

(v) Require that THE cytology [reviewing] REVIEW be performed by AN INDIVIDUAL WHO QUALIFIES AS a supervisory [level] cytotechnologist or a [cytopathologist] PATHOLOGIST;

(vi) Require the [pathologist] INDIVIDUAL who directs the [cytopathology] laboratory to establish and administer an ongoing quality assurance program using standards [accepted by professional cytology organizations] ACCEPTABLE TO THE SECRETARY;

(vii) Require cytology laboratories to reject unsatisfactorily prepared specimens, make appropriate comments regarding the quality of the specimen, and maintain records on unsatisfactorily prepared specimens for 5 years subject to review by the Department;

(viii) Require cytology laboratories to maintain and store for 5 years from the date of examination any slide that was examined [for disease or disease agents];

(ix) Require all cytology reports to be retained for at least 10 years;

(x) Prohibit [physicians] ANY PERSON from sending [pap smear] CYTOLOGY specimens to A LABORATORY, INCLUDING out-of-state laboratories not licensed by the Department; [and]

(XI) REQUIRE ALL INDIVIDUALS WHO EXAMINE GYNECOLOGICAL SLIDES ACQUIRED FROM PERSONS IN THIS STATE TO DEMONSTRATE SATISFACTORY PERFORMANCE IN AN APPROVED CYTOLOGY PROFICIENCY TESTING PROGRAM; AND

[(xi)] (XII) Establish any additional standards the Secretary considers necessary to assure that medical laboratories engaged in cytology provide safe and reliable services [to the citizens of the State].

(2) The requirements of paragraph (1) of this subsection are in addition to any other relevant provision of this subtitle or relevant regulation adopted in accordance with any other provision of this subtitle governing medical laboratories.

[(d)](E) (1) To assure compliance with standards adopted under subsection [(c)] (D) of this section, the Secretary shall adopt regulations to establish and conduct a cytology proficiency testing program for all cytology personnel [in the State] that examine GYNECOLOGICAL cytology specimens.

(2) All cytology proficiency tests [conducted] under the State cytology proficiency testing program shall be [handcarried, on site and under the supervision of an official] CONDUCTED BY AN EMPLOYEE [of the Laboratories Administration] of the Department of Health and Mental Hygiene WHO SHALL:

(I) HAND CARRY ALL TESTING MATERIALS TO THE TESTING SITE;

AND

(II) DIRECTLY SUPERVISE THE ON-SITE PROFICIENCY TESTING.