



# **CANADIAN SOCIETY OF CYTOLOGY**

## **GUIDELINES FOR PRACTICE**

### **AND QUALITY ASSURANCE**

#### **IN CYTOPATHOLOGY**

This is the third revision of the document entitled "Guidelines for the Establishment of Quality Assurance Programs in Cytology" which was prepared by the Quality Control Committee of the Canadian Society of Cytology and introduced in June 1978. First revision: February 1989; second revision: September 1996; third revision: January, 2005. The CSC would like to thank the following individuals who provided comment on this version of the document: M. Auger, S. Boerner, T. Colgan, M. Duggan, L. Geldenhuys, L. MacDonald, R. MacIntosh, R. O'Connor, M. Weir, H. Yazdi,

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## INTRODUCTION

This is the third revision of cytology quality assurance guidelines presented by the Canadian Society of Cytology. The expectations for continuous quality improvement and monitoring for all of laboratory medicine have significantly increased since the previous version. However, the practice of cytopathology has long embraced the concepts of quality management especially as it applies to gynecologic cervical cytology screening. Although this document covers general quality assurance recommendations for cytology, it is mainly focused on quality monitoring of gynecologic cytology. The CSC has been actively reviewing and endorsing recent guidelines for non-gynecologic cytology including breast and thyroid. Up to date practice guidelines on these and other sites can be found at the CSC website<sup>1</sup>. This document refers to quality practices specific to cytology and does not cover general laboratory safety and quality practices. It is assumed that a cytology laboratory must adhere to all standards expected of a medical laboratory as well as those specifically relating to the practice of cytology. The CSC QA guidelines are meant to serve as a basis for quality programs in the Canadian cytology laboratory; however, it is recognized that more specific guidelines and standards may exist in regional jurisdictions and take precedence over these Pan-Canadian recommendations.

- C.M. McLachlin, MD, Chair, Canadian Society of Cytology, January 2005

### 1.0 DEFINITIONS

#### 1.1 Cytopathology

Cytopathology is the practice of medicine specializing in diagnosis through the evaluation of the cellular manifestations of disease and consulting in the decision-making related to the patient's subsequent management.

#### 1.2 Cytopathology divisions

Cytopathology is subdivided into "Gynecological" (GYN) and "Non-Gynecological" (Non-GYN) sections. The former usually relates to the evaluation of cervico-vaginal cytology while the latter includes all other types of cytological specimens, even those from other regions of the female genital organs.

#### 1.3 Guidelines

Guidelines are a recommended strategy or range of strategies of laboratory practice. Variation due to patient-or laboratory-specific factors is a reasonable expectation.

#### 1.4 Standards

Standards are accepted principles of laboratory practice in which variation is not expected.

### 1.5 Quality assurance

Quality assurance is a practice aimed at achieving the highest degree of diagnostic performance by an individual laboratory. This is accomplished by the implementation of a specific and detailed quality assurance program which assesses the laboratory's performance by measuring a set of performance indicators, determines if the performance conforms to accepted standards and seeks to improve the performance when the accepted standards are not met.

1.5.1 Quality assurance practices should be documented on a continuing basis. A periodic report should be generated at least annually and its content discussed with the laboratory personnel. Further distribution is at the discretion of the individual laboratory, but should comply with local, provincial, and federal regulations.

1.5.2 The specific details of a quality assurance program are the responsibility of the laboratory director, but should include guidelines and standards related to:

1. Personnel
2. Physical facility
3. Equipment
4. Specimen collection, requisition and accessioning
5. Preparation and staining techniques
6. Pathologist responsibilities
7. Cytotechnologist responsibilities
8. Screening practices
9. Diagnostic practices
10. Reporting
11. Records
12. Gynecologic cytology utilization registry
13. Quality Assurance
14. Performance Evaluation
15. Proficiency testing
16. Continuing education

### 1.6 Compliance with relevant legislation

The laboratory should comply with all relevant federal, provincial and local legislation.

### 1.7 Ethics

The laboratory director and associate pathologists should comply with the rules and regulations of the provincial medical colleges and adopt the guidelines advocated by the Canadian Medical Association in regard to interactions with industry<sup>2</sup>.

