

**Standards2Quality\***

**Guidelines for  
Quality Management  
in Surgical Pathology  
Professional Practices**

**A Proposal for  
Laboratory Physicians in Ontario**

**\*A project of Path2Quality (a collaboration of the OMA Section on  
Laboratory Medicine and the Ontario Association of Pathologists)  
supported by CancerCare Ontario**

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## BACKGROUND and PREAMBLE

Ontario's laboratory physicians share a common goal – the desire for an effective and efficient laboratory system that serves the best interests of the Province's citizens. Laboratory physicians advocate for a laboratory system that will provide high quality and timely laboratory testing. Central in this is a focus on providing excellent patient care, with every effort to ensure patient safety.

Path2Quality is the collaborative initiative of the Ontario Medical Association (OMA) Section on Laboratory Medicine and the Ontario Association of Pathologists (OAP). This initiative focuses on improving quality management systems that help guide the professional work of laboratory physicians.

On November 27, 2009, Path2Quality, in conjunction with the Health Policy Department of the OMA, hosted a symposium of the many organizations involved or interested in quality assurance as it applies to the professional work of Ontario's laboratory physicians. The purpose of the symposium was three-fold:

- To help clarify for front-line practitioners their responsibilities for quality assurance to these organizations;
- To provide an opportunity for the profession, *via* Path2Quality, to present to those organizations front-line practitioners' issues, concerns and needs related to quality assurance; and,
- To refine the role of Path2Quality in this arena moving forward.

### **Standards2Quality**

- *Collaboration of OMA Section on Laboratory Medicine and Ontario Association of Pathologists – representing the 'front-line'*
- *Builds on stakeholder symposium held November, 2009*
- *Provides the best advice about quality management programs for their professional work from the laboratory physicians of Ontario*

At the Symposium, participants identified the need for a comprehensive framework for quality management that encompasses all of its various domains, embraces all of the stakeholders, and helps promote synergy among their collective efforts thereby minimizing the development of ad hoc quality management approaches to guidelines development, accreditation, etc.

It was suggested that Path2Quality assume the challenge of developing this framework, which would include the following key elements and attributes:

- Acknowledges all of the key stakeholders, building upon the momentum created by the symposium;
- Is guided by an overarching vision, principles,

- goals and objectives;
- Embraces all the sub-specialties of laboratory medicine;
  - Goes beyond external quality assurance (EQA) and internal quality assurance (IQA) to encompass all the domains of quality assurance;
  - Includes a broader definition of “professional work” to reflect all the professional competencies of laboratory physicians, e.g., health advocate, communicator, health manager, educator, in addition to those competencies listed by the Royal College;
  - Is sufficiently robust to create the value proposition that secures interest / buy-in at the institutional level;
  - Strives for a clear definition of standards (be they licensure requirements, laboratory accreditation, peer assessment, or best practices); and,
  - In the case of best practice guidelines, would address key practice environment issues such as appropriate resourcing, workload, etc.

As one of the first steps in pursuing this initiative, Path2Quality sought and received funding from CancerCare Ontario to develop a comprehensive set of guidelines for internal quality assurance, focused on the medical/ professional interpretative processes involved in cancer diagnosis.

The draft guidelines provided in this consultation document strive to clarify for laboratory physicians (whether working as individuals or in groups) the basic policies and procedures that should be in place in a quality management program to govern the medical processes of surgical pathologic interpretation, including cancer diagnosis.

It is acknowledged that many professional groups will already have in place policies and procedures that satisfy the recommendations in this document. While the terminology any individual group uses may not be perfectly coincident with that used in this document, there should be no implication that any professional group’s policies and procedures (and related quality management program and oversight governance structure) need to be modified, if the key elements promoted in this document are accomplished in some other manner or by some other means.

### ***Resource Implications***

*For any progress to be made with the recommended quality program described, appropriate resources will have to be provided (both professional and support). Current resources are not sufficient to accomplish the program development, and subsequent implementation, which will be required.*

In contrast, it may be that other professional groups may not have in place policies and procedures that satisfy the suggestions provided in this document. The implementation of the recommendations in such cases may require significant resourcing. This document makes no attempt to suggest how to deal with this issue, nor how to deal with the considerable resources required to maintain high-functioning surgical pathology

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professional quality management programs already in place. This issue is referred for resolution to the Ministry of Health and Long Term Care, the stewards of health care system resource allocation.

### ***Work for the Future***

- *Dealing with resource implications – for new quality programs, and to maintain those currently in place*
- *Development of appropriate governance and accountability supports*
- *Development of an evidence-base for quality programs*
- *Development of standards and benchmarks*
- *Examination of the role of laboratory directors, and others*

This document describes a number of quality management program components and makes suggestions for how those components might be monitored. Implicit is that there should be standards or benchmarks against which performance might be measured. It is recognized that there are not yet provincially agreed upon professional standards or benchmarks for such performance measurement, nor yet an evidence-base for them. It is further recognized that definitional clarity and precision will be required in order that any one group's performance may be compared with another, or with that of a provincial standard. In each of these domains a great deal of work is still required; and, again, appropriate resources will have to be devoted for this purpose.

Further, the medical interpretive/ professional work processes referred to in this document often integrate with technical and other supporting services and processes, and high-functioning quality management systems are also required for

these. The quality management programs for these more technical aspects of laboratory work may be individual institution-based and/ or described in programs such as the Quality Management Program – Laboratory Service's Ontario Laboratory Accreditation (QMP-LS OLA) program or that of the College of American Pathologists (CAP). Pathologists and laboratory directors contribute to these technical quality management programs. What has become clear over the last few years, however, is that clearer definition of the role of pathologists and laboratory directors in this respect is desirable.

Finally, it should be noted that, though the draft guidelines provided in this document for consultation focus on the practice of surgical pathology, they are readily modifiable for application to other areas of pathology and laboratory medicine, and many other disciplines of medicine.

These draft guidelines have been developed through the collaborative efforts of the Path2Quality members\* (members of the executives of the OMA Section and OAP) with the assistance of a project manager and CancerCare Ontario's Program in Evidence Based Care. The guidelines were built upon accepted principles of quality monitoring and were based on a comprehensive review of national and international laboratory quality monitoring guidelines, including an evidence-based literature review.

The first draft of these guidelines was forwarded to the laboratory physicians of Ontario for review and feedback (Appendix 1). Additionally, the draft guidelines were provided to nine national and international experts in the field (Appendix 2). Feedback has been, and will continue to be, incorporated into this document that is being shared with other stakeholders – this is a document in 'evolution', and its limitations and inadequacies are solely the responsibility of the Path2Quality volunteers (Appendix 3) who worked to produce the draft. Feedback is encouraged, and may be directed to:

**OMA**

***Attn: Section on Laboratory Medicine***

***Suite 900***

***150 Bloor St W***

***Toronto, ON***

***M5S 3C1***

## USING THESE GUIDELINES

This document contains a number of linked sections and documents:

### **SECTION 1 – Surgical Pathology Professional Quality Management Program Guidelines**

This section describes the guidelines that apply to the overarching quality management program that each professional group performing surgical pathology should have in place, and includes suggestions for a committee to oversee the associated quality plan that should be developed by each professional group.

### **SECTION 2 - Foundational Elements**

This section describes elements that broadly apply to the quality management system suggested in this document, or are applicable to many quality assurance policies and processes that a group should develop, based on the guidelines in Section 5 – they are not repeated in each of the guidelines in Section 5.

### **SECTION 3 - Surgical Pathology Workflow Process Map**

This section includes a process map that describes the main steps (green rectangles) involved in the surgical pathologist's review of any case, and the main decision points (blue diamonds) before case sign-out.

At a number of points in the workflow processes described, there are references to Surgical Pathology Patient Safety Checklists (PSCs; purple rectangles) provided. These checklists may be found in Section 4 of this document.

At points in the workflow processes various key quality assurance reviews (yellow bubbles) are suggested as appropriate monitors of the quality of professional work. Each of these is further described in the associated quality assurance guidelines provided in Section 5.

### **SECTION 4 - Patient Safety Checklists**

These Surgical Pathology PSCs are analogous to those currently employed by surgical services, and those that are being developed by other disciplines. The four Surgical Pathology PSCs suggested are not intended to be used literally in the sign-out of every case, but instead are meant to be a reference standard that surgical pathologists may use to ensure that their day-to-day practice meets best practice.

## **SECTION 5 - Quality Assurance Guidelines**

This section describes a variety of guidelines to help monitor the quality of various aspects of the professional work of surgical pathologists. Each has associated with it the description of its ‘trigger’ – some important step in the workflow process or a broader quality goal. Each has a principle or purpose described for it, suggestions for related policies and processes, exceptions (if they exist), consideration of how individual practice type might influence the policy developed, the responsibilities of the individual surgical pathologist and others in respect of the policy, and the monitors (indicators) that might be used to accomplish the activity in question.

Hyperlinks to associated documents will be provided in the web-based document that will be forthcoming; in the meantime these hyperlinks are indicated in blue and are underlined, in the text and in the “Associated Documents” field for each guideline.

## **SECTION 6 - Glossary**

This section contains the common understanding and definition of terms used throughout the document. The glossary at this point contains gaps and will require ongoing clarification and additions..

