GOALS AND OBJECTIVES
QUALITY ASSURANCE AND QUALITY CONTROL

This document frames one method to provide education about QA/QC, with respect to medicine in general, and pathology in particular. This document first frames the overall objectives and pre-existing educational lectures and materials, then details specific elective QA/QC rotations.

A. OVERALL QA/QC CURRICULUM

MEDICAL EXPERT:

The resident is expected to demonstrate their understanding of the importance of quality and patient safety in the context of anatomical pathology. Specifically, they are expected to demonstrate understanding and competence in the areas listed below.

1. Technical aspects of quality assurance and quality control, and should be able to:
   - describe qualities of a good H&E stain
   - define the following terms: positive control; negative control; optimization; verification; validation; predictive marker; prognostic marker; class I and class II markers; pre-analytic; analytic; post-analytic.
   - understand the preanalytic factors which may affect the reliability of immunohistochemical studies.
   - define the utility of external quality assessment programs such as QMPLS

2. Professional aspects of quality assurance and quality control, including:
   - the fundamental institutional requirements needed for quality and patient safety in the laboratory
   - how to handle a suspected specimen mix-up
   - how to resolve and analyze diagnostic discrepancies
   - define a critical result (critical diagnosis), and describe how it is documented and how it is handled
   - demonstrate the ability to perform a root cause analysis

3. Legislation and regulations, including:
   - basic familiarity with QCIPA and apology legislation
- describe the regulatory framework in which Ontario laboratories exist.

PROFESSIONAL:

The resident is expected to:
- deliver highest quality care with integrity, honesty, and compassion.
- practice medicine in a manner ethically and legally consistent with obligations of a physician.
- be punctual and courteous.
- communicate with staff for organization of work.
- recognize his/her own limits, and seek out and act on constructive criticism.

COMMUNICATOR:

The resident is expected to:
- understand the elements of an accurate and complete pathology report.
- define addendum reports and amended (corrected) report, and define the situations in which each report type is appropriate.
- communicate appropriately with technical, clerical and professional staff.
- be familiar with the disclosure and apology legislation in the province of Ontario.

SCHOLAR:

The resident is expected to:
- be familiar with selected literature and working guidelines recommended in this document.
- be able to conduct a literature search.
- critically evaluate a journal article.
- use evidence-based medicine and best practices guidelines.
- identify problems, formulate and carry out a plan of action, and reassess the results in the context of quality improvement.

COLLABORATOR:

The resident is expected to:
- understand and participate in the pathology team.
- collaborate with peers, technical staff, and professional staff.

MANAGER:

The resident is expected to:
- understand basic management principles, including management styles and leadership models.
- understand how to utilize resources effectively, and learn the costs of various tests in the context of the TOH hospital budget (immunohistochemistry, special stains, FISH, molecular tests, consultations, etc.).
- understand the hospital and laboratory organizational structure.
- understand the basics of malpractice.

HEALTH ADVOCATE:

The resident is expected to:
- understand the concept of a just culture and appropriate accountability.
- describe the “swiss cheese” model as described by James Reason.
- understand the concept of cognitive biases and how they influence the diagnostic process.
- advocate for best practices as supported by the literature in anatomical pathology.

B. PRE-EXISTING EDUCATIONAL MATERIAL RELATED TO QA/QC

1. CanMEDs lectures on manager, communicator, and health advocate roles.

   Manager: organization of hospitals, laboratories, and role of accreditation and regulatory bodies, characteristics of functional teams, leadership styles.

   Communicator: importance of clarity and timeliness of communication; critical diagnoses.

   Health advocate: cultural factors, including the concept of a just culture, appropriate accountability, cognitive biases, etc.

2. Immunohistochemistry and histology

   a. Lectures given by Dr. S. Robertson, B. Parks and J. Levac on the principles and practice of immunohistochemistry, including (to be given January 2016):
      - positive and negative controls.
      - validation and optimization.
      - factors affecting antigenicity, with particular emphasis on fixation volume and time.

   b. Practical sessions given by J. Levac on the techniques of frozen section.

3. Lecture given by Dr. I. Teo on diagnostic level QA/QC, including the Standards2Quality document and methods for classifying diagnostic discrepancies (to be given February 2016)
4. Cytology
   
   a. Pre-existing week within the cytology training schedule that concerns quality control as related to cytology.

