

(f) If FDA approves the request, issuance of the waiver will state the duration of the waiver and list any limitations associated with it. If FDA denies the request, the issuance of a denial of a waiver request will state the basis for denial and will provide the address and procedures for requesting reconsideration of the request under § 1.691.

(g) Unless FDA notifies a requestor that its waiver request has been approved, an accredited third-party certification body must not use the audit agent to conduct a regulatory audit of such eligible entity until the 13-month limit in § 1.650(c) has elapsed.

**§ 1.664 When would FDA withdraw accreditation?**

(a) *Mandatory withdrawal.* FDA will withdraw accreditation from a third-party certification body:

(1) Except as provided in paragraph (b) of this section, if the food or facility certified under this subpart is linked to an outbreak of foodborne illness or chemical or physical hazard that has a reasonable probability of causing serious adverse health consequences or death in humans or animals;

(2) Following an evaluation and finding by FDA that the third-party certification body no longer complies with the applicable requirements of this subpart; or

(3) Following its refusal to allow FDA to access records under § 1.658 or to conduct an audit, assessment, or investigation necessary to ensure continued compliance with this subpart.

(4) If payment of the third-party certification body's annual fee is not received within 90 days of the payment due date, as specified in § 1.725(c)(3).

(b) *Exception.* FDA may waive mandatory withdrawal under paragraph (a)(1) of this section, if FDA:

(1) Conducts an investigation of the material facts related to the outbreak of human or animal illness;

(2) Reviews the relevant audit records and the actions taken by the accredited third-party certification body in support of its decision to certify; and

(3) Determines that the accredited third-party certification body satisfied

the requirements for issuance of certification under this subpart.

(c) *Discretionary withdrawal.* FDA may withdraw accreditation, in whole or in part, from a third-party certification body when such third-party certification body is accredited by an accreditation body for which recognition is revoked under § 1.634, if FDA determines there is good cause for withdrawal, including:

(1) Demonstrated bias or lack of objectivity when conducting activities under this subpart; or

(2) Performance that calls into question the validity or reliability of its food safety audits or certifications.

(d) *Records access.* FDA may request records of the accredited third-party certification body under § 1.658 and, where applicable, may request records under § 1.625 of an accreditation body that has been recognized under § 1.625, when considering withdrawal under paragraph (a)(1), (a)(2), or (c) of this section.

(e) *Notice to the third-party certification body of withdrawal of accreditation.* (1) FDA will notify a third-party certification body of the withdrawal of its accreditation through issuance of a withdrawal that will state the grounds for withdrawal, the procedures for requesting a regulatory hearing under § 1.693 on the withdrawal, and the procedures for requesting reaccreditation under § 1.666.

(2) Within 10 business days of the date of issuance of the withdrawal, the third-party certification body must notify FDA electronically, in English, of the name of the custodian who will maintain the records required by § 1.658, and provide contact information for the custodian, which will at least include an email address, and the street address where the records will be located.

(f) *Effect of withdrawal of accreditation on eligible entities.* A food or facility certification issued by a third-party certification body prior to withdrawal will remain in effect until the certification terminates by expiration. If FDA has reason to believe that a certification issued for purposes of section 801(q) or 806 of the FD&C Act is not valid or reliable, FDA may refuse to

consider the certification in determining the admissibility of the article of food for which the certification was offered or in determining the importer's eligibility for participation in VQIP.

(g) *Effect of withdrawal of accreditation on recognized accreditation bodies.*

(1) FDA will notify a recognized accreditation body if the accreditation of a third-party certification body it accredited is withdrawn by FDA. Such accreditation body's recognition will remain in effect if, no later than 60 days after withdrawal, the accreditation body conducts a self-assessment under § 1.622 and reports the results of the self-assessment to FDA as required by § 1.623(b).

(2) FDA may revoke the recognition of an accreditation body whenever FDA determines there is good cause for revocation of recognition under § 1.634.

(h) *Public notice of withdrawal accreditation.* FDA will provide notice on the Web site described in § 1.690 of its withdrawal of accreditation of a third-party certification body and provide a description of the basis for withdrawal.

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**§ 1.665 What if I want to voluntarily relinquish accreditation or do not want to renew accreditation?**

(a) *Notice to FDA of intent to relinquish or not to renew accreditation.* A third-party certification body must notify FDA electronically, in English, at least 60 days before voluntarily relinquishing accreditation or before allowing accreditation to expire without seeking renewal. The certification body must provide the name and contact information of the custodian who will maintain the records required under § 1.658(a) after the date of relinquishment or the date accreditation expires, as applicable, and make them available to FDA as required by § 1.658(b) and (c). The contact information for the custodian must include, at a minimum, an email address and the physical address where the records required by § 1.658(a) will be located.

(b) *Notice to recognized accreditation body and eligible entities of intent to relinquish or not to renew accreditation.* No later than 15 business days after noti-

fying FDA under paragraph (a) of this section, the certification body must notify its recognized accreditation body and any eligible entity with current certifications that it intends to relinquish accreditation or to allow its accreditation to expire, specifying the date on which relinquishment or expiration will occur. The recognized accreditation body must establish and maintain records of such notification under § 1.625(a).

(c) *Effect of voluntary relinquishment or expiration of accreditation on food or facility certifications issued to eligible entities.* A food or facility certification issued by a third-party certification body prior to relinquishment or expiration of its accreditation will remain in effect until the certification expires. If FDA has reason to believe that a certification issued for purposes of section 801(q) or 806 of the FD&C Act is not valid or reliable, FDA may refuse to consider the certification in determining the admissibility of the article of food for which the certification was offered or in determining the importer's eligibility for participation in VQIP.

(d) *Public notice of voluntary relinquishment or expiration of accreditation.* FDA will provide notice on the Web site described in § 1.690 of the voluntary relinquishment or expiration of accreditation of a certification body under this subpart.

**§ 1.666 How do I request reaccreditation?**

(a) *Application following withdrawal.* FDA will reinstate the accreditation of a third-party certification body for which it has withdrawn accreditation:

(1) If, in the case of direct accreditation, FDA determines, based on evidence presented by the third-party certification body, that the third-party certification body satisfies the applicable requirements of this subpart and adequate grounds for withdrawal no longer exist; or

(2) In the case of a third-party certification body accredited by an accreditation body for which recognition has been revoked under § 1.634:

(i) If the third-party certification body becomes accredited by another recognized accreditation body or by