§ 576-a. Clinical laboratories and cytotechnologists examining Pap smears. 1. Definitions. As used in this section, unless the context clearly requires otherwise, the following terms shall have the following meanings:

(a) "Cytotechnologist". A clinical laboratory professional specializing in the analysis of cytopathology samples, including Pap smears, for cervical cancer and related diseases who meets the qualifications specified by the department.

(b) "Cytotechnologist work standard". (i) A limitation on the number of Pap smears (also known as gynecologic slides) and non-gynecologic slides a cytotechnologist may examine during a particular time period, or other limitation on the quantity, speed or manner of examination of slides by a cytotechnologist, under regulations of the department.

(ii) The department may establish regulations for cytotechnologist workload standards that shall be at least as stringent as federal regulations.

(c) "Employ". To employ or contract with a cytotechnologist to examine gynecologic slides.

(d) "Clinical laboratory". A clinical laboratory issued a permit pursuant to this title.

(e) "Work day". A twenty-four hour period during which a cytotechnologist examines gynecologic slides for a clinical laboratory.

2. Compliance with cytotechnologist work standard. No cytotechnologist shall exceed the applicable cytotechnologist work standard. No clinical laboratory shall require, authorize, encourage or permit any cytotechnologist to exceed the applicable cytotechnologist work standard. In determining whether a cytotechnologist exceeds the applicable cytotechnologist work standard, all work done by the cytotechnologist during a given work day shall be considered, without regard to which clinical laboratory or other person for which or whom it was performed.

3. Record-keeping. (a) Each clinical laboratory shall maintain records, in a form prescribed by the department, which set forth, for each cytotechnologist employed by the clinical laboratory:

(i) the name of the cytotechnologist;

(ii) the number of hours worked by the cytotechnologist in each work day;

(iii) the number of gynecologic slides and non-gynecologic slides examined by the cytotechnologist during each work day; and

(iv) such other information as the department may require by regulation.

(b) Such records of clinical laboratories and cytotechnologists shall be made available for inspection and copying by the department upon request.

4. Multiple employers. Whenever a cytotechnologist is employed by more than one clinical laboratory or other person during a work day, the cytotechnologist shall advise each clinical laboratory of any previous employment during the work day and the amount of work performed, to insure that the applicable cytotechnologist work standard is not exceeded.

5. Standards for gynecologic slides. (a) A gynecologic slide of a Pap smear shall not be tested or reported on if:

(i) the apparent condition of the specimen indicates that it is unsatisfactory for testing or that it is inappropriate for the test requested;

(ii) it has been collected, labeled, preserved or otherwise handled in such a manner that it has become unsatisfactory or unreliable as a test specimen;

(iii) the slide is broken;

(iv) it contains insufficient cells or the cells are obscured by inflammation, blood or lubricating ointment, so that an adequate diagnosis cannot be made; or

(v) the slide is otherwise unsatisfactory, as defined by department regulations.

(b) If the slide is unsatisfactory as set forth in this subdivision, the clinical laboratory shall have an affirmative duty to advise the collecting physician or other practitioner that the slide is unsatisfactory and request the submission of a new slide.

6. Re-examination of slides. The department shall prescribe, by

regulation, a system of targeted re-examination of gynecologic slides examined and found to be not abnormal or questionable. The factors to be considered in the targeted re-examination may include, but are not limited to, the prior cancer and other history of the patient, the results of previous slide examinations, and the experience and ability of the cytotechnologist. Each clinical laboratory shall follow the prescribed re-examination system.

7. Notwithstanding any provisions of subdivision one of this section to the contrary, the department may, pursuant to regulation, increase the maximum number of slides which may be examined in a work day for clinical laboratories using slide examination or preparation technology approved by the federal food and drug administration, provided that such standards shall be at least as stringent as federal standards promulgated under the federal clinical laboratory improvement amendments of nineteen hundred eighty-eight or other applicable federal law.

8. Violations. (a) Sections twelve, twelve-a, and twelve-b of this chapter shall apply to violations of this section, except that the civil penalty for a violation of this section by a cytotechnologist shall not exceed five hundred dollars.

(b) If any clinical laboratory or other person violating this section is licensed, certified or registered by the department under other provisions of law, the violation of this section may be grounds for disciplining the person under such law.