### **NOTE:**

References to key literature that may be of interest to the reader are included throughout this document.

## SECTION 1 SURGICAL PATHOLOGY PROFESSIONAL QUALITY MANAGEMENT PROGRAM GUIDELINE

<b>Trigger:</b> The need that laboratory physicians in Ontario provide high quality and efficient surgical pathology services.	
<b>Principle/ Purpose</b>	<p>A surgical pathology professional quality management program is essential if a professional group provides diagnostic interpretive surgical pathology services.</p> <p>A professional group’s “Surgical Pathology Professional Quality Management Plan” should help the group ensure high quality patient care and patient safety in their professional practice. It provides effectiveness and responsiveness of the surgical pathology services that a group provides and ensures compliance with regulatory and organizational requirements of surgical pathologists.</p>
<b>Policy</b>	<p>A surgical pathology professional quality management plan should be developed based on provincial, national and international standards, and using the best available evidence.</p> <p>The “Surgical Pathology Professional Quality Management Plan” should support efficient, effective, high quality and appropriate surgical pathology services, with a focus on patient safety.</p> <p>Quality assurance and quality improvement should be key components of the plan.</p> <p>The plan should contain elements of quality management that relate directly to the professional practice of surgical pathology.</p> <p>The plan should integrate with other quality management systems in the organization (e.g. hospital accreditation, hospital quality of care programs, Ontario Laboratory Accreditation, and similar).</p> <p>All surgical pathologists should participate in the plan and its processes.</p> <p>The quality plan should be undertaken in a collaborative and transparent manner.</p> <p>Internal audits should be benchmarked and compared with best practice outcomes and regulatory requirements, and should be monitored to provide the basis for improvement plans.</p>

	<p>The process for reporting professional quality indicators and other quality information should follow the requirements of the organization and applicable regulations.</p>
<p><b>Surgical Pathology Professional Quality Management Plan Overview</b></p>	<p>To provide leadership in and support for quality assurance and improvement, surgical pathologists should:</p> <p><b>a) Establish a Surgical Pathology Professional Quality Management Committee (SPPQMC)</b></p> <p><b>Membership and Roles:</b></p> <ul style="list-style-type: none"> <li>• A senior pathologist should serve as the Chair of the SPPQMC and this individual should be chosen to reflect the organization of the professional group. Most often the Chair will be the Laboratory Director but may, in large professional groups, be a delegated responsibility.</li> <li>• The Committee should be comprised of pathologists and be supplemented by others as appropriate and as required to perform its work.</li> <li>• The committee should be separate from the committees and quality management programs for the technical work processes whenever possible. Integration of the professional and technical quality programs will be determined by the host institution’s organizational structure.</li> </ul> <p><b>Responsibilities:</b></p> <p>The SPPQMC will:</p> <ul style="list-style-type: none"> <li>• Develop terms of reference that include appropriate governance elements – including (in conjunction with the host institution) articulation of the responsible body to which it will report.</li> <li>• Meet on a regularly scheduled basis.</li> <li>• Oversee the preparation of an annual surgical pathology professional quality improvement plan and associated objectives.</li> <li>• Establish plans to meet those objectives.</li> <li>• Monitor, evaluate, improve upon, and report the performance with respect to the surgical pathology professional quality improvement plan at least annually.</li> <li>• Establish performance standards and benchmarks for the professional group.</li> <li>• Ensure critical incident reporting meets local and provincial requirements and standards.</li> <li>• Make recommendations to the responsible body regarding quality improvement initiatives and policies related to surgical pathology.</li> <li>• Advise on professional education to support continuous quality</li> </ul>

	<p>improvement.</p> <ul style="list-style-type: none"><li>• Ensure that best practice information supported by available scientific evidence is provided to surgical pathologists in the group.</li><li>• Carry-out any other responsibilities provided for in regulation, or as determined by the responsible body.</li><li>• Operate in a non-punitive and non-coercive way, encouraging a culture of open and constructive communication.</li></ul> <p><b>Reporting Structure:</b></p> <p>The SPPQMC will:</p> <ul style="list-style-type: none"><li>• Provide regular reports to the Laboratory Director and Chief of Staff (for hospitals).</li><li>• Provide other regular reports to the responsible body as described in its terms of reference – these will vary professional group to professional group according to their institutional situations.</li></ul> <p><b>b) Develop a Surgical Pathology Professional Quality Management Plan</b></p> <p>The plan will articulate:</p> <ul style="list-style-type: none"><li>• A purpose statement which includes goals that:<ul style="list-style-type: none"><li>• Support continuous quality improvement.</li><li>• Encourage timely, accurate and complete surgical pathology reports.</li><li>• Help to minimize error and enhance patient safety.</li><li>• Are fair and objective as well as focused on improvement and education.</li><li>• Protect professional and patient privacy.</li><li>• Meet regulatory requirements and standards for good medical practice.</li></ul></li><li>• Policies and procedures that encompass the entire surgical pathology workflow process, as well as procedures for monitoring related outcomes.</li><li>• How all processes are regularly measured, monitored, and improved as necessary.</li></ul> <p>The plan will also:</p> <ul style="list-style-type: none"><li>• Consider the complexity, structure, responsibilities, and needs of each professional group's circumstances and organization.</li><li>• Interface with other quality management programs such as Ontario Laboratory Accreditation, the institution's quality of care program, when appropriate.</li><li>• Establish quality objectives and priorities based on criteria such as problematic and high risk work processes.</li></ul>
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	<ul style="list-style-type: none"> <li>• Assign responsibilities and timelines for action items.</li> <li>• When possible, incorporate the input of clients and stakeholders that deal with patient outcomes.</li> <li>• Communicate changes to policies and procedures, and the outcome of any monitoring activities in an open and transparent manner.</li> <li>• Be regularly reviewed for its effectiveness, and modified and improved as required.</li> </ul>
<b>Practice Type Considerations</b>	The Surgical Pathology Professional Quality Management Plan and its committee structure may need to be modified for professional groups with a small number of surgical pathologists. In this circumstance, partnership with other surgical pathology professional groups may be necessary to meet the requirements for best practice.
<b>Responsibilities - Laboratory Director and SPPQMC Chair</b>	<p>Depending on the structure of the professional group, the role of the Chair of the SPPQMC may be delegated to an appropriate individual. However, the final responsibility for quality processes rests with the Laboratory Director.</p> <p>The Chair of the SPPQMC is responsible for the oversight of the development and monitoring of the Surgical Pathology Professional Quality Management Plan.</p> <p>The Laboratory Director should ensure that there is appropriate professional time and infrastructure support for the Surgical Pathology Professional Quality Management Plan and its requirements.</p>
<b>Responsibilities – Pathologists</b>	<p>Each surgical pathologist should understand and participate in the Surgical Pathology Professional Quality Management Plan. This may be demonstrated by:</p> <ul style="list-style-type: none"> <li>• Notifying the Laboratory Director and/ or SPPQMC Chair in a timely manner of any critical incident, quality deficiencies, or problems with compliance with quality assurance policies and procedures.</li> <li>• Participating in the quality improvement plan and in service satisfaction surveys and similar quality initiatives.</li> <li>• Supporting their colleagues through professionalism in their work, and by maintaining a positive work environment that contributes to quality patient reports and outcomes.</li> <li>• Supplying accurate and timely data as required for performance monitoring and reporting.</li> <li>• Adhering to regulations, and to established policies and procedures, performing self-checking, utilizing patient safety checklists, and paying attention to detail in the performance of their work.</li> </ul>
<b>Monitors</b>	<p>Monitoring should be based on approved policies and procedures that encompass the entire surgical pathology work flow process.</p> <p>Other forms of oversight and monitoring of the professional work of the surgical pathologists may include receipt of, and actions related to:</p> <ul style="list-style-type: none"> <li>• Status reports related to corrective, preventive, and improvement</li> </ul>

	<p>activities.</p> <ul style="list-style-type: none"> <li>• Reports and assessments from management and external/ regulatory bodies.</li> <li>• Quality indicators supplied by patient care or other services.</li> <li>• Indicators used for monitoring should be defined, documented, controlled, analyzed, and improved as necessary to potentiate quality improvement initiatives. Monitoring should:                         <ul style="list-style-type: none"> <li>• Be performed on a regularly scheduled basis.</li> <li>• Be conducted and reported against agreed criteria, with mandatory minimum goals identified.</li> <li>• Incorporate the use of recent best practice benchmarking data related to the laboratory’s practice.</li> <li>• Take into consideration the professional group’s practice environment; scope of testing, and available resources.</li> <li>• Be useful in determining corrective, preventive, and improvement actions when required.</li> </ul> </li> </ul> <p>The monitoring data for individual surgical pathologists should be available to them for their review; such data should be maintained in such a way as to preserve individual confidentiality whenever possible, and be in accordance with the SPPQMC policies and processes.</p>
<p><b>Associated Documents</b></p>	<ul style="list-style-type: none"> <li>• <a href="#">Foundational Elements</a></li> <li>• <a href="#">Intra-operative Consultation Patient Safety Checklist</a></li> <li>• <a href="#">Gross Examination Patient Safety Checklist</a></li> <li>• <a href="#">Pre-interpretative Patient Safety Checklist</a></li> <li>• <a href="#">Post-interpretative Patient Safety Checklist</a></li> <li>• <a href="#">QA Guideline – Intra-departmental Consultation</a></li> <li>• <a href="#">QA Guideline – External Consultation</a></li> <li>• <a href="#">QA Guideline – Intra-operative Consultation</a></li> <li>• <a href="#">QA Guideline – Previous Surgical Pathology/ Cytology</a></li> <li>• <a href="#">QA Guideline – Utilization and Compliance</a></li> <li>• <a href="#">QA Guideline – External Review</a></li> <li>• <a href="#">QA Guideline – Addendum Reports, including Those Documenting</a></li> </ul>