## 2.0 **LABORATORY PERSONNEL**

### 2.1 Director of Cytopathology

The cytopathology laboratory should be under the direction of a legally qualified physician with specialist qualifications in pathology and cytopathology training equivalent to the training objectives of the Royal College of Physicians and Surgeons of Canada. It is recommended that the Director have extra training and/or sufficient experience in cytopathology to oversee the quality of the laboratory. The Director should be available to the laboratory at all times of operation; a deputy pathologist should be appointed in the absence of the director.

### 2.2 Associate pathologists

Associate pathologists must be legally qualified physicians with specialist qualifications in pathology, and cytopathology training equivalent to the training objectives of the Royal College of Physicians and Surgeons of Canada.

### 2.3 Cytotechnologists

Cytotechnologists must meet the requirements for and maintain certification with the Canadian Society of Medical Laboratory Sciences in Diagnostic Cytology<sup>3</sup>, as well as necessary certification by local/provincial authorities.

### 2.4 Support personnel

Personnel whose qualifications are appropriate to the laboratory director/hospital personnel bylaws can perform clerical and laboratory assistant functions.

### 2.5 Personnel file

Up-to-date records including qualifications and experience should be maintained on all personnel.

## **3.0 PHYSICAL FACILITIES**

3.1 The cytopathology laboratory should comply with all safety, quality and professional requirements that pertain to medical laboratories within their jurisdiction.

### 3.2 Laboratory space

3.2.1 Working conditions in the laboratory should be conducive to high quality performance. The microscopy area should be quiet, orderly and of adequate size for the number of individuals employed. Ergonomic assessment of furnishings is strongly recommended.

3.2.2 The work areas should be functionally arranged so as to minimize problems in handling specimens, screening, and reporting.

3.2.3 There must be physical separation of the microscope screening / reporting area from the specimen handling / preparatory portion of the laboratory.

3.2.4 The laboratory should meet all appropriate regulations for safety including WHMIS and local fire, safety and health precautions.

### 3.3 Equipment

3.3.1 It is strongly recommended that all laboratories be computerized to facilitate accessioning, reporting, archiving records, and quality assurance practices. A computerized laboratory should have a sufficient number of computer stations for its needs. All personnel should be appropriately trained in their use and updated as required.

3.3.2 There should be an adequate number of binocular microscopes of high optical and mechanical quality to meet screening and reporting needs. Ergonomically designed microscopes are recommended.

3.3.3 A multi-headed microscope to facilitate quality control and continuing education is strongly recommended.

3.3.4 All equipment used in the laboratory should be of high quality and satisfy Canadian manufacturing standards. There should be an active program of preventive maintenance with documentation for microscopes and all other items of equipment.

## **4.0 REQUISITION FORMS, SPECIMEN COLLECTION, AND ACCESSIONING**

### 4.1 Requisition Form:

The information required includes the following:

1. Patient names as required for proper identification
2. Provincial health number, address and/or hospital identification number
3. Date of birth (including day, month and year)
4. Name of referring health care provider
5. Anatomic site and laterality of the specimen
6. Appropriate medical history
7. Date of specimen collection

### 4.2 Specimen labeling

The specimen container should be clearly labeled with the patient name, identifying number and/or date of birth as well as the anatomic site and laterality of the specimen. Slides should be labeled with at least the patient name.

#### 4.3 Specimen collection

Proper specimen collection is an important initial step to assure optimal cytological assessment. All technologists and pathologists should be aware the recommended collection techniques and these techniques should be documented in the laboratory manual. Copies of these techniques should be provided to the Health Care Providers.

#### 4.4 Specimen accessioning

4.4.1 Specimens should be accessioned by the laboratory only if ordered by an appropriate health care provider.

4.4.2 There should be a clear specimen rejection policy that is developed according to the needs of each specific laboratory. That policy should be communicated to all users of the laboratory.

4.4.3 Each specimen received should be accessioned with a unique number cross referenced with the patient's name, together with all of the information from the requisition. The specimens should be easily retrievable according to any of the above data; a daily logbook may be required if the laboratory is not equipped with a computerized accessioning and reporting system.

