**Section 450.1155 Cytology**

Cytology services at all clinical laboratories shall comply with the following requirements:

a) Personnel

1) Director of the clinical laboratory shall meet the requirements set forth in Section 450.210 of this Part.

2) Supervisor of clinical laboratory personnel shall meet the requirements set forth in Section 450.410 of this Part.

3) Cytotechnologist shall meet the requirements set forth in Section 450.430 of this Part.

b) Specimens

1) The laboratory order form shall include last menstrual period, age of patient, previous pap smear history and previous history of carcinoma, including if the patient is at high risk for developing cervical cancer or its precursors in the judgment of the physician.

2) If the laboratory order form does not include the information required in subsection (b), the laboratory must request this information prior to the issuance of the report. If the information is not received within 5 working days the report may be issued and the laboratory record noted that the history was not received. In no event should a positive specimen report be delayed. The laboratory shall have in place a program for improvement of client compliance with this requirement.

c) Preparation

1) The quality of stains shall be evaluated daily by the director and suboptimal stains corrected immediately.

2) All solutions shall be filtered and/or replaced at least once each day of use.

3) Gynecologic and non-gynecologic specimens shall be stained separately.

4) All staining and subsequent preparation of cytopathologic specimens shall be done at the laboratory or adjacent site locations under the same ownership and management and quality assurance procedures, where the slides are examined.

5) All automated equipment used in the preparation of specimens shall be used in accordance with manufacturer's recommendations.

6) Each cytologic slide shall be clearly labeled with the name of the patient prior to receipt in the laboratory. In the laboratory, it shall be labeled with a permanent label which may utilize a unique identification system notation. The label shall withstand long term storage.

d) Examination

1) An individual who examines cytologic slides for neoplasms on a full-time or part-time basis, shall not screen more than 100 slides or the number of slides set by the United States Government for a calendar day and no more than 400 slides in one five day work week for a daily average of 80 slides per calendar day.

2) All gynecologic smears interpreted to be suspicious or positive and all non-gynecologic specimens shall be reported by the director. The report shall be signed by a pathologist.

3) All gynecologic smears which are interpreted to be negative and are from patients who are identified as high risk for developing cervical cancer based upon the information provided by the physician who submitted the specimen, shall be rescreened by a second cytotechnologist or a pathologist before reporting patient results.

4) For each abnormal cytology result, the laboratory director shall make available for review all prior cytology specimens, if on file in the laboratory.

e) Reports

1) Diagnostic nomenclature shall be clearly defined in the procedure manual and made available to the physician who requested the cytology examination.

2) The laboratory report shall: distinguish between a non-diagnostic smear and a negative result; contain narrative descriptions for any abnormal or malignant/pre-malignant results; include the presence of endometrial cells if endometrial cells are present out of cycle; indicate evidence of any infection; and contain provisions for any recommendations.

3) Each screener shall maintain a work log which documents and identifies the number of gynecologic and non-gynecologic slides screened. When a screener works at one or multiple laboratories, that individual shall leave a signed copy of the work log at each laboratory each week that screener works at the laboratory.

f) Storage

Slides showing malignancy or pre-malignancy conditions and, all abnormal slides and reports shall be stored for ten years from the date of examination. All other slides and reports shall be retained for five years before discarding.

g) Quality Control

1) Rescreening

A) For each cytotechnologist supervisor, the director shall, on a regular basis, rescreen at least ten percent of the gynecologic smears interpreted by each supervisor to be negative. This ten percent of slides rescreened may include up to 50% of this total which may be slides double screened because of high-risk status pursuant to subsection (d)(3) of this Section. In no laboratory shall more than 50% of the rescreened (subsection (d)(3)) slides be utilized to fulfill the ten percent rescreen requirement). The director shall assure that for each cytotechnologist, at least ten percent of the gynecologic smears interpreted to be negative are rescreened by the director or cytotechnologist supervisor on a regular basis. Records of rescreened slides shall be maintained in a manner which allows periodic performance review of each cytotechnologist supervisor and cytotechnologist.

B) The director shall establish a program to compare cytology reports with tissue biopsies and determine the causes of any discrepancies.

2) Evaluation

A) The director shall evaluate each cytotechnologist's slide examination performance to include smears interpreted to be suspicious or positive and rescreened negative cases.

B) At least annually, the laboratory director shall evaluate each cytotechnologist's individual case reviews against the laboratory's overall statistical rates, document any discrepancies, include reasons for deviations, and document any corrective action taken.

3) Statistical Evaluations

Annually, the laboratory shall establish a statistical evaluation of the number of cytology cases examined, number of specimens processed by specimen type, number of patients reported by diagnosis, false-negative (as determined by the rescreening program or biopsy proven) and false-positive rates (biopsy proven), number of unsatisfactory specimens submitted by each physician or laboratory and the number of complaints received from individuals ordering or receiving test reports. All laboratories shall utilize this information to provide assistance and training to physicians on proper preparation and submission of cytology slides upon request of a physician.

(Source: Added at 13 Ill. Reg. 11573, effective July 1, 1989)