	<p><u><a href="#">Revisions and Corrections</a></u></p> <ul style="list-style-type: none"><li>• <u><a href="#">QA Guideline – Critical Diagnoses/ Results</a></u></li><li>• <u><a href="#">QA Guideline – Retrospective Reviews</a></u></li><li>• <u><a href="#">QA Guideline – Turnaround Times</a></u></li><li>• <u><a href="#">QA Guideline – Service Satisfaction</a></u></li></ul>
<b>References</b>	<ul style="list-style-type: none"><li>• Excellent Care for All Act; 2010. Bill 46, An Act respecting the care provided by health care organizations. <a href="http://www.ontla.on.ca/bills/bills-files/39_Parliament/Session2/b046ra.pdf">http://www.ontla.on.ca/bills/bills-files/39_Parliament/Session2/b046ra.pdf</a></li><li>• Ontario Laboratory Accreditation Requirements and Guidance Information, Section II. Version 5; 2010.</li><li>• Ontario Regulation 156/10 made under the Public Hospitals Act; filed May 3, 2010.</li><li>• Ontario Regulation 448/10 made under the Public Hospitals Act; approved December 1, 2010.</li><li>• Ontario Regulation 444/10 made under the Excellent Care for All Act, 2010; filed December 2, 2010.</li><li>• Personal Health Information Protection Act 2004 S.O. 2004, Chapter 3 - Schedule A. <a href="http://www.e-laws.gov.on.ca/html/statutes/english/elaws_statutes_04p03_e.htm">http://www.e-laws.gov.on.ca/html/statutes/english/elaws_statutes_04p03_e.htm</a></li><li>• Public Hospitals Act, 1990. <a href="http://www.e-laws.gov.on.ca/html/statutes/english/elaws_statutes_90p40_e.htm">http://www.e-laws.gov.on.ca/html/statutes/english/elaws_statutes_90p40_e.htm</a></li><li>• Quality of Care Information Protection Act; 2004. <a href="http://www.e-laws.gov.on.ca/html/statutes/english/elaws_statutes_04q03_e.htm">http://www.e-laws.gov.on.ca/html/statutes/english/elaws_statutes_04q03_e.htm</a></li></ul>

## SECTION 2 FOUNDATIONAL ELEMENTS

This section describes some guidelines for the overarching principles that should apply to a quality management system for the professional work of surgical pathologists. Additionally, those elements of professional quality assurance that are relevant to the entire surgical pathology professional reporting process, or that apply to the multiple quality assurance guidelines in Section 5, are described.

- **Essential Attributes of Quality Management Programs**

The quality management programs that professional groups devise to guide their surgical pathology practices should focus on the goals of patient safety, and on high quality and efficient professional work processes and results reporting – and, the program should encourage all participating surgical pathologists to actively contribute to these goals.

Quality assurance activities in the first instance should focus on critical hand-off points in work processes (i.e. points at which reporting and other defects and errors are prone to occur). To this end, every effort should be made to eliminate un-necessary work process variability, and all work processes should be regularly measured, monitored, and improved, as necessary.

The program should monitor work processes and outcomes in the form of aggregated data, and also be able to respond and deal with sentinel events and individual critical incidents.

All activities of a professional quality management program should be objective and aimed at constructive feedback to, and the improvement of the work of, the professional group and of the individual surgical pathologists in that group.

The quality management system devised should be as comprehensive as possible. It should balance and guard the interests of the group and institution housing it, as well as those of the surgical pathologists in that group. The quality management program should clearly articulate the roles and responsibilities of all involved, and include descriptions of dispute resolution processes. Indemnification, when appropriate, should be described for those organizing and maintaining the program.

- **Integration with Other Quality Programs**

These guidelines focus on professional practice of surgical pathologists. It has been assumed that surgical pathologists work within accredited laboratories and the quality management processes for the technical work that supports them meets the high standards encouraged by organizations such as the Quality Management Program –

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Laboratory Services, Accreditation Canada, the College of American Pathologists, and similar.

Likewise, it is assumed that the surgical pathologists work in organizations with quality management programs that support all of the constituent clinical services, and that the program described in this document should integrate with that more broadly-based institution-wide program – in doing so, the form that the surgical pathology professional quality management program takes at any institution may vary, to meet broader institutional requirements.

- **Appropriate Training, Licensure, Credentialing and Continuing Professional Development of Surgical Pathologists**

This document does not address the appropriate medical and specialty training and the examination of surgical pathologists, which is the domain of the academic training programs and of The Royal College of Physicians and Surgeons of Canada (or equivalents), nor their licensure which in Ontario is the domain of the Ontario College of Physicians and Surgeons.

Likewise, this document does not deal with the credentialing of surgical pathologists which is the responsibility of the hospitals or other institutions for which they work. The requirement that surgical pathologists continuously develop themselves professionally via continuing medical and other education, similarly, is not the subject of this document.

It is assumed that the surgical pathologists working in the professional groups referred to in this document will have met all of the requirements prescribed by these regulatory and governing groups, and have the appropriate experience for the work that they perform.

Any quality assurance program governing the professional work of surgical pathologists should, however, describe the expectations of each of its pathologists with respect to the above, and ensure there is appropriate related documentation.

- **Documentation**

Documentation of all aspects of the quality management program described is of paramount importance, whether related to individual patient cases or to the various policies, processes, monitors, and reviews suggested for such programs.

For individual patient cases, there should be a clear audit trail available that describes the contribution of various individuals (whether technical, support or professional) to the various components of the work and quality assurance processes. The surgical pathologist responsible for the case should be clearly indicated, as should contact information for the institution or group performing the work.

All quality assurance program elements, including the overarching [Surgical Pathology Professional Quality Management Program Guideline](#), the [Surgical Pathology Professional Quality Management Committee](#) terms of reference, and the various associated quality assurance policies and procedures should be appropriately documented, and have standard format, including indication of their author, date of issue or revision, and authorization. Document control processes that include an audit trail should be in place, and obsolete documents appropriately archived.

The results of quality assurance reviews and monitoring should likewise be documented according to predefined policies and procedures, and their integrity and confidentiality appropriately guarded. The results of reviews and monitoring should be regularly reported in summary form to those governing the quality management program (e.g. hospital medical advisory or quality of care committees, or similar), according to predefined standards and at predefined intervals.

A policy and procedure manual describing the work of surgical pathologists should be in place and describe the standard operating procedures for the work of the surgical pathologists, including those responsibilities that are those of the individual pathologists and those that are the responsibility of the group. This manual should describe the recommended work processes, reporting standards, and similar, as well as the various associated quality assurance program elements.

- **Privacy, Confidentiality, and Duty to Report**

All aspects of the quality management program described in this document must meet applicable statutory and regulatory requirements for privacy and confidentiality of patients' personal information. Likewise, the program should abide by the institutional policies for same.

Every effort should be made to keep confidential the results of assessment and monitors employed in the various quality assurance reviews described in this document. Where applicable, these should be anonymized.

When critical incidents are encountered the institution's policies and procedures for dealing with these will be used, and may include, reporting to the Laboratory Director, to the Chief of Staff (in hospitals), to the Board's Quality of Care Committee (in hospitals), and similar. In all instances, the moral and ethical standards of the profession will be met, and the rules of all governing bodies, such as the College of Physicians and Surgeons of Ontario, adhered to. Additionally, the specifics of some forms of critical incident reporting are described in various forms of legislation, for instance the Excellent Care for All Act.

Consideration of seeking Quality of Care Information Protection Act (QCIPA) protection for information may be appropriate in some quality assurance reviews.

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- **Guidelines for Review of Previously Reported Cases**

In various circumstances (including in the various quality assurance monitoring activities outlined in the guidelines in this document) previously reported cases may be reviewed *post facto*. The review of those previously reported cases may serve as a valuable quality assurance check.

The review process may include examination of/ for:

- Completeness/ adequacy of patient identifiers;
- Completeness/ adequacy of clinical history provided;
- Use of other relevant clinical and diagnostic data;
- Review of relevant previous surgical pathology and cytology material;
- Adequacy of specimen sampling;
- Macroscopic description;
- Use of special stains and other ancillary tests;
- Microscopic description, if employed;
- Final diagnosis and comments;
- Report format and clarity;
- Transcription, typographic, or similar errors;
- Other elements determined appropriate.

