bias or prejudice and have not participated in the accreditation decision or be subordinate to a person who has participated in the accreditation decision to investigate and decide appeals;

(3) Advise third-party certification bodies of the final decisions on their appeals; and

(4) Maintain records under § 1.625 of appeals, final decisions on appeals, and the bases for such decisions.

### **§ 1.621 How must a recognized accreditation body monitor the performance of third-party certification bodies it accredited?**

(a) A recognized accreditation body must annually conduct a comprehensive assessment of the performance of each third-party certification body it accredited under this subpart by reviewing the accredited third-party certification body's self-assessments (including information on compliance with the conflict of interest requirements of §§ 1.643 and 1.657); its regulatory audit reports and notifications submitted to FDA under § 1.656; and any other information reasonably available to the recognized accreditation body regarding the compliance history of eligible entities the accredited third-party certification body certified under this subpart; or that is otherwise relevant to a determination whether the accredited third-party certification body is in compliance with this subpart.

## 21 CFR Ch. I (4–1–23 Edition)

(b) No later than 1 year after the initial date of accreditation of the third-party certification body and every 2 years thereafter for duration of its accreditation under this subpart, a recognized accreditation body must conduct onsite observations of a representative sample of regulatory audits performed by the third-party certification body (or its audit agents) (or, in the case of a third-party certification body that is an individual, such individual) accredited under this subpart and must visit the accredited third-party certification body's headquarters (or other location that manages audit agents conducting food safety audits under this subpart, if different than its headquarters). The recognized accreditation body will consider the results of such observations and visits in the annual assessment of the accredited third-party certification body required by paragraph (a) of this section.

### **§ 1.622 How must a recognized accreditation body monitor its own performance?**

(a) A recognized accreditation body must annually, and as required under § 1.664(g), conduct a self-assessment that includes evaluation of compliance with this subpart, including:

(1) The performance of its officers, employees, or other agents involved in accreditation activities and the degree of consistency in conducting accreditation activities;

(2) The compliance of the recognized accreditation body and its officers, employees, and other agents involved in accreditation activities, with the conflict of interest requirements of § 1.624; and

(3) If requested by FDA, any other aspects of its performance relevant to a determination whether the recognized accreditation body is in compliance with this subpart.

(b) As a means to evaluate the recognized accreditation body's performance, the self-assessment must include onsite observation of regulatory audits of a representative sample of third-party certification bodies it accredited under this subpart. In meeting this requirement, the recognized accreditation body may use the results of onsite observations performed under § 1.621(b).