4.4.4 The time and date of specimen receipt should be recorded.

4.4.5 The specimen accession number should be recorded on each slide by permanent marking or label.

### **5.0 PREPARATION AND STAINING TECHNIQUES**

5.1 The laboratory should carry out sufficient preparation and staining of cytologic specimens in order to maintain a high level of technical competence and quality.

5.2 Each area of the laboratory in which specimen preparation and staining are performed must have available a laboratory manual detailing the specific methodology required for the technique performed in that area. The manuals should be updated on a regular basis, dated and signed by the director of the laboratory and circulated among the cytotechnologists and pathologists working in the laboratory.

5.3 The Papanicolaou staining technique or an acceptable alternative should be used.

5.4 Staining quality should be checked and documented daily with appropriate correction of suboptimal results. Stains should be filtered or replaced regularly to maintain potency and freedom from contamination.

5.5 All cytotechnologists should be aware of the problem of cell transfer contamination and take adequate precautions to avoid this hazard.

## **6.0 PATHOLOGIST'S RESPONSIBILITIES**

### **6.1 Director of Cytopathology**

6.1.1 The director or a deputy pathologist is responsible for all quality assurance activities, the safety and the overall performance of the laboratory.

6.1.2 Either the director or a deputy pathologist should be available to the laboratory at all times of operation to ensure appropriate laboratory performance.

6.1.3 The director should encourage all laboratory personnel to achieve the highest quality of laboratory practice.

6.1.4 The director is responsible for ensuring that the quality assurance program is followed and periodic quality assurance reports are generated, at least annually.

6.1.5 The director should ensure that the laboratory manuals are updated, at least annually.

6.1.6 The director should meet at least quarterly or more frequently if necessary with all laboratory personnel to discuss issues relating to the laboratory performance. An agenda should be generated, the proceedings minuted, and circulated.

6.1.7 The director is responsible for facilitating laboratory-based continuing education and identifying areas of deficiency amongst the personnel in terms of knowledge, attitude, and skill.

6.1.8 The director is responsible for facilitating remedial training.

### **6.2 Associate Pathologists**

6.2.1 Each pathologist should have malpractice insurance commensurate with his or her practice needs.

6.2.2 Each pathologist should be readily available for consultations with cytotechnologists, laboratory and clinical colleagues, and other allied health care providers.

6.2.3 Each pathologist is expected to participate in continuing education activities relating to cytopathology and to keep up to date with the current literature.

## **7.0 CYTOTECHNOLOGIST'S RESPONSIBILITIES**

### **7.1 Supervisory Cytotechnologist (or equivalent)**

7.1.1 The supervisory cytotechnologist should have demonstrated experience in cytopathology and management skills and is responsible for the daily supervision of the laboratory.

7.1.2 The supervisory cytotechnologist is responsible, along with the director, for maintaining and updating the laboratory manuals.

7.1.3 The supervisory cytotechnologist should ensure the quality of the preparation of the specimens by supervising the responsible technologists.

7.1.4 The supervisory cytotechnologist should train all technologists in new cytopreparation techniques as needed.

7.1.5 The supervisory cytotechnologist should ensure that all appropriate supplies have been ordered both for the laboratory and the health care provider-clients.

7.1.6 The supervisory cytotechnologist should ensure that all maintenance contracts on equipment are being carried out at appropriate intervals.

7.1.7 The supervisory cytotechnologist should represent the interests of the cytotechnologists at all laboratory meetings.

### **7.2 All cytotechnologists**

7.2.1 Each cytotechnologist is expected to participate in continuing educational activities and to document them.

7.2.2 Cytotechnologists with established competence are responsible for rescreening specimens identified for quality control review.

## **8.0 SCREENING PRACTICES**

8.1 A cytotechnologist should initially screen all fine needle aspirates. A cytotechnologist must initially screen all other non-GYN and all GYN specimens. Approved commercial devices for automated screening may be used following protocols recommended by the manufacturer and regulatory bodies.

### **8.2 Cytotechnologists workload**

Neither economic considerations alone nor expediency must determine the number of cytology slides to be screened by a cytotechnologist in a working day or 24 hour period.

The number and type of cytology slides to be screened should not, through fatigue, affect adversely the cytotechnologist's ability to find, recognize, and interpret correctly abnormal cells that may be representative of a disease process.