- **Guidelines for Dealing with Report Defects/ Discrepancies/ Discordances/ Errors**

If report defects/ discrepancies/ discordances/ errors are revealed by any of the forms of review the professional group employs, there should be in place a policy and predetermined processes for their investigation and resolution, and for the documentation of same.

At a minimum, the pathologist who becomes aware of a report defect/ discrepancy/ discordance/ error should:

- Discuss the report defect/ discrepancy/ discordance/ error with the pathologist responsible for the report in question, to determine if there is agreement that the report contains a report defect/ discrepancy/ discordance/ error;
  - If they agree that there is a report defect/ discrepancy/ discordance/ error, they will attempt to determine why the report defect/ discrepancy/ discordance/ error arose, the clinical import of the report defect/ discrepancy/ discordance/ error, and the appropriate action;
  - If they disagree that there is a report defect/ discrepancy/ discordance/ error, resolution may be sought by various means, for instance:

- consultation with others in the professional group;
- consultation with the Laboratory Director;
- external consultation.

This discussion and follow- up should be documented.

At a minimum, when a report defect/ discrepancy/ discordance/ error is determined to be present, the pathologist responsible for the report in question should:

- Directly communicate with the clinician for those patients whose treatment or clinical management may need to be modified;
- If appropriate, document the above in an addendum to the original report;
- If an addendum report is issued, ensure that any originally issued reports are clearly marked in such a way as to ensure that they are not confused or misinterpreted as the final report for the case.

At a minimum, the policy and processes the professional group should have in place should predefine for cases of potential report defect/ discrepancy/ discordance/ error:

- Processes for the various surgical pathologists involved to follow, including mechanisms for dispute resolution;
  - Criteria to determine when notification of clinicians should take place;
  - Criteria to determine when addendum reports should be issued;
  - Criteria to determine if the Laboratory Director should be notified;
  - Criteria to determine if critical incident reporting, including notification of the Chief of Staff, or equivalent, is required;
  - How the pathologist responsible for the report in question will be notified, when that pathologist is not immediately available;
  - Documentation and tracking of report defects/ discrepancies/ discordances/ errors, including those that are not considered to warrant communication with the clinician, addendum report, etc.;
  - How professional group improvement plans will be based on the above.
- **Guidelines for Classification of Report Defects/ Discrepancies/ Discordances/ Errors**

There is not yet agreement in the literature about how best to classify report defects/ discrepancies/ discordances/ errors. One method that may be familiar to many is that described by the Association of Directors of Anatomic and Surgical Pathology (Recommendations on Quality Control and Quality Assurance in Anatomic Pathology. *Am J Surg Pathol*.1991;15:1007-1009). Depending on the type of review undertaken, discordances may be described in that scheme as minor or major, depending on clinical, or potential, clinical impact.

Others have provided more complex and sophisticated classification schemes. Meier et al (Meier, FA et al, Amended Reports - Development of a Taxonomy of Defects. *Am J Clin Pathol.* 2008;130:238-246), for instance, suggest a classification of report defects into those related to misinterpretations (false-positives and false-negatives, each with sub-classifications as primary and secondary; misclassifications; and others), misidentifications, specimen defects, report defects, and other.

In developing schemes for classification of report defects/ discrepancies/ discordances/ errors, professional groups should consider whether it is, or is not, advisable and advantageous to attempt to assign some measure of clinical impact. There are arguments for both approaches; many groups may find it less cumbersome to use schemes independent of the consideration of clinical impact for the purposes of surgical pathology defect/ discrepancy/ discordance/ error analysis and classification. If that route is taken, the host institution's program for reporting incidents with clear, or likely, adverse clinical outcome may be used, as a parallel and complementary system by which to register those cases.

Each professional group should explore the various classification schemes available in the literature, and choose one appropriate to its needs and the needs of the larger quality system in which they report. There has not yet been developed a classification system that will allow standardized report defect/ discrepancy/ discordance/ error reporting to the provincial level, i.e. no system that will allow the performance of one professional group to be compared with another.

- **Responsibilities of a Pathologist Requesting an External Consultation**

Common circumstances in which external opinions are required include limited test menu and insufficient professional expertise on-site. Sometimes external consults are requested to resolve divergent opinions following intra-departmental consultation. Other prompts include a request by a clinician or patient for an external review. As part of a professional group's Surgical Pathology Professional Quality Management Plan, there should be defined policies and procedures for sending external consultations and reviews in these varied circumstances.

A pathologist sending a consultation request to an external consultant should ensure that the external consultant is provided complete and adequate clinical information. This may include seeking information not originally provided by the clinician who sent the specimen in the first instance.

The pathologist sending a consult to an external consultant should ensure that representative materials are included for review. This may include some or all of the slides or other materials prepared from the specimen. Every effort should be made to guard the integrity of those slides and material (e.g. they will be transported to the external consultant in such a way as to minimize the risk of breakage or loss).

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Every effort should be made to ensure that some diagnostic material is retained on-site, in order that, in the unusual circumstance of the loss of the consult material, it will not un-necessarily prejudice patient diagnosis. In only very unusual circumstances should all diagnostic material be sent to the consultant; in those cases, sending the material in two separate parts may deal with the possibility of the loss of one part.

- **Responsibilities of the External Consultant**

If a professional group offers an external consultation service and takes in consults from other groups or institutions there should be defined policies and procedures that govern that consultation work, and describe the expectations with respect to it. At a minimum:

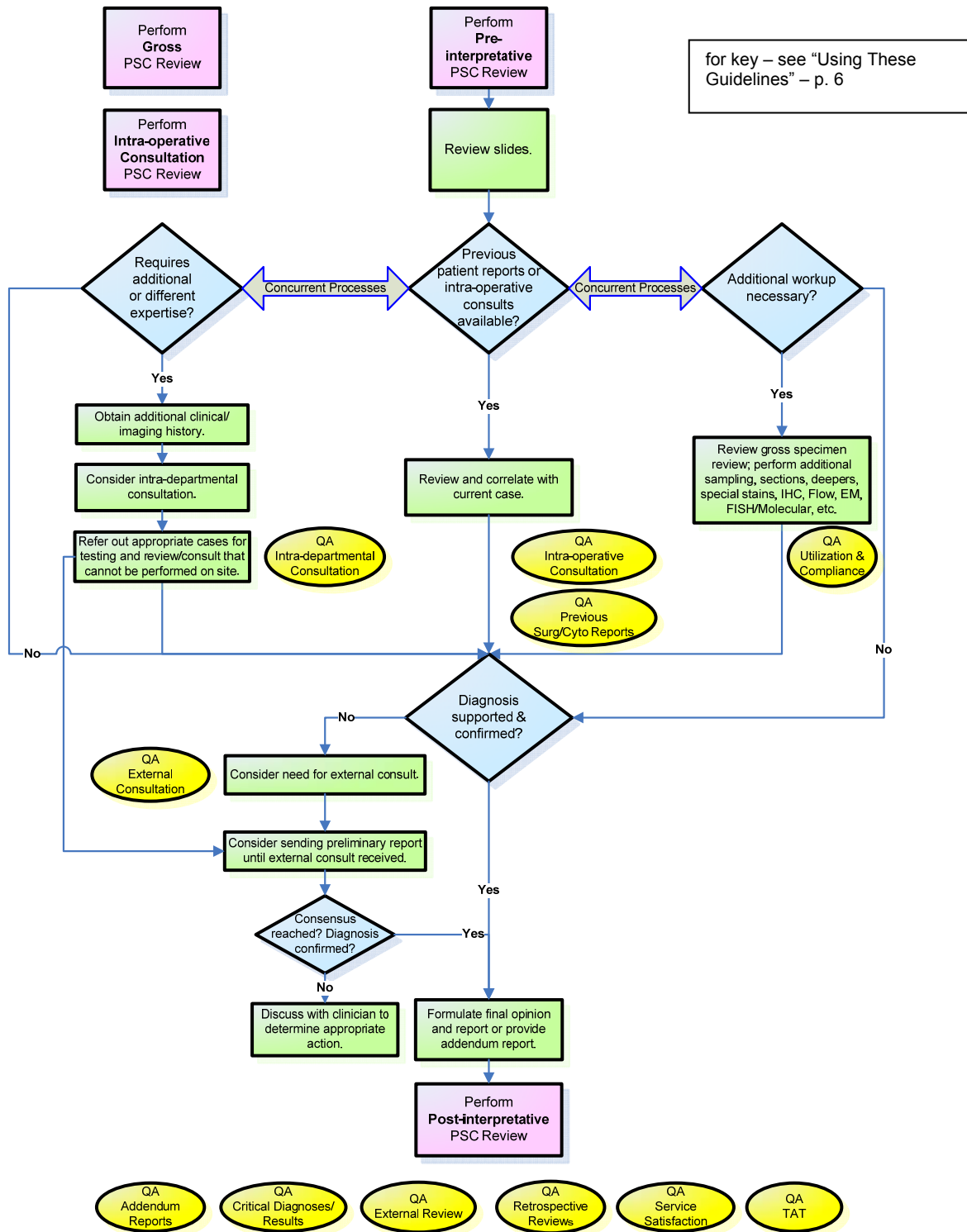
- All materials provided by the originating surgical pathologist or institution should be reviewed; or, alternatively, the consultant's report will make clear which selected materials were reviewed.
- The consultant should review the original report, and if questions exist regarding clinical history or other aspects of the report, the originating surgical pathologist or institution should be contacted for clarification.
- Ideally, the consultant should be part of a sub-specialty team. In difficult cases, other members of the team should also review the case.
- The consultant should provide a timely and complete opinion, and in some instances provide detailed comment.
- The consultation report should embody all the elements described elsewhere in this document (e.g. a record of quality assurance processes used by the consultant).
- In the event that the external consultant remains unsure of the diagnosis, further consultation to another experienced consultant should be considered.
- If a definitive diagnosis was rendered by the original surgical pathologist, and if there is a discrepancy between the original and consult diagnoses, the case should be reviewed by a second pathologist, if available, and this should be recorded in the consultation report. A detailed comment should be included with the consultant's diagnosis. Furthermore, consideration should be given to the need for verbal communication to the original pathologist.
- The materials sent in consultation should be kept intact and in good order.
- The materials sent to the consultant should be returned to the originating pathologist or institution, unless there is expressed consent to do otherwise.
- Every effort will be made to guard the integrity of those slides and material referred (e.g. they will be transported back to the requesting pathologist in such a way as to minimize the risk of breakage or loss).
- The consultant should have backup when away, ideally other members of his/her professional group.