C. SPECIFIC QA/QC ROTATIONS

1. Introduction to practical aspects of quality assurance in pathology (1 block, mandatory)

   Supervisors: Dr. I. Teo (or delegate), M. Harnarine (TOH charge histology, or delegate), J. Levac (TOH charge immunohistochemistry, or delegate), L. Hart (EORLA integrated quality manager, or delegate).

The objective of this block is to obtain practical exposure to the routine QA/QC practices in anatomical pathology, and to apply previously learned theory in real-life situations. Scheduling of the individual units may vary within the block, depending upon the supervisor's availability and other time constraints.

A. Diagnostic QA/QC in anatomical pathology (Dr. I. Teo, or delegate)

   The resident will participate for one week in the routine diagnostic-level QA/QC evaluation, including documentation of 2nd review cases, evaluation of cases with external reviews, evaluation of molecular reports, evaluation of amended reports, and evaluation of frozen/permanent section diagnoses. During this time, the resident will have ample time to consider questions regarding professional ethics, professional behaviours, and become familiar with how to evaluate diagnostic discrepancies.

B. Immunohistochemistry

   The resident may spend one week with Joelle Levac (charge technologist, immunohistochemistry, or delegate), and learn the practical details about:
   - optimization of a new reagent/lot
   - validation of a new antibody/lot
   - basic troubleshooting of immunohistochemical stains.
   Case studies may also be used for illustrative purposes.

C. Histology

   The resident may spend one week with M. Harnarine (charge technologist, histology, or delegate), and will learn practical details about:
   - basic troubleshooting of histology problems, including investigations of 'floaters' and carryovers.
   - the QA/QC measures and characteristics of a good H&E stains.
- tissue processing
Case studies may also be used for illustrative purposes.

D. Regulation and administration
The resident may spend one week with L. Hart (EORLA integrated quality manager), and will learn practical details about:
- audit and analyze data to identify potential problem areas, designing a solution and 'closing the quality loop'.
- introduction to OLA requirements.
- external quality assessment, and their responsibilities, and accountabilities.

**ASSESSMENT:**
The resident will be evaluated all CanMEDs roles by the supervisors.
There will be a test comprising of short answer questions, the majority of which will derived from the required reading materials.
A short (10-15 minute) presentation on one of the topics set out in the 'laboratory management national curriculum' for AP and GP residents will also be a method for evaluation.
Attendance of senior resident at divisional CQI meeting.

**REQUIRED READING:**
- Laboratory Administration for Pathologists, by EA Wagar, RE Horowitz, and GP Seigal. CAP Press. 2011. (to be available in the residents' room)
- Standards2Quality guidelines, version 2 (September 2013).
- CAP IQIC article on immunohistochemistry recommendations
These latter two resources are available in Dr. Teo's folder on the V drive under 'QA QC resources for residents'.

2. QA/QC additional training and project (1 block, elective/non-mandatory).

Supervisor: Dr. I. Teo (or delegate)
The objective of this additional training is to provide the resident with the resources and an introduction to the skills necessary to initiate and advance continuing quality initiatives.

The objective of this project is to apply new and previously learned theory in a QA/QC project. The resident will be expected to design the project, extract and analyse the data, draw conclusions, and design a robust, workable quality improvement intervention strategy.

This project should ultimately culminate in either a one-hour presentation during academic half-day, at the divisional CQI meeting, or as a presentation at a provincial,
local, national, or international meeting. It will be conducted with the support of from the supervisor listed above.

The resident should learn:
- how to design and manage a project focused upon quality improvement
- learn and apply principles of change management and leadership
- understand hospital systems and other available resources.

ASSESSMENT:
The resident will be evaluated on all CanMEDs roles.
Basic certification of completion of IHI open school online courses. 
(http://app.ihi.org/lms/home.aspx)

RECOMMENDED RESOURCES:

REQUIRED READING:
- Laboratory Administration for Pathologists, by EA Wagar, RE Horowitz, and GP Seigal. CAP Press. 2011.
- Standards2Quality guidelines, version 2 (September 2013).
- CAP IQIC article on immunohistochemistry recommendations

Additional textbooks:
- WHO laboratory management handbook

Additional web-based resources:
CMPA
OLA
QMPLS
CAP-ACP
College of American Pathologists

Additional relevant news stories and reports:
the Windsor report
the Goudge inquiry
the Newfoundland inquiry
the Creaghan report (Miramichi, New Brunswick)

Laboratory Management Elective Goals and Objectives. (University of Michigan)
Laboratory Management National Curriculum Anatomical and General Pathology Residency Training.

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