

notify HCFA of the receipt of those samples.

(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event.

(6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.

[57 FR 7146, Feb. 28, 1992, as amended at 58 FR 5228, Jan. 19, 1993]

§ 493.803 Condition: Successful participation.

(a) Each laboratory performing tests of moderate complexity (including the subcategory) and/or high complexity must successfully participate in a proficiency testing program approved by HCFA, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA.

(b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, HCFA imposes sanctions, as specified in subpart R of this part.

(c) If a laboratory fails to perform successfully in a HCFA-approved proficiency testing program, for the initial unsuccessful performance, HCFA may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle

sanctions except when one or more of the following conditions exists:

(1) There is immediate jeopardy to patient health and safety.

(2) The laboratory fails to provide HCFA or a HCFA agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance.

(3) The laboratory has a poor compliance history.

[57 FR 7146, Feb. 28, 1992, as amended at 60 FR 20048, Apr. 24, 1995; 63 FR 26737, May 14, 1998]

§ 493.807 Condition: Reinstatement of laboratories performing tests of moderate complexity (including the subcategory), high complexity, or any combination of these tests, after failure to participate successfully.

(a) If a laboratory's certificate is suspended or limited or its Medicare or Medicaid approval is cancelled or its Medicare or Medicaid payments are suspended because it fails to participate successfully in proficiency testing for one or more specialties, subspecialties, analyte or test, or voluntarily withdraws its certification under CLIA for the failed specialty, subspecialty, or analyte, the laboratory must then demonstrate sustained satisfactory performance on two consecutive proficiency testing events, one of which may be on site, before HCFA will consider it for reinstatement for certification and Medicare or Medicaid approval in that specialty, subspecialty, analyte or test.

(b) The cancellation period for Medicare and Medicaid approval or period for suspension of Medicare or Medicaid payments or suspension or limitation of certification under CLIA for the failed specialty, subspecialty, or analyte or test is for a period of not less than six months from the date of cancellation, limitation or suspension of the CLIA certificate.

[58 FR 5228, Jan. 19, 1993, as amended at 60 FR 20048, Apr. 24, 1995]