- A consultant pathologist should not abandon his/ her consultation practice without fair warning to the community served. Every effort should be made to find alternative solutions.

- **Infrastructure and Other Supports**

The quality management program described in this document assumes a number of infrastructure supports, or enablers, are provided for the professional group of surgical pathologists in question. Chief amongst these enablers are sufficient personnel (professional and support staff) and information technology resources to develop and maintain the program. A robust and multifaceted program as described in this document cannot be accomplished without adequate resourcing. The scoping of the resource implications of the program described here is not the focus of this document – again, that issue is referred for resolution to the Ministry of Health and Long Term Care, the stewards of Ontario’s health care system resource allocation.

### SECTION 3 SURGICAL PATHOLOGY WORKFLOW PROCESS MAP



## SECTION 4 PATIENT SAFETY CHECKLISTS

1.0	GROSS EXAMINATION PATIENT SAFETY CHECKLIST	Reference Examples (not all inclusive)		
		CAP-LAP Anatomic Pathology/ General Checklists 06.17.2010	Quality Management in Anatomic Pathology, CAP 2005	OLA All Inclusive Version 5 Dec 2010
1.1	The patient identifiers and other information provided on the requisition match those on the specimen container, and match any other related patient record (e.g. in the laboratory information system).			
1.2	The specimen submitted is appropriate for examination and is not on the organization's examination exemption list.	ANP.10016	Page 12	V.C.1.2 V.C.2
1.3	The gross examination is performed by a pathologist, a pathology resident, or by other qualified personnel who are under the supervision of a pathologist.	ANP.11600 ANP.11610 ANP.11640		VI.3
1.4	Pertinent previous clinical history, diagnostic imaging and laboratory reports are available for review.	ANP.10050 GEN.10050 GEN.20377 GEN.20425 GEN.40750	Page 34, 39	V.D.1.8 VIII.2- AP027
1.5	The referring physician or appropriate other personnel is contacted for additional information, if required.			VIII.1
1.6	A standardized protocol or guideline is used for the dissection, description, and histologic and other sampling of the specimen.	ANP.11605 ANP.11670		
1.7	If a pathology resident or other personnel performs the examination, they will review unusual or unexpected findings with the pathologist.			
1.8	When unusual findings or situations are encountered, the pathologist exercises professional discretion to perform those studies indicated.	ANP.23036	Page 12	
1.9	Tissue for special procedures or research protocols is obtained at the direction of the pathologist, does not	ANP.12075	Page 13	

	compromise patient care, and is performed according to institutional policies, including institutional review board (IRB) requirements.			
<b><i>If any checklist element does not meet quality expectations, appropriate corrective actions are taken and documented.</i></b>				

2.0	INTRA-OPERATIVE CONSULTATION PATIENT SAFETY CHECKLIST	Reference Examples (not all inclusive)		
		CAP-LAP Anatomic Pathology/ General Checklists 06.17.2010	Quality Management in Anatomic Pathology CAP 2005	OLA All Inclusive Version 5 Dec 2010
2.1	Pertinent previous clinical history, diagnostic imaging and laboratory reports are available for review.		Page 34	V.D.1.8 VIII.1 VIII.2- AP027
2.2	The referring physician or appropriate other personnel is contacted for additional information, if required.			
2.3	Specimens from concurrent consultations are kept separate.		Page 38	
2.4	Tissue for frozen section or other rapid analysis is selected taking into account the possible need for fixed tissue or subsequent studies.			
2.5	Each frozen section slide or other preparation created is labeled with two unique patient identifiers.	ANP.11800 ANP.11460	Page 38	V.C.1.2.1 V.C.2.2
2.6	Frozen section slides or other preparations are of sufficient quality for intra-operative diagnosis.	ANP.11810 ANP.11734		V.C.1- AP021 VII.8
2.7	If a verbal report is given, the referring physician or delegate is contacted directly by the pathologist.	ANP.11900		VIII.9.1 - AP013
2.8	The patient's identification is checked before delivery of any verbal report.	ANP.11950	Page 38	VA.1.8 VA.1.10
2.9	Results provided verbally are read-back by the referring physician, or delegate, and checked for accuracy by the pathologist.	GEN.40935 GEN.41340		VIII.9.1
2.10	The performance of an intra-operative consultation, its results, any verbal communication to the referring physician, and the date and time of any communication	ANP.11850		VIII.9.1

	are permanently documented in the report for the specimen.			
2.11	Following the intra-operative consultation, tissue is submitted for further studies as required.			

***If any checklist element does not meet quality expectations, appropriate corrective actions are taken and documented.***

3.0	PRE-INTERPRETATIVE PATIENT SAFETY CHECKLIST	Reference Examples (not all inclusive)		
		CAP-LAP Anatomic Pathology/ General Checklists 06.17.2010	Quality Management in Anatomic Pathology CAP 2005	OLA All Inclusive Version 5 Dec 2010
	<b>Patient Demographics</b>			
3.1	The patient demographics are consistent with the submitted specimen.	GEN.40750		
	<b>Patient Clinical History</b>			
3.2	Pertinent previous clinical history, diagnostic imaging and laboratory reports are available for review.	ANP.10050 GEN.10050 GEN.20377 GEN.20425 GEN.40750	Page 34, 39	V.D.1.8 VIII.2- AP027
3.3	The referring physician or appropriate other personnel is contacted for additional information, if required.			VIII.1
	<b>Case Material Correctness</b>			
3.4	Slides and other preparations created are uniquely and permanently identified with adequate and legible information.	ANP.21100 ANP.21150		V.C.1.2.1, V.C.2.2.2 V.C.2.3
3.5	The patient record (including any transcribed portions), the specimen requisition and slides, and any other case materials match.			
	<b>Gross Description</b>			
3.6	The specimen type matches the requisition and other records.	ANP.11500		V.C.2.1 V.D
3.7	The description is complete, understandable and follows established protocols.	ANP.12200	Page 62	VIII.2
3.8	The description contains adequate information regarding tissue type/ material, number of tissue/	ANP.12200	Page 62, 64	AP025 AP029

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	material pieces, dimensions and/or weight of tissue/ material, any lesions, and other information for pathologic diagnosis.			AP031
3.9	Appropriate sections are taken, or other preparations made, for the type of specimen submitted.		Page 62	
3.10	There is documentation of the sections taken or other preparations made in the report.	ANP.12250		VIII.2.8
3.11	Annotated specimen drawings, photographs, radiographs, and similar (if required), are available for review.	ANP.12200		
3.12	The individual responsible for the gross description is documented.	ANP.11660		VIII.2- AP032
	<b>Slide and Other Preparation QC/QA</b>			
3.13	The material in the slides or other preparations matches the gross description.	ANP.12300	Page 39	
3.14	Slides and stains, and other preparations, are of sufficient quality.	ANP.11713 ANP.11714 ANP.12098 ANP.21382 ANP.22900	Page 81, 101	V.C.1- AP021 VII.1 VII.8- AP022
<b><i>If any checklist element does not meet quality expectations, appropriate corrective actions are taken and documented..</i></b>				

