

§ 493.565

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(2) An audit of meetings concerning the accreditation process.

(3) Evaluation of accreditation inspection results and the accreditation decision-making process.

(4) Interviews with the accreditation organization's staff.

(f) *Onsite inspection of a State licensure program.* An onsite inspection of a State licensure program office may include, but is not limited to, the following:

(1) A review of documents.

(2) An audit of meetings concerning the licensure or approval process.

(3) Evaluation of State inspection results and the licensure or approval decision-making process.

(4) Interviews with State employees.

§ 493.565 Selection for validation inspection—laboratory responsibilities.

A laboratory selected for a validation inspection must do the following:

(a) Authorize its accreditation organization or State licensure program, as applicable, to release to CMS or a CMS agent, on a confidential basis, a copy of the laboratory's most recent full, and any subsequent partial inspection.

(b) Authorize CMS or a CMS agent to conduct a validation inspection.

(c) Provide CMS or a CMS agent with access to all facilities, equipment, materials, records, and information that CMS or a CMS agent determines have a bearing on whether the laboratory is being operated in accordance with the requirements of this part, and permit CMS or a CMS agent to copy material or require the laboratory to submit material.

(d) If the laboratory possesses a valid certificate of accreditation, authorize CMS or a CMS agent to monitor the correction of any deficiencies found through the validation inspection.

§ 493.567 Refusal to cooperate with validation inspection.

(a) *Laboratory with a certificate of accreditation.* (1) A laboratory with a certificate of accreditation that refuses to cooperate with a validation inspection by failing to comply with the requirements in § 493.565—

(i) Is subject to full review by CMS or a CMS agent, in accordance with this part; and

(ii) May be subject to suspension, revocation, or limitation of its certificate of accreditation under this part.

(2) A laboratory with a certificate of accreditation is again deemed to meet the condition-level requirements by virtue of its accreditation when the following conditions exist:

(i) The laboratory withdraws any prior refusal to authorize its accreditation organization to release a copy of the laboratory's current accreditation inspection, PT results, or notification of any adverse actions resulting from PT failure.

(ii) The laboratory withdraws any prior refusal to allow a validation inspection.

(iii) CMS finds that the laboratory meets all the condition-level requirements.

(b) *CLIA-exempt laboratory.* If a CLIA-exempt laboratory fails to comply with the requirements specified in § 493.565, CMS notifies the State of the laboratory's failure to meet the requirements.

§ 493.569 Consequences of a finding of noncompliance as a result of a validation inspection.

(a) *Laboratory with a certificate of accreditation.* If a validation inspection results in a finding that the accredited laboratory is out of compliance with one or more condition-level requirements, the laboratory is subject to—

(1) The same requirements and survey and enforcement processes applied to laboratories that are not accredited and that are found out of compliance following an inspection under this part; and

(2) Full review by CMS, in accordance with this part; that is, the laboratory is subject to the principal and alternative sanctions in § 493.1806.

(b) *CLIA-exempt laboratory.* If a validation inspection results in a finding that a CLIA-exempt laboratory is out of compliance with one or more condition-level requirements, CMS directs the State to take appropriate enforcement action.