QUALITY CONTROL IN CYTOLOGY

27.1 INTRODUCTION
Cytopathologists are concerned about and committed to quality assurance and quality control in their laboratories. These practices include, among others, the use of intralaboratory and extradepartmental consultations, case reviews, correlation of cytologic and histopathologic specimens and review of completed diagnostic reports.

OBJECTIVES
After reading this lesson, you will be able to:
- describe Quality control in cytology
- explain various methods of quality control in cytology.

27.2 QUALITY ASSURANCE MEASURES
Cytopathology is a practice of medicine and represents a medical consultation, in both gynecologic and nongynecologic anatomic sites. The basic principles of quality assurance apply to all types of cytologic specimens. The following represents several minimum quality assurance measures.

1. Laboratory Directors
The laboratory should be directed by a legally qualified physician with a specialist qualification in pathology, including special training and expertise in cytopathology. The director or designated medical professional is responsible for proper performance and reporting of all tests done in the cytopathology laboratory. The director or designated cytopathologist should
be physically present in the laboratory to direct the staff, be available for consultations, review all reactive and abnormal gynecologic cytology samples, review fine needle aspiration samples, and review all nongynecologic samples.

2. **Cytotechnologists**

   A suitably qualified person should be recruited for this position.

3. **Physical Laboratory Facilities**

   The laboratory should be clean, well lighted, adequately ventilated, and functionally arranged so as to minimize problems in specimen handling, evaluation, and reporting. The area for specimen preparation and handling should be separate from the area where specimens are evaluated and reported. Formaldehyde and xylene (if in use) should be carefully monitored due to the possible presence of hazardous vapor concentrations.

4. **Safety Precautions**

   Laboratory personnel must be protected against hazards (chemical, electric, fire, infections, or others) by using well-ventilated hoods and biologic safety hoods for handling potentially infectious material. Fire precautions should be posted and tested.

5. **Equipment**

   An adequate number of binocular microscopes of good quality and proper working order must be available. Laboratory instruments and equipment should be under periodic maintenance to monitor and ensure malfunctions do not adversely affect analytical results.

6. **Specimen Collection**

   Cytologic specimens should be accepted and examined only if requested by a licensed medical practitioner and collected in accordance with instructions regarding recommended collection techniques. The cytopathology laboratory should inform the originator of the sample if the specimens are “unsatisfactory” and detail adequacy qualifiers such as presence or absence of a transformation zone component or obscuring factors in “satisfactory samples”.

7. **Preparation, Fixation, and Staining Procedures**

   The specimens must be identified with the patient’s name and/or a unique identifier and must be accompanied by a requisition form with the requesting physician’s name, address, date of specimen collection, specimen source, and appropriate clinical information about the patient. When the specimen arrives in the laboratory the laboratory staff affix an accession number or bar code label on each slide for further identification. The
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laboratory should have written criteria for rejecting specimens. Fixation while the specimen is still wet is recommended for conventional cell samples. The Papanicolaou staining procedure is strongly suggested for most cytologic samples, unless additional staining procedures are warranted. Staining solutions and chemicals used in the cytopathology laboratory should be labeled with the time of preparation, purchase, or both. Staining solutions should be filtered regularly to avoid contamination and should be covered when not in use. Effective measures to prevent cross-contamination between gynecologic and nongynecologic specimens during the staining process must be used.

8. Slide Evaluation Workload

Regulations as to the number of specimens a cytotechnologist may evaluate in a 24-hour period are currently set at 100 slides per an 8-hour day. This regulation may not do justice to the various conditions that influence the quality of the slide evaluation performance. The percentage of atypical cases evaluated versus the percentage of negative cases in varying populations as well as screening of nongynecologic specimens should be considered when workloads are established. This regulation ensures that the number and type of cytologic samples evaluated do not, through fatigue, adversely affect the cytotechnologist’s performance.

9. Cytologic Terminology

The vaginal/ectocervical/endocervical cytology sample should be interpreted preferably by using the Bethesda System. The nongynecologic material should be interpreted in medical terms.

10. Laboratory Records, Logs, and Files

Each specimen should be recorded and a sequential accession number assigned together with the name of the patient and the originator of the sample. Test records must be retained for at least 5-10 years. The negative gynecologic cell samples should be retained on file for a minimum of 5 years and negative fine needle aspirates for 10 years or indefinitely if they exhibit abnormal features. The modern cytopathology laboratory should use a computerized file system.

INTEXT QUESTIONS 27.1

1. For conventional cell samples ................. is recommended while the specimen is wet.

2. ................. staining procedure is suggested for most cytologic samples.
3. cytotechnologist may evaluate in a 24-hour period ................. number of slides per an 8-hour day
4. The vaginal cytology sample should be interpreted using ................. System.
5. Test records must be retained for at least ................. years
6. Negative fine needle aspirates should be retained for ................. years

WHAT HAVE YOU LEARNT

- Quality control practices include, the use of intralaboratory and extradepartmental consultations, case reviews, correlation of cytologic and histopathologic specimens and review of completed diagnostic reports.
- The laboratory should be directed by a legally qualified physician with a specialist qualification in pathology, including special training and expertise in cytopathology
- A suitably qualified person should be recruited as cytotechnologists
- The laboratory should be clean, well lighted, adequately ventilated, and functionally arranged so as to minimize problems in specimen handling, evaluation, and reporting
- Laboratory personnel must be protected against hazards
- An adequate number of binocular microscopes of good quality and proper working order must be available
- Cytologic specimens should be accepted and examined only if requested by a licensed medical practitioner and collected in accordance with instructions regarding recommended collection techniques
- The specimen as it arrives in the laboratory should be given an accession number or bar code label on each slide for further identification.
- The laboratory should have written criteria for rejecting specimens.
- Fixation while the specimen is still wet is recommended for conventional cell samples.
- The Papanicolaou staining procedure is strongly suggested for most cytologic samples, unless additional staining procedures are warranted.
- Staining solutions and chemicals used in the cytopathology laboratory should be labeled with the time of preparation, purchase, or both
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- Regulations as to the number of specimens a cytotechnologist may evaluate in a 24-hour period are currently set at 100 slides per an 8-hour day.
- The vaginal/ectocervical/endocervical cytology sample should be interpreted preferably by using the Bethesda System.
- The nongynecologic material should be interpreted in medical terms.
- Test records must be retained for at least 5-10 years.
- The negative gynecologic cell samples should be retained on file for a minimum of 5 years and negative fine needle aspirates for 10 years.

TERMINAL QUESTIONS

1. Write briefly about objective of quality assurance in cytopathology.
2. Enumerate the various measures of quality assurance.
3. How long do you need to maintain the records of cytopathology specimens?

ANSWERS TO INTEXT QUESTIONS

27.1
1. Fixation
2. Papanicolaou
3. 100
4. Bethesda
5. 5-10
6. 10