4.0	POST-INTERPRETATIVE PATIENT SAFETY CHECKLIST	Reference Examples (not all inclusive)		
		CAP-LAP Anatomic Pathology/ General Checklists 06.17.2010	Quality Management in Anatomic Pathology CAP 2005	OLA All Inclusive Version 5 Dec 2010
	<b>Provisional (Preliminary) Report – if required</b>			
4.1	The report describes what work or other information is pending/ incomplete, and why the report is not a final/ completed one.	GEN.61750	Page 15	
4.2	The report clearly indicates that the findings are preliminary and may be modified at the time of issuing the final/ completed report.		Page 15	
	<b>Pathology (Final) Report</b>			
4.3	Any standardized protocols employed by the professional group for reporting the specimen are adhered to.			VIII.1
4.4	The gross description, microscopic findings (if recorded), and any other information included support the pathologic diagnosis.	ANP.12300		VIII.2– AP029 AP030 AP031
4.5	Any inadequacies or limitations of the specimen or its examination are documented.	ANP.11475	Page 62	V.C.2.6 VIII.2.4
4.6	The results of specialized studies are correlated with the morphologic diagnosis, documented and incorporated into the final diagnosis.	ANP.12400 ANP.54000	Page 14, 101	VIII.2.13
4.7	For reports that include tests that provide independent predictive information, details of specimen processing, and the test and the scoring methods used are included in the report.	ANP.22969	Page 101	VI.9, VIII.2.13
4.8	The record of any intra-operative consultation performed is incorporated in the final report.	ANP.10150 ANP.10200 ANP.12000 GEN.41077		VIII.2- AP028. VIII.9.1 VIII.9.1.1
4.9	Any discordance between the final diagnosis and the gross description, intra-operative consultation and/or other tests performed, is reconciled and explained in the report.	ANP.10100 ANP.12400		VIII.10

4.10	Recommendations for further studies are included.			VI.10
4.11	Significant, unexpected and critical findings are communicated promptly to the clinician and that communication documented.	ANP.12175 GEN.41320 GEN.41330	Page 16	VI.3 VIII.1 VIII.5 VIII.5.1, VIII.5.2, VIII.9.1.1
4.12	All necessary sections of the report are completed (including required synoptic report fields).	ANP.12385 ANP.22969 ANP.23036 ANP.23037 ANP.23038 ANP.23039 GEN.41096	Page 61, 62, 64, 101	VIII.2, VIII.1.3
4.13	No transcription or formatting errors are present.		Page 39	VIII.2
4.14	All quality assurance processes employed during the course of specimen examination and reporting are documented.			
4.15	The pathologist responsible for report (including any preliminary report/s) is clearly indicated in the report, along with contact information for the institution/professional group.	ANP.12100 ANP.54050		VIII.2 – AP032 VIII.3
	<b>Addendum Reports (including those with revisions or corrections) – if required</b>			
4.16	The reason for the addendum is clearly indicated in the report, and along with any background information and findings that may have served as its basis.	GEN.41308	Page 15, 16, 54	VIII.2.13 VIII.11.3
4.17	The information in the original report and the original diagnosis are reviewed and changed if required. If a change is made, that change is clearly identified.	GEN.41307	Page 15, 16	II.D.5.8
4.18	The clinician is notified, if necessary and that notification documented.	GEN.41307	Page 16, 44	I.C.11 II.D.5.6
4.19	The original report is retained and can be retrieved – ensuring that it cannot be mistaken as the active/ final report.	GEN.41310		II.D.5.10 VIII.11.1 VIII.11.2

***If any checklist element does not meet quality expectations, appropriate corrective actions are taken and documented.***

## SECTION 5 SURGICAL PATHOLOGY QUALITY ASSURANCE GUIDELINES

### Quality Assurance Guideline - Intra-departmental Consultation

<b>Trigger:</b> Consider intra-departmental consultation.	
<b>Principle/ Purpose</b>	<p>Peer review is a commonly used method of ensuring diagnostic accuracy in surgical pathology. This guideline refers to those intra-departmental consultations that occur prospectively, i.e., before case sign-out.</p> <p>Intra-departmental consultation occurs when a pathologist seeks an opinion from other pathologist/s within their own professional group. This may involve either a direct request from one pathologist to another to consult on all or selected slides/ material from a case. It may also involve consult on all or selected slides/ material in the course of a case conference or similar.</p> <p>Intra-departmental consultation should be encouraged and facilitated.</p> <p>Consultation with intra-departmental colleagues should lead to improved decision-making, uniformity in use of diagnostic terminology, grading systems and criteria, and should increase the compliance with quality assurance processes. Teamwork, continuing education, and exchange of ideas and expertise should be enhanced.</p>
<b>Policy</b>	<p>As part of the <a href="#">Surgical Pathology Professional Quality Management Plan</a>, there should be a policy that outlines the procedure for consultation with intra-departmental colleagues, including the documentation of those consults. This policy should refer to both individual pathologist intra-departmental consultation and case conference type scenarios, if both are employed by the group.</p> <p>The <a href="#">Surgical Pathology Professional Quality Management Plan</a> should provide guidance as to the types of cases that are appropriate for consultation.</p> <p>It is difficult to specify for all situations the types or proportions of cases that should be subject to intra-departmental consultation. Generally, the case pathologist should seek an intra-departmental consultation:</p> <ul style="list-style-type: none"><li>• If there is any doubt about a diagnosis or a clinically significant finding.</li><li>• For critical diagnoses.</li><li>• In cases where there is known diagnostic and clinically significant variability.</li><li>• For rare disorders that have clinical importance.</li></ul> <p>A professional group should determine which sorts of cases require mandatory intra-departmental consultation and which are discretionary.</p>

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	<p>Intra-departmental consultations should be sought prior to final case sign-out.</p> <p>That an intra-departmental consultation occurred should be documented in the patient report.</p> <p>The intra-departmental consultant pathologist’s opinion should be kept on file; it need not necessarily be part of the patient report.</p> <p>It is acknowledged that depending on local preference the name of the consulting pathologist/s may or may not be included in the patient report; in any case, if that name is used, it will only be so with the express consent of the intra-departmental consult pathologist (that consent may be deemed received if the local policy is to include such names).</p> <p>It is acknowledged that depending on local preference, and in many cases dependent on the laboratory information system in use, the form that the intra-departmental consult documentation takes may vary:</p> <ul style="list-style-type: none"> <li>• The documentation may be in hard copy.</li> <li>• The record may be kept electronically but not visible in the circulated report.</li> <li>• The intra-department consult pathologist’s electronic signature may be required along with the case pathologist’s electronic signature.</li> </ul>
<p><b>Exceptions</b></p>	<ul style="list-style-type: none"> <li>• If there is no other pathologist with appropriate expertise on-site, or if the question at hand is not resolvable on-site, the case should be referred-out for external consult and/or testing.</li> <li>• Showing a slide to a colleague “out of interest” is not considered an intra-departmental consultation (for the purposes of “consultation” some form of permanent documentation is required of the consulting pathologist).</li> </ul>
<p><b>Practice Type Considerations</b></p>	<ul style="list-style-type: none"> <li>• The types of cases that are considered appropriate for intra-departmental consultation may vary depending on the typical caseload of the professional group, and may be modified, for instance, when new diagnostic procedures or terminologies are introduced, or with the introduction of new pathologists.</li> <li>• Groups that report a wide variety of case types with a relatively low incidence of malignancy may choose to have a policy stating that all first-time diagnoses that may lead to a significant clinical intervention should be subject to consult prior to case sign-out (e.g., new diagnoses of malignancy). These groups may also choose to directly refer certain types of cases for external consultation.</li> <li>• Groups with a subspecialty-based practice and/ or a relatively high incidence of malignancies may choose to focus consultations on cases where the diagnosis is likely to result in significant clinical actions or is prone to diagnostic variability.</li> </ul>
<p><b>Responsibilities - Intra-departmental</b></p>	<ul style="list-style-type: none"> <li>• The intra-departmental consult pathologist/s should review all relevant patient material and clinical information related to the case, as needed. The reviewing pathologist may choose to perform the review ‘blinded’.</li> </ul>

<p><b>Consult Pathologist/s</b></p>	<ul style="list-style-type: none"> <li>• The opinion of the intra-departmental consult pathologist should be documented as per department policy, for the case pathologist to consider when finalizing the report.</li> <li>• The intra-departmental consult pathologist's electronic signature may be required depending upon the group's reporting policy.</li> </ul>
<p><b>Responsibilities - Case Pathologist</b></p>	<ul style="list-style-type: none"> <li>• After the consultation, the case pathologist should determine the best diagnosis, based on all the data available at the time. The need for further review, including external consultation should be considered.</li> <li>• The case pathologist should document that a consultation took place, and the involvement of other pathologist/s in the final patient report.</li> </ul>
<p><b>Monitors</b></p>	<p>The <a href="#">Surgical Pathology Professional Quality Management Committee</a> should collect and review data on intra-departmental consultations, for the professional group and for each pathologist. As data is collected, it should be compared to established benchmarks and trended over time.</p> <p>Distinguishing this measure from a number of other quality indicators where a standard or benchmark may be established that it is desirable not to exceed - in contrast, for intra-departmental consultations minimums or floors should be established</p> <p><b>Minimum Requirements:</b></p> <ul style="list-style-type: none"> <li>• Number of intra-departmental consults by professional group (including individual pathologist and case conference types of consults), compared with number of all cases in same time period</li> </ul> <p><b>Indicator Examples:</b></p> <ul style="list-style-type: none"> <li>• % of cases with individual pathologist type consultation</li> <li>• % of cases with case conference type consultation</li> </ul> <p><b>Optional:</b></p> <ul style="list-style-type: none"> <li>• Number of intra-departmental consults by individual pathologist, compared with number of all that individual's cases in same time period</li> <li>• Number of intra-departmental consults by specific anatomic site or disease type, compared with number of all such cases in same time period</li> </ul> <p><b>Indicator Examples:</b></p> <ul style="list-style-type: none"> <li>• % of individual pathologist's cases with individual pathologist type consultation</li> <li>• % of cases of specific anatomic site or disease type that had an intra-departmental consultation</li> </ul> <p><b>Frequency:</b></p> <ul style="list-style-type: none"> <li>• Quarterly (or as appropriate for the group)</li> </ul>
<p><b>Associated Document</b></p>	<ul style="list-style-type: none"> <li>• <a href="#">Surgical Pathology Professional Quality Management Guideline</a></li> <li>• <a href="#">Surgical Pathology Professional Quality Management Committee Terms of</a></li> </ul>