Precise workload limitations may be difficult to define because of variations in types of cytology specimens being screened as well as variations in other responsibilities in the laboratory. The types and complexity of specimens should determine the total number of slides screened by a cytotechnologist in an average working day.

8.3 The number of slides screened by a cytotechnologist, exclusively screening full-time without other duties or distractions may vary but should not be higher than 60-80 in an average 8 hour working day.

8.4 A cytotechnologist with other duties in addition to screening should have a proportionately reduced workload. For example, a total of 4 hours spent on slide screening should require a prorated workload no greater than  $4/8 \times (60-80) = 30-40$  slides to be screened.

8.5 A cytotechnologist must not be expected to screen more than 90 slides in a 24 hour time period (on average about 10 slides per hour devoted exclusively to screening).

8.6 It may be feasible to screen a larger number of routine GYN slides than GYN slides in follow up of a previously detected abnormality.

8.7 The number of Non-GYN slides screened in a similar time period should be proportionately lower depending on the complexity of the specimen.

8.8 The director and supervisory cytotechnologist should determine when circumstances for adequate screening by a cytotechnologist require that lesser numbers of slides be screened in a daily time period.

8.9 Each slide preparation should be evaluated to determine whether or not the material is satisfactory for diagnostic purposes and consistent with the stated site of origin.

8.10 Cytologic abnormalities should be dotted or otherwise appropriately marked to be adequately representative of the screened material. Interpretative notations should be made on appropriate working documents, along with the identification of the screener(s).

## 8.11 Referral to the pathologist

8.11.1 Gynecological cytology screened as “Negative for Intraepithelial Lesion or Malignancy” (excluding reparative changes) may be finalized by a cytotechnologist. All other Gynecologic cytology must be referred to a pathologist for reporting<sup>4</sup>. Laboratories may choose to refer some or all negative cases for screening by a second cytotechnologist or to a pathologist for sign out depending on their practice.

8.11.2 All Non-GYN cytology should be referred to a pathologist for reporting.

## **9.0 DIAGNOSTIC PRACTICES**

9.1 The director and associate pathologists should work co-operatively to establish the pathologist’s workload per usual working day and 24 hour period. The same considerations and caveats regarding workloads for cytotechnologists should apply.

9.2 The pathologist should report a sufficient variety of GYN and Non-GYN material in a year to maintain diagnostic competence.

9.3 The pathologist should obtain pertinent clinical information, when appropriate.

9.4 The pathologist should report all cytology referred to them by the cytotechnologists.

9.5 When requested, the pathologist should review any case of concern presented to them by a cytotechnologist or another pathologist.

9.6 There should be timely and adequate feedback on case material by the pathologists to the cytotechnologists.

## **10.0 REPORTING**

10.1 If the report form is separate from the requisition form, it should include all the information as on the requisition form and the date of the report.

10.2 Reports on negative GYN cytology (not including repair) may be finalized by the screening cytotechnologist if that is the practice of the laboratory. All other cases must be finalized by a pathologist.

10.3 The report should document the names of the cytotechnologist(s) and the pathologist(s) involved in the cases, and the signature (which can be electronic) of the cytotechnologist or pathologist who finalized the report.

10.4 Each report should have a clearly stated diagnosis that represents the highest degree of abnormality present. Other abnormalities can be documented/described in the microscopic/comment section.

10.5

## Reporting terminology

10.5.1 It is recommended that the most current version of The Bethesda System (TBS) should be used as the primary diagnosis for gynecologic cytology<sup>4</sup>.

10.6 For non-gynecologic cytology, the report should provide clear communication using interpretive terminology and published classification systems. (see also<sup>1</sup>)

## 10.7 Specimen adequacy

10.7.1 If the specimen cellularity or preparation is unsatisfactory, interfering with the interpretation, this should be stated and recommendations provided for the submission of an adequate specimen.

10.7.2 Specimens considered to be non-representative of the stated tissue site should result in a report that indicates such concern.

