

§ 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 as-

signed 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