<b>Examples</b>	<p><a href="#">Reference</a></p> <ul style="list-style-type: none"> <li>• <a href="#">Foundational Elements</a></li> <li>• <a href="#">QA Guideline – External Consultation</a></li> </ul>
<b>References</b>	<ul style="list-style-type: none"> <li>• Association of Directors of Anatomic and Surgical Pathology. Recommendations for Quality Assurance and Improvement in Surgical and Autopsy Pathology. <i>Am J Clin Pathol.</i> 2006;126:337-340.</li> <li>• College of American Pathologists Commission on Laboratory Accreditation. Anatomical Pathology Checklist. Northfield, Ill: College of American Pathologists; 2010.</li> <li>• College of American Pathologists Commission on Laboratory Accreditation. Laboratory General Checklist. Northfield, Ill: <i>College of American Pathologists; 2010.</i></li> <li>• Nakhleh RE. What is quality in surgical pathology? <i>J Clin Pathol.</i> 2006;59:669-672.</li> <li>• Nakhleh RE, Fitzgibbons PL. Quality Management in Anatomic Pathology. Promoting Patient Safety Through Systems Improvement and Error Reduction. Northfield, IL: College of American Pathologists. 2005.</li> <li>• Raab SR, Grzybicki DM. Quality in Cancer Diagnosis. <i>CA Cancer J Clin.</i> 2010;60:139-165.</li> <li>• Raab SS, Grzybicki DM, Mahood LK, et al. Effectiveness of Random and Focused Review in Detecting Surgical Pathology Error. <i>Am J Clin Pathol.</i> 2008;130:905-912.</li> <li>• Renshaw AA, Gould EW. Comparison of Disagreement and Amendment Rates by Tissue Type and Diagnosis. Identifying Cases for Directed Blinded Review. <i>Am J Clin Pathol.</i> 2006;126:736-739.</li> <li>• Renshaw AA, Gould EW. Measuring Errors in Surgical Pathology in Real-Life Practice. Defining What Does and What Does Not Matter. <i>Am J Clin Pathol.</i> 2007;127:144-152.</li> <li>• Renshaw AA, Gould EW. Measuring the Value of Review of Pathology Material by a Second Pathologist, <i>Am J Clin Pathol.</i> 2006;125:737-739.</li> <li>• Renshaw A, Pinnar N, Jiroutek M, et al. Blinded Review as a Method for Quality Improvement in Surgical Pathology. <i>Arch Pathol Lab Med.</i> 2002;126:961-963.</li> <li>• The Royal College of Pathologists of Australia. Provision of Second and Subsequent Opinions with Particular Reference to Histopathology Cytology &amp; Specimens for Morphological Examinations. Revised March 2007. Number 2/1999.</li> <li>• Tomaszewski JE, Bear HD, Connally JA, et al. Consensus Conference on Second Opinions in Diagnostic Anatomic Pathology Who, What, and When; <i>Am J Clin Pathol.</i> 2000;114:329-335.</li> <li>• Troxel, DB. Error in Surgical Pathology. <i>Am J Surg Pathol.</i> 2004;28:1092-1095.</li> <li>• Zardawi IM, Bennett G, Jain S, et al. Internal quality assurance activities of a surgical pathology department in an Australian teaching hospital. <i>J Clin Pathol.</i> 1998;51:695-699.</li> </ul>

**Quality Assurance Guideline -  
 External Consultation**

<b>Trigger:</b> Refer out appropriate cases for testing and consult that cannot be performed on site.	
<b>Principle/ Purpose</b>	<p>External consultation occurs when a surgical pathologist seeks an opinion from another pathologist/s external to their professional group.</p> <p>External consultation may be required due to lack of test menu or professional expertise on-site, or to resolve divergent opinions following an intra-departmental consultation.</p> <p>External consultation is distinguished from “external review” (see <a href="#">QA Guideline – External Review</a>) which occurs in a variety of circumstances; external review occurs after a final case report is issued, while external consultation occurs before a final diagnosis is rendered and a final case report issued.</p>
<b>Policy</b>	<p>As part of the <a href="#">Surgical Pathology Professional Quality Management Plan</a>, there should be a policy that outlines the procedure for requesting external consultation, including the review and documentation of the resulting consultation opinion.</p> <p>The <a href="#">Surgical Pathology Professional Quality Management Plan</a> should provide guidance as to the types of cases that are appropriate for external consult.</p> <p>The external consultation should be sought prior to final report sign-out. A preliminary report noting that an external consultation is being sought should be provided.</p> <p>The selection of an external consultant and/ or laboratory should be based primarily upon the quality of the service that will be provided. Prior to selection, and on an ongoing basis, the professional group should ensure that external consultants and laboratories are qualified to perform the requested services/ tests.</p> <p>The involvement of an external pathologist and/ or laboratory and the results of the consultation should be documented in the final reports of the cases in question.</p> <p>The professional group should have tracking and audit processes, to ensure that external consultations are sent as described, and that the related consultation reports are received, documented, and retained. Monitoring for outstanding cases should occur on a regular basis.</p>

	For quality assurance purposes, the external consultation should be forwarded to the case pathologist for review, whether or not the original pathologist finalizes the report.
<b>Exceptions</b>	None.
<b>Practice Type Considerations</b>	<ul style="list-style-type: none"> <li>• The types of cases requiring external consultation may depend on the typical caseload of the department, its test menu, and the availability of intra-departmental expertise.</li> <li>• When the case pathologist does not have significant subspecialty expertise external consultation outside of the province and/ or country may be required.</li> </ul>
<b>Responsibilities-Case Pathologist</b>	<ul style="list-style-type: none"> <li>• The case pathologist should determine the best preliminary diagnosis based on all the data available at the time.</li> <li>• When external consultation is sent-out, the case pathologist should:                     <ul style="list-style-type: none"> <li>• Choose an appropriate external laboratory and/ or consultant – available, and with the appropriate skills to deal with the consult.</li> <li>• Ensure the external laboratory and/ or consultant understands the reasons for the consult.</li> <li>• Provide the external laboratory/ consultant with the preliminary report for the case, and any other materials required for the consultation.</li> <li>• Communicate to the requesting clinician in the written preliminary report that an external consult is being sought, and the likely resultant diagnostic delay.</li> </ul> </li> <li>• Once the external consultation report is received, the case pathologist should document the external consult and involvement of the external laboratory/ pathologist, with their opinion, in the final case report.</li> <li>• See also <a href="#">Responsibilities of a Pathologist Requesting an External Consultation</a></li> </ul>
<b>Monitors</b>	<p>The <a href="#">Surgical Pathology Professional Quality Management Committee</a> should collect and review data on external consultations, for the professional group and for each pathologist. As data is collected, it should be compared to established benchmarks and trended over time.</p> <p><b>Minimum Requirements:</b></p> <ul style="list-style-type: none"> <li>• Number of external consults by professional group, compared with number of all cases in same time period</li> </ul> <p><b>Indicator Examples:</b></p> <ul style="list-style-type: none"> <li>• % of cases sent for external consultation</li> </ul> <p><b>Optional:</b></p> <ul style="list-style-type: none"> <li>• Number of external consults by individual pathologist, compared with number of all that individual's cases in same time period</li> <li>• Number of external consults by specific anatomic site or disease type, compared with number of all such cases in same time period</li> </ul>

