and complaint response procedures, its notification agreements with HCFA, its removal or withdrawal of laboratory accreditation procedures, its current list of accredited laboratories, and its announced or unannounced inspection process. We have determined that CAP has complied with the general requirements under § 493.501, the applicable parts of § 493.506, and the CLIA requirements for approval as an accreditation organization under various subparts of part 493.

Our evaluation identified areas of the CAP requirements that are more stringent than the CLIA requirements and apply to the laboratory as a whole. Rather than include them in the appropriate subparts multiple times, we

list them here:

• CAP requires its accredited laboratories to possess documentation of all State laws and to follow them.

- CAP lists extensive requirements for the Laboratory Information System (LIS), which cover but are not limited to:
- + The preservation, storage, and retrieval of laboratory and patient data;
- + The review of LIS programs for appropriate content and testing before use when a new program is to be put in place or when changes are made to existing programming;

+ The maintenance of the LIS facility, which must be clean, well ventilated, and at proper temperature and

humidity;

+ The protection of LIS against power

interruptions and surges;

- + The protection of the LIS, its data, patient information, and programs from unauthorized use;
- + The entry of data and result reporting;
- + The verification and maintenance of LIS hardware and software;
- + The routine and emergency service and maintenance of the LIS; and
- + An evaluation from the laboratory director of the LIS performance as it pertains to patient and clinician needs.
- + In addition, the LIS operators must have procedure manuals readily available, be adequately trained in LIS operation, and know what must be done to preserve data and equipment in emergency situations such as software or hardware failure or in the event of fire;
- CAP accredits laboratories that perform testing for any of the following areas and sets specific standards with which their accredited laboratories must comply:
- + Athletic drug testing (for anabolic steroids, beta-blockers, cannabinoids, narcotics, and stimulants);
 - + Forensic urine drug testing;

+ Parentage testing; and

+ Reproductive laboratory testing (embryology and andrology).

Subpart H—Participation in Proficiency Testing for Laboratories Performing Tests of Moderate or High Complexity, or Both

The CAP requirements for proficiency testing (PT) are in comformance with the CLIA law, which states that standards shall require all laboratories be tested by PT for each examination for which PT is available. The CAP PT requirements are more stringent than the CLIA regulations at subpart I, which list specific tests for which the laboratory must participate in a HCFA approved PT program. CLIA exempts waived testing from PT, whereas CAP requires its accredited laboratories to participate in its HCFA approved PT program for all testing, including procedures waived under CLIA.

We have determined that the actions taken by CAP to correct unsatisfactory (one failure) and unsuccessful (2 in a row or 2 out of 3 failures) PT performance of its laboratories is equivalent to those of CLIA; in the cases of unsatisfactory performance and the CLIA phase-in allowances, CAP is more stringent. CAP has initiated an on-going electronic monitoring process that flags both unsatisfactory and unsuccessful results for all PT performance, both CLIA required analytes and all other testing for which PT is available and is required by CAP. CAP accredited laboratories are allowed 15 days to respond in writing to each unsatisfactory result, indicating how the problem was investigated, the cause of the problem, the specific corrective action that was taken to prevent recurrence, and evidence that the problem was successfully corrected.

CLIA regulations state that the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with an unsatisfactory score, take remedial action and document it. Unsuccessful PT performance, when identified by CAP, initiates immediate communication with the laboratory director. A written response must be submitted to CAP, explaining why the adverse results occurred, a description of the investigation of the problem and the actions taken to correct the problem. The laboratory must submit this information within ten working days. If, after review by CAP, it is determined that the laboratory's approach is scientifically valid and PT performance is within acceptable limits, no further action is taken. If the laboratory does not respond, fails to address the

problem seriously, or cannot bring performance into acceptable limits, the CAP would evaluate the situation and either request that the laboratory cease testing for the analyte or specialty or subspecialty in question, or, if warranted, revoke accreditation.

CLIA regulations allow a phase-in period for unsuccessful PT performance, which, for previously regulated laboratories (which includes most CAP accredited laboratories), impose no sanctions under § 493.803 (Condition: Successful Participation) until the end of 1994. As the phase-in period ends, the sanctions under CLIA and the actions taken by CAP become

equivalent.

CAP also offers a voluntary continuing education and external quality assurance program for PAP smear cytology. The Interlaboratory Comparison Program in Cervicovaginal Cytopathology currently enrolls approximately 1,800 CAP accredited laboratories that perform cytology testing. The number of laboratories this program can enroll is dependent upon the availability of the referenced glass slide material (cervicovaginal smears). When CAP has sufficient quantities to accommodate all of its 2,600 accredited laboratories that perform gynecologic (GYN) cytology, it intends to offer this program as a cervicovaginal cytopathology pathology proficiency testing survey in which its accredited laboratories will be required to participate. Currently there is no HCFA approved cytology PT program capable of enrolling all CLIA certified laboratories that perform GYN cytology

Subpart J—Patient Test Management for Moderate or High Complexity Testing, or Both

The CAP has expanded and in some cases revised its requirements to be equivalent to the CLIA requirements at §§ 493.1101 through 493.1111, on an overall basis. We have determined that CAP's requirements for an accredited laboratory to include on report forms the dates and times of specimen collection (when appropriate) and the release of the report are more stringent than the requirements under CLIA as well as their requirement that reports must be legible. The CAP also requires its accreditated laboratories to use referral laboratories that are appropriately CLIA certified.

Subpart K—Quality Control for Tests of Moderate or High Complexity, or Both

The quality control (QC) requirements of CAP have been evaluated against the phased-in, complexity based