§ 1.656 What reports and notifications must an accredited third-party certification body submit?

(a) *Reporting results of regulatory audits.* An accredited third-party certification body must submit a regulatory audit report, as described in § 1.652(b), electronically, in English, to FDA and to the recognized accreditation body that granted its accreditation (where applicable), no later than 45 days after completing such audit.

(b) *Reporting results of accredited third-party certification body self-assessments.* An accredited third-party certification body must submit the report of its annual self-assessment required by § 1.655 electronically to its recognized accreditation body (or, in the case of direct accreditation, electronically and in English, to FDA), within 45 days of the anniversary date of its accreditation under this subpart. For an accredited third-party certification body subject to an FDA request for cause, or § 1.631(f)(1)(i), § 1.634(d)(1)(i), or § 1.635(c)(1)(i), the report of its self-assessment must be submitted to FDA electronically, in English, within 60 days of the FDA request, denial of renewal, revocation, or relinquishment of recognition of the accreditation body that granted its accreditation. Such report must include an up-to-date list of any audit agents it uses to conduct audits under this subpart.

(c) *Notification to FDA of a serious risk to public health.* An accredited third-party certification body must immediately notify FDA electronically, in English, if during a regulatory or consultative audit, any of its audit agents or the accredited third-party certification body itself discovers a condition that could cause or contribute to a serious risk to the public health, providing the following information:

(1) The name, physical address, and unique facility identifier, if designated by FDA, of the eligible entity subject to the audit, and, where applicable, the registration number under subpart H of this part;

(2) The name, physical address, and unique facility identifier, if designated by FDA, of the facility where the condition was discovered (if different from that of the eligible entity) and, where applicable, the registration number assigned to the facility under subpart H of this part; and

(3) The condition for which notification is submitted.

(d) *Immediate notification to FDA of withdrawal or suspension of a food or facility certification.* An accredited third-party certification body must notify FDA electronically, in English, immediately upon withdrawing or suspending any food or facility certification of an eligible entity and the basis for such action.

(e) *Notification to its recognized accreditation body or an eligible entity.* (1) After notifying FDA under paragraph (c) of this section, an accredited third-party certification body must immediately notify the eligible entity of such condition and must immediately thereafter notify the recognized accreditation body that granted its accreditation, except for third-party certification bodies directly accredited by FDA. Where feasible and reliable, the accredited third-party certification body may contemporaneously notify its recognized accreditation body and/or the eligible entity when notifying FDA.

(2) An accredited third-party certification body must notify its recognized accreditation body (or, in the case of direct accreditation, FDA) electronically, in English, within 30 days after making any significant change that would affect the manner in which it complies with the requirements of this subpart and must include with such notification the following information:

(i) A description of the change; and

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

§ 1.657 How must an accredited third-party certification body protect against conflicts of interest?

(a) An accredited third-party certification body must implement a written program to protect against conflicts of interest between the accredited third-party certification body (and its officers, employees, and other agents involved in auditing and certification activities) and an eligible entity seeking a food safety audit or food or facility certification from, or audited or certified by, such accredited third-party

certification body, including the following:

(1) Ensuring that the accredited third-party certification body and its officers, employees, or other agents involved in auditing and certification activities do not own, operate, have a financial interest in, manage, or otherwise control an eligible entity to be certified, or any affiliate, parent, or subsidiary of the entity;

(2) Ensuring that the accredited third-party certification body and, its officers, employees, or other agents involved in auditing and certification activities are not owned, managed, or controlled by any person that owns or operates an eligible entity to be certified;

(3) Ensuring that an audit agent of the accredited third-party certification body does not own, operate, have a financial interest in, manage, or otherwise control an eligible entity or any affiliate, parent, or subsidiary of the entity that is subject to a consultative or regulatory audit by the audit agent; and

(4) Prohibiting an accredited third-party certification body's officer, employee, or other agent involved in auditing and certification activities from accepting any money, gift, gratuity, or other item of value from the eligible entity to be audited or certified under this subpart.

(5) The items specified in paragraph (a)(4) of this section do not include:

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

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

(b) An accredited third-party certification body may accept the payment of fees for auditing and certification services and the reimbursement of direct costs associated with an audit of an eligible entity only after the date on which the report of such audit was completed or the date a food or facility certification was issued, whichever is 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 accredited third-party certification body's officers, employees, and other agents involved in auditing and certification activities will be considered the financial interests of such officers, employees, and other agents involved in auditing and certification activities.

(d) An accredited third-party certification body must maintain on its Web site an up-to-date list of the eligible entities to which it has issued food or facility certifications under this subpart. For each such eligible entity, the Web site also must identify the duration and scope of the food or facility certification and date(s) on which the eligible entity paid the accredited third-party certification body any fee or reimbursement associated with such audit or certification.

§ 1.658 What records requirements must a third-party certification body that has been accredited meet?

(a) A third-party certification body that has been accredited must maintain electronically for 4 years records created during its period of accreditation (including documents and data) that document compliance with this subpart, including:

(1) Any audit report and other documents resulting from a consultative audit conducted under this subpart, including the audit agent's observations, correspondence with the eligible entity, verification of any corrective action(s) taken to address deficiencies identified during the audit;

(2) Any request for a regulatory audit from an eligible entity;

(3) Any audit report and other documents resulting from a regulatory audit conducted under this subpart, including the audit agent's observations, correspondence with the eligible entity, verification of any corrective action(s) taken to address deficiencies identified during the audit, and, when sampling and analysis is conducted, laboratory testing records and results from a laboratory that is accredited in