

D2005

(Rev. 140, Issued: 05-29-15, Effective: 05-29-15, Implementation: 05-29-15)

§493.801(a) Standard: Enrollment

(a)(4) Authorize the proficiency testing program to release to HHS all data required to--

Interpretive Guidelines §493.801(a)(4)

The laboratory director authorizes PT data to be released to regulatory agencies when he/she signs the CLIA application for certification. The laboratory should also provide the PT program with the appropriate accreditation organization or Federal or State Agency address to which PT results must be sent. Laboratories that are accredited by a CMS-approved accreditation organization must meet the PT requirements in subpart H of the CLIA regulations, including, but not limited to, releasing all required PT data to its accreditation organization (§493.551(b)(3)).

All CLIA-exempt laboratories must enroll and participate in a CMS-approved program(s) for all analytes performed that are listed in Subpart I.

(i) Determine the laboratory's compliance with this subpart; and

(ii) Make PT results available to the public as required in section 353(f)(3)(F) of the Public Health Service Act.