## 10.8 Management recommendations

Each gynecological cytology report should include a management recommendation if that is the expected practice<sup>5,6,7</sup>. Ideally, management recommendations should be developed in association with stakeholders from Family Medicine, Obstetrics and Gynecology, and other involved groups. The presence/absence of a population based information system (cytology registry) and its impact on management recommendations should be taken into consideration.

10.9 The accession file should be monitored at frequent intervals to ensure that all accessioned cases have a finalized report.

## **11.0 RECORDS**

11.1 All slides, cell blocks and reports for the previous 2 years should be stored on site. Material from other years should be easily retrieved.

11.2 The laboratory should retain all slides, cell blocks and reports as currently recommended by this society<sup>1</sup> and as local regulations dictate. At a minimum, all negative gynecologic and non-gynecologic cytology slides and cell blocks should be retained for five years. All slides and cell blocks on abnormal gynecologic and non-gynecologic material should be retained for twenty years. Reports should be kept indefinitely.

## 12.0 GYNECOLOGICAL CYTOLOGY UTILIZATION REGISTRY

In provinces without an organized cervical screening information system (GYN cytology registry), it is recommended that each laboratory maintain a database of GYN cytology specimens to include patient demographics, referring physician, diagnosis, management recommendation, and date of test. The database should be searched at set intervals to determine if the management recommendations pertaining to at least HSIL, AIS and carcinoma were followed. If no record is found, a reminder letter should be sent to the physician or patient, depending on what the local legislation allows.

## 13.0 QUALITY ASSURANCE (QA)

Assuring the quality of slide preparation, screening and the interpretation of detected abnormalities is an integral part of cytology practice. QA guidelines and standards must be adapted to a range of laboratory situations with varied volumes, types of specimens and personnel. There should be continuing effort for development and improvement of quality assurance practices beyond what is outlined in this document.

13.1 A small proportion of slides from each batch prepared should be reviewed on a daily basis, for adequacy of preparation, including fixation and staining.

### 13.2 Gynecological cytology

#### 13.2.1 Rescreening of negative GYN cytology

Rescreening practices include 1) Prospective - Targeted, Random and Rapid and 2) Retrospective. All manual rescreening should be conducted by a cytotechnologist with established competence. The laboratory should document details of the rescreening practices used.

##### 13.2.1.1 Prospective Rescreening

A total of 10% of negative GYN cytology shall be rescreened prospectively. Slides shall be selected by a combination of random and targeted methods for a total of 10% of all cases.

13.2.1.1.1 Targeted rescreening is a strategy whereby a slide is rescreened if the patient belongs to a high-risk group. This may include the following:

##### Atypical Clinical History

1. Recent history of vaginal bleeding or spotting.
2. History of cervical/ vaginal/vulvar carcinoma.
3. Recent previous cytology reported as  $\geq$  atypical squamous or glandular cells.
4. Abnormal cervix on speculum examination.
5. History of DES exposure.

13.2.1.1.2 Random rescreening involves rescreening a randomly selected proportion of negative GYN cytology. This has been a widely practiced technique, but its value in the detection of false-negative screening has been questioned<sup>8,9,10,11,12</sup>.

13.2.1.1.3 Rapid screening involves reviewing all negative GYN cytology using a specified time period (<1 minute)<sup>13</sup>. The use of this method precludes the 10% rescreen.

#### 13.2.1.2 Retrospective rescreening

All negative GYN cytology from the previous 3 years in a woman with current cytology showing  $\geq$  HSIL or AIS should be rescreened by a cytotechnologist and then referred to a pathologist<sup>14</sup>.

#### 13.2.2 Follow-up program

Gynecological diagnoses should be correlated with follow up biopsy material. As a minimum, follow up on diagnoses of HSIL, AIS and carcinoma should be sought to determine the correlation rates. This information may be available from the laboratories' own files or another source, e.g., provincial Cytology Registry. In some cases cytological and histological tissue sampling may be at variance requiring further follow-up to resolve an apparent discrepancy<sup>15</sup>. The data should be used to streamline and standardize diagnostic criteria in the laboratory.

### 13.3 Non-gynecological cytology (see also <sup>1</sup>)

13.3.1 Follow up program Positive Non-GYN cytology should be correlated with the corresponding biopsy or autopsy material at regular intervals, recognizing that in some cases cytological and histological tissue sampling may be at variance requiring further follow-up to resolve what at first may appear to be a biopsy discrepancy.

