requirements of the CLIA regulations. We have determined that after the additions and revisions made by CAP, the QC requirements of CAP are more stringent than the CLIA requirements, when taken as a whole. Some specific requirements of QC that are more stringent are:

- The CAP does not allow a two year phase-in for QC requirements and requirements are effective without delay;
- The CAP imposes QC requirements equally upon all testing performed by their accredited laboratories, including CLIA's waived procedures. All testing is considered high complexity by CLIA definition;
- The CAP laboratory safety requirements are specific and detailed. Environmental safety requirements address electrical voltage, facility ventilation, lighting, temperature, humidity, and emergency power source and require remedial actions to be taken when necessary. CAP also has requirements in place for handling and disposal of biohazardous materials, fire safety and prevention of fire hazards, as well as all OSHA regulations as they pertain to the laboratory;
- The CAP requires procedure manuals to include the principle and clinical significance for each test, and the procedure manuals must also include documentation of initial and annual reviews;
- CAP accredited laboratories that rely on manufacturers' quality control of microbiological media must have a copy of the National Committee for Clinical Laboratory Standards Document M–22–A (Quality Assurance for Commercially Prepared Microbiological Culture Media) and provide documentation that its media supplier carries out the quality assurance guidelines enumerated in Document M–22–A;
- CLIA regulations allow cytology slide preparations made using automated, semi-automated, or other liquid-based slide preparations that cover half or less of a slide to be counted as one half slide for cytology workload purposes. This allows a maximum of 200 such preparations to be examined by an individual in a 24 hour period. The CAP does not recognize these preparations as half slides, but rather as full slides to be included in an individuals's 100 slide, 24 hour maximum allowable workload;
- CAP requires its accredited laboratories to use the appropriate reagent grade water for the testing performed, stating which type of water (from type I through Type III) must be used in specific tests. Source water must also be evaluated for silicone levels;
- CAP accredited laboratories must verify all volumetric glassware and pipettes for accuracy and reproductability prior to use and recheck them periodically. These activities must be documented;
- CAP accredited laboratories that perform maternal serum alpha-fetoprotein and amniotic fluid alpha-fetoprotein have specific requirements that must be met. These include a qualitative specimen evaluation, requesting and reporting information necessary for interpretation of results; i.e., gestational age, maternal birth date, race, maternal weight, insulin-dependent diabetes mellitus, multiple gestations, median ranges calculated and recalculated yearly, results reported in multiples of the mean, etc;
- The CAP lists specific requirements for newer methodologies. Molecular pathology and flow cytometry standards are presented in separate checklists and immunohistochemistry has specific requirements within histology; and
- CAP record retention requirements are the same or longer than those of CLIA.

The CAP has made additions and revisions to its requirements to make them equivalent to the CLIA regulations. Some examples of these changes are:

- All reagents must be used within their indicated expiration date;
- The laboratory must use components of reagent kits only with other kits of the same lot number, unless otherwise specified by the manufacturer;
- Conforming revisions were made to the CAP standards for calibration and calibration;
- Qualitative and quantitative test control procedure requirements were revised to specify the following more clearly:

+ Control specimens must be tested in the same manner as patient specimens;

+ Reagent performance and adequacy must be verified before placing the material in service. The results of the verification checks must be recorded; and

+ Stains are checked for intended reactivity each day of use;

- CAP has imposed a 100 slide maximum number of cytology slides that an individual may evaluate in a 24 hour period;
- Records must be maintained of the number of cytology slides evaluated by each individual;
- The technical supervisor in cytology (pathologist) must establish each individual's slide limit and re-assess this limit every six months;
- Also, in cytology, CAP requires a minimum of ten percent of negative (GYN) cases be re-screened by a qualified individual and the results of these slides not be released until the rescreens are complete; and
- All previous negative cytology smears available within the past five years must be reviewed on a patient having a current positive smear.

Subpart M—Personnel for Moderate and High Complexity Testing

The Standards for Laboratory Accreditation of the CAP states at Standard I, Director and Personnel Requirements, under item D, Personnel, that all laboratory personnel must be in compliance with applicable federal, state, and local laws and regulations. This standard is implemented in the general laboratory requirement that there must be evidence in personnel records that all testing personnel have been evaluated against CLIA regulatory requirements for high complexity testing and that all individuals qualify. CAP has added requirements to all levels of laboratory personnel, most of which refer to the CLIA regulatory requirements. We have determined that the personnel requirements of the CAP are equal to or more stringent than the personnel requirements of CLIA.

Subpart P—Quality Assurance for Moderate or High Complexity Testing or Both

We have determined that CAP's requirements are equal to or more stringent than the CLIA requirements of this subpart. CAP has made revisions to its checklist requirements for quality assurance to equate to the CLIA requirements. CAP also offers an educational program, Q-Probes, to its accredited laboratories, which provides further information on quality assurance to the large, full service laboratories; this program allows peer review and comparisons between facilities.

Subpart Q—Inspections

We have determined that the CAP inspection requirements, taken as a whole, are equivalent to the CLIA inspection requirements. CAP has made some program modifications pertinent to its overall inspection process, specifically involving the training of all inspectors. CAP has initiated a Laboratory Accreditation Programs Inspector Training Seminars program. Two seminars in each of the 13 CAP regions are presented currently, with 60 such seminars to be presented nationally per year beginning in 1995. Training seminar participants include inspection team leaders and team members.