

(c) Based on the evaluations conducted under paragraphs (a) and (b) of this section, the recognized accreditation body must:

(1) Identify any area(s) where deficiencies exist;

(2) Quickly implement corrective action(s) that effectively address those deficiencies; and

(3) Establish and maintain records of any such corrective action(s) under § 1.625.

(d) The recognized accreditation body must prepare, and as required by § 1.623(b) submit, a written report of the results of its self-assessment that includes the following elements. Documentation of conformance to ISO/IEC 17011:2004 may be used, supplemented as necessary, in meeting the requirements of this paragraph.

(1) A description of any corrective actions taken under paragraph (c) of this section;

(2) A statement disclosing the extent to which the recognized accreditation body, and its officers, employees, and other agents involved in accreditation activities, complied with the conflict of interest requirements in § 1.624; and

(3) A statement attesting to the extent to which the recognized accreditation body complied with applicable requirements of this subpart.

§ 1.623 What reports and notifications must a recognized accreditation body submit to FDA?

(a) *Reporting results of assessments of accredited third-party certification body performance.* A recognized accreditation body must submit to FDA electronically, in English, a report of the results of any assessment conducted under § 1.621, no later than 45 days after completing such assessment. The report must include an up-to-date list of any audit agents used by the accredited third-party certification body to conduct food safety audits under this subpart.

(b) *Reporting results of recognized accreditation body self-assessments.* A recognized accreditation body must submit to FDA electronically, in English:

(1) A report of the results of an annual self-assessment required under § 1.622, no later than 45 days after completing such self-assessment; and

(2) For a recognized accreditation body subject to § 1.664(g)(1), a report of such self-assessment to FDA within 60 days of the third-party certification body's withdrawal. A recognized accreditation body may use a report prepared for conformance to ISO/IEC 17011:2004, supplemented as necessary, in meeting the requirements this section.

(c) *Immediate notification to FDA.* A recognized accreditation body must notify FDA electronically, in English, immediately upon:

(1) Granting (including expanding the scope of) accreditation to a third-party certification body under this subpart, and include:

(i) The name, address, telephone number, and email address of the accredited third-party certification body;

(ii) The name of one or more officers of the accredited third-party certification body;

(iii) A list of the accredited third-party certification body's audit agents; and

(iv) The scope of accreditation, the date on which it was granted, and its expiration date.

(2) Withdrawing, suspending, or reducing the scope of an accreditation under this subpart, and include:

(i) The basis for such action; and

(ii) Any additional changes to accreditation information previously submitted to FDA under paragraph (c)(1) of this section.

(3) Determining that a third-party certification body it accredited failed to comply with § 1.653 in issuing a food or facility certification under this subpart, and include:

(i) The basis for such determination; and

(ii) Any changes to accreditation information previously submitted to FDA under paragraph (c)(1) of this section.

(d) *Other notification to FDA.* A recognized accreditation body must notify FDA electronically, in English, within 30 days after:

(1) Denying accreditation (in whole or in part) under this subpart and include:

(i) The name, address, telephone number, and email address of the third-party certification body;

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(ii) The name of one or more officers of the third-party certification body;

(iii) The scope of accreditation requested; and

(iv) The scope and basis for such denial.

(2) Making any significant change that would affect the manner in which it complies with the applicable requirements of this subpart and include:

(i) A description of the change; and

(ii) An explanation for the purpose of the change.

§ 1.624 How must a recognized accreditation body protect against conflicts of interest?

(a) A recognized accreditation body must implement a written program to protect against conflicts of interest between the recognized accreditation body (and its officers, employees, and other agents involved in accreditation activities) and any third-party certification body (and its officers, employees, and other agents involved in auditing and certification activities) seeking accreditation from, or accredited by, such recognized accreditation body, including the following:

(1) Ensuring that the recognized accreditation body (and its officers, employees, or other agents involved in accreditation activities) does not own or have a financial interest in, manage, or otherwise control the third-party certification body (or any affiliate, parent, or subsidiary); and

(2) Prohibiting officers, employees, or other agents involved in accreditation activities of the recognized accreditation body from accepting any money, gift, gratuity, or item of value from the third-party certification body.

(3) The items specified in paragraph (a)(2) of this section do not include:

(i) Money representing payment of fees for accreditation services and reimbursement of direct costs associated with an onsite assessment of the third-party certification body; or

(ii) Lunch of de minimis value provided during the course of an assessment and on the premises where the assessment is conducted, if necessary to facilitate the efficient conduct of the assessment.

(b) A recognized accreditation body may accept the payment of fees for ac-

creditation services and the reimbursement of direct costs associated with assessment of a certification body only after the date on which the report of such assessment was completed or the date of which the accreditation was issued, whichever comes later. Such payment is not considered a conflict of interest for purposes of paragraph (a) of this section.

(c) The financial interests of the spouses and children younger than 18 years of age of a recognized accreditation body's officers, employees, and other agents involved in accreditation activities will be considered the financial interests of such officers, employees, and other agents involved in accreditation activities.

(d) A recognized accreditation body must maintain on its Web site an up-to-date list of the third-party certification bodies it accredited under this subpart and must identify the duration and scope of each accreditation and the date(s) on which the accredited third-party certification body paid any fee or reimbursement associated with such accreditation. If the accreditation of a certification body is suspended, withdrawn, or reduced in scope, this list must also include the date of suspension, withdrawal, or reduction in scope and maintain that information for the duration of accreditation or until the suspension is lifted, the certification body is reaccredited, or the scope of accreditation is reinstated, whichever comes first.

§ 1.625 What records requirements must an accreditation body that has been recognized meet?

(a) An accreditation body that has been recognized must maintain electronically for 5 years records created while it is recognized (including documents and data) demonstrating its compliance with this subpart, including records relating to:

(1) Applications for accreditation and renewal of accreditation under § 1.660;

(2) Decisions to grant, deny, suspend, withdraw, or expand or reduce the scope of an accreditation;

(3) Challenges to adverse accreditation decisions under § 1.620(c);

(4) Its monitoring of accredited third-party certification bodies under § 1.621;