## 14.0 PERFORMANCE EVALUATION

All measures used to evaluate performance should be uniformly applied and documented. If possible, laboratory and individual performance should be separately measured. A system of annual peer comparison of performance indicators and proficiency testing results should be established.

### 14.1 Performance indicators

Performance indicators listed below and productivity rates for each cytotechnologist and pathologist should be documented on at least an annual basis. Results should be discussed with members of the laboratory. If desired, the pertinent results may be communicated to the individual health care providers (e.g. specimen adequacy). Details of the methodologies should be documented. There are presently no national performance standards, however, it is suggested that individual laboratories should aim to equate their results with performance indicators from comparable laboratories and published data.

## 14.2 Gynecological cytology: performance indicators

14.2.1 The total number and rates of satisfactory with and without transformation zone and unsatisfactory GYN cytology should be measured for the laboratory and if possible, for each cytotechnologist, and health care provider-client.

14.2.2 The total number and rates of the major GYN diagnoses should be measured for the laboratory, and if possible, for individual cytotechnologists, and individual pathologists.

14.2.3 The false-negative rate of the laboratory and individual cytotechnologists should be separately measured <sup>12</sup>. A false-negative result is identified through prospective random rescreening and is defined as a screening error of an abnormality  $\geq$  LSIL. The laboratory may also choose to document screening misses including ASC or AGC.

14.2.4 The cyto-histological correlation rates for HSIL, ASC-H, AIS and Carcinoma on GYN cytology should be measured against the results of the follow-up surgical material, or clinical outcome (if more appropriate).

14.2.5 The turnaround time (from the date the specimen is received in the laboratory to the date the finalized report is issued) should be documented.

## 14.3 Non-Gynecological cytology: performance indicators (see also <sup>1</sup>)

14.3.1 The total number of Non-GYN cases categorized by anatomic site and type of specimen, should be documented.

14.3.2 The rates of major diagnostic categories (e.g. unsatisfactory, negative, atypical, suspicious, malignant) should be calculated for major groups of Non-GYN cytology (e.g. Breast, Thyroid, Respiratory, etc).

14.3.3 Correlation of the results of fine needle aspirates (especially those of commonly aspirated sites) with their corresponding surgical material is recommended. When possible, unsatisfactory, sensitivity, and specificity rates should be calculated. Of the remaining Non-GYN material, at least the malignant diagnoses should be correlated with the tissue results or clinical outcome (if more appropriate).

14.3.4 The turn-around time (from the date that the specimen is received in the laboratory to the date the finalized report is issued) should be documented.

## 14.4 External proficiency testing

A review of both normal and abnormal cytology exchanged between co-operating laboratories on a national, provincial or regional basis is a valuable contribution to the

field of performance assessment. Several established programs are available (Quality Management Program – Laboratory Services of Ontario, Checkpath Program of the American Society of Clinical Pathologists, PAP Program of the College of American Pathologists.) and if not already mandated by provincial regulations, each laboratory is strongly encouraged to participate in some form of external proficiency testing.

14.5 A mechanism for taking remedial and corrective action should be in place when the performance indicators and proficiency testing results are considered suboptimal.

## **15.0 CONTINUING EDUCATION PRACTICES**

15.1 Each laboratory should have a subscription or online access to one or more of the cytology journals, e.g. Cancer Cytopathology, Acta Cytologica and Diagnostic Cytopathology. There should be a good supply of appropriate, current cytology textbooks. Books and journals should be easily accessible.

15.2 Each cytotechnologist and pathologist is expected to independently pursue continuing education in the specialty. They should participate in scientific meetings, review courses, or specialty conferences, and should update his/her knowledge of cytology practice by reading the current literature.

15.3 Performance evaluations should be used to identify those with deficiencies in knowledge and skills who would benefit from a more directed educational program.

15.4 The laboratory director should facilitate continuing education by ensuring an appropriate educational environment.

15.5 There should be a regular schedule of lectures, or symposia, particularly in the larger laboratories. The staff should be relieved of their duties to take advantage of these educational opportunities.

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