	<p><b>Indicator Examples:</b></p> <ul style="list-style-type: none"> <li>• % of individual pathologist's cases with external consultation</li> <li>• % of cases of specific anatomic site or disease type that had external consultation</li> </ul> <p><b>Frequency:</b></p> <ul style="list-style-type: none"> <li>• Quarterly (or as appropriate for the group)</li> </ul>
<p><b>Associated Documents</b></p>	<ul style="list-style-type: none"> <li>• <a href="#">Surgical Pathology Professional Quality Management Guideline</a></li> <li>• <a href="#">Surgical Pathology Professional Quality Management Committee Terms of Reference</a></li> <li>• <a href="#">Foundational Elements</a></li> <li>• <a href="#">QA Guideline – External Review</a></li> </ul>
<p><b>References</b></p>	<ul style="list-style-type: none"> <li>• Association of Directors of Anatomic and Surgical Pathology. Recommendations for Quality Assurance and Improvement in Surgical and Autopsy Pathology. <i>Am J Clin Pathol.</i> 2006;126:337-340.</li> <li>• Azam M, Nakhleh RE. CAP Laboratory Improvement Programs. Surgical Pathology Extradepartmental Consultation Practices. A College of American Pathologists Q-Probes Study of 2746 Consultations From 180 Laboratories. <i>Arch Pathol Lab Med.</i> 2002;126:405-412.</li> <li>• College of American Pathologists Commission on Laboratory Accreditation. Anatomical Pathology Checklist. Northfield, Ill: College of American Pathologists; 2010.</li> <li>• College of American Pathologists Commission on Laboratory Accreditation. Laboratory General Checklist. Northfield, Ill: College of American Pathologists; 2010.</li> <li>• Nakhleh RE, Fitzgibbons PL. Quality Management in Anatomic Pathology. Promoting Patient Safety Through Systems Improvement and Error Reduction. Northfield, IL: College of American Pathologists; 2005.</li> <li>• Raab SR, Grzybicki DM. Quality in Cancer Diagnosis. <i>CA Cancer J Clin.</i> 2010;60:139-165.</li> <li>• Raab SS, Grzybicki DM, Mahood LK, et al. Effectiveness of Random and Focused Review in Detecting Surgical Pathology Error. <i>Am J Clin Pathol.</i> 2008;130:905-912.</li> <li>• Renshaw AA, Gould EW. Measuring the Value of Review of Pathology Material by a Second Pathologist. <i>Am J Clin Pathol.</i> 2006;125:737-739.</li> <li>• The Royal College of Pathologists of Australia. Provision of Second and Subsequent Opinions with Particular Reference to Histopathology Cytology &amp; Specimens for Morphological Examinations. Revised March 2007. Number 2/1999.</li> <li>• Tomaszewski JE, Bear HD, Connally JA, et al. Consensus Conference on Second Opinions in Diagnostic Anatomic Pathology Who, What, and When; <i>Am J Clin Pathol.</i> 2000;114:329-335.</li> <li>• Troxel, DB. Error in Surgical Pathology. <i>Am J Surg Pathol.</i> 2004;28:1092-1095.</li> </ul>

**Quality Assurance Guideline -  
 Intra-operative Consultation**

<b>Trigger:</b> Review and correlate intra-operative consults with current case.	
<b>Principle/ Purpose</b>	<p>Intra-operative consultations include rapid interpretations with gross and, in many cases, microscopic (frozen section) examinations. Other techniques may be employed, depending on specimen type.</p> <p>The correlation of intra-operative consultation materials with more permanent preparations and their associated final diagnoses is necessary to resolve discrepancies between the different techniques.</p> <p>Review of discordances aids in the measure of intra-operative consultation performance and improves recognition of morphologic alterations related to the various techniques employed.</p> <p>Rates of deferred diagnoses should also be reviewed as the rates vary depending upon expertise, types of specimens and resections encountered by a professional group.</p>
<b>Policy</b>	<p>As part of the <a href="#">Surgical Pathology Professional Quality Management Plan</a>, there should be a policy that outlines the processes for, and the documentation of, the comparison of intra-operative consultation results with final diagnoses.</p> <p>The review should include an analysis of the turnaround times required for intra-operative consultations.</p> <p>The review should include an analysis of those diagnoses deferred, and the appropriateness of that deferral.</p> <p>See also <a href="#">Guidelines for Review of Previously Reported Cases</a>, <a href="#">Guidelines for Dealing with Report Defects/ Discrepancies/ Discordances/ Errors</a>, and <a href="#">Guidelines on Classification of Report Defects/ Discrepancies/ Discordances/ Errors</a>.</p>
<b>Exceptions</b>	<ul style="list-style-type: none"> <li>• Certain specialized studies or cases, such as Moh frozen sections, may be exempt from the process.</li> <li>• Deferred diagnoses should not be considered discordant results.</li> </ul>
<b>Practice Type Considerations</b>	<p>This guideline applies to all types of practice.</p>
<b>Responsibilities - Intra-operative Consult Pathologist</b>	<ul style="list-style-type: none"> <li>• Refer to <a href="#">Intra-operative Consultation Patient Safety Checklist</a> prior to providing a report to the clinician.</li> <li>• When report defects or discordances are revealed, the case pathologist should participate in their investigation and resolution, according to the policies and processes the professional group usually employs.</li> </ul>

<p><b>Responsibilities - Case Pathologist</b></p>	<ul style="list-style-type: none"> <li>• When practical (this may depend on the size of the professional group) it is preferable that the case pathologist be another pathologist (and not the same individual as the intra-operative consult pathologist)</li> <li>• The case pathologist should compare both the intra-operative consult report and materials with the permanent material.</li> <li>• This review and comparison should be documented in the final case report and should include comment on any inconsistencies or discordances.</li> </ul>
<p><b>Monitors</b></p>	<p>The <a href="#">Surgical Pathology Professional Quality Management Committee</a> should collect and review data on the appropriateness and accuracy of intra-operative consults and deferral rates, for the professional group and for each pathologist. As data is collected, it should be compared to established benchmarks and trended over time.</p> <p><b>Minimum Requirements:</b></p> <ul style="list-style-type: none"> <li>• Number of cases where review of the intra-operative consultation revealed report defects or diagnostic discordances of various kinds, compared with number of all cases in same time period, for professional group overall</li> <li>• Number of cases where intra-operative consultation diagnosis deferred (sub-classified as appropriate or inappropriate), compared with number of all cases in same time period, for professional group overall</li> <li>• Times from specimen receipt to intra-operative consult report (may be defined by the group as verbal or written report to the clinician), for professional group overall</li> </ul> <p><b>Indicator Examples:</b></p> <ul style="list-style-type: none"> <li>• % of cases with report defects or diagnostic discordances of various kinds, for professional group overall</li> <li>• % of cases with deferred diagnosis (sub-classified as appropriate or inappropriate), for professional group overall</li> <li>• Mean turnaround time, for professional group overall</li> </ul> <p><b>Optional:</b></p> <ul style="list-style-type: none"> <li>• Number of cases where review of the intra-operative consultation revealed report defects or diagnostic discordances of various kinds, compared with number of all cases in same time period, by individual pathologist</li> <li>• Number of cases where intra-operative consultation diagnosis deferred (sub-classified as appropriate or inappropriate), compared with number of all cases in same time period, for individual pathologist</li> <li>• Times from specimen receipt to intra-operative consult report (may be defined by the group as verbal or written report to the clinician), by individual pathologist</li> <li>• Times from when intra-operative material available to pathologists to intra-operative consult report, for professional group overall</li> <li>• Times from when intra-operative material available to pathologists to intra-operative consult report, by individual pathologist</li> </ul>

	<ul style="list-style-type: none"> <li>• Further analysis of the above by specific anatomic site or disease type, or for other attributes</li> </ul> <p><b>Indicator Examples:</b></p> <ul style="list-style-type: none"> <li>• % of cases with report defects or diagnostic discordances of various kinds, by individual pathologist</li> <li>• % of cases with deferred diagnosis (sub-classified as appropriate or inappropriate), by individual pathologist</li> <li>• Mean turnaround time, by individual pathologist</li> </ul> <p><b>Frequency:</b></p> <ul style="list-style-type: none"> <li>• Monthly (or as appropriate for the group)</li> </ul>
<p><b>Associated Documents</b></p>	<ul style="list-style-type: none"> <li>• <a href="#">Surgical Pathology Professional Quality Management Guideline</a></li> <li>• <a href="#">Surgical Pathology Professional Quality Management Committee Terms of Reference</a></li> <li>• <a href="#">Intra-operative Consult Patient Safety Checklist</a></li> <li>• <a href="#">Foundational Elements</a></li> <li>• <a href="#">QA Guideline – External Review</a></li> </ul>
<p><b>References</b></p>	<ul style="list-style-type: none"> <li>• AP Quality Document # 170-20-02, Version 1, Diagnostic Services of Manitoba.</li> <li>• Association of Directors of Anatomic and Surgical Pathology. Recommendations for Quality Assurance and Improvement in Surgical and Autopsy Pathology. <i>Am J Clin Pathol.</i> 2006;126:337-340.</li> <li>• Coffin CM, Spilker K, Xhou H, et al. Frozen Section Diagnosis in Pediatric Surgical Pathology. A Decade's Experience in a Children's Hospital. <i>Arch Pathol Lab Med.</i> 2005;129:1619-1625.</li> <li>• College of American Pathologists Commission on Laboratory Accreditation. Anatomical Pathology Checklist. Northfield, Ill: College of American Pathologists; 2010.</li> <li>• College of American Pathologists Commission on Laboratory Accreditation. Laboratory General Checklist. Northfield, Ill: College of American Pathologists; 2010.</li> <li>• Ferreiro JA, Myers JL, Bostwick DG. Accuracy of Frozen Section Diagnosis in Surgical Pathology: Review of a 1-Year Experience With 24,880 Cases at Mayo Clinic Rochester. <i>Mayo Clin Proc.</i> 1995;70:1137-1141.</li> <li>• Gephardt GN, Zarbo RJ. Interinstitutional Comparison of Frozen Section Consultations. <i>Arch Pathol Lab Med.</i> 1996;120:804-809.</li> <li>• Nakhleh RE. What is quality in surgical pathology? <i>J Clin Pathol.</i> 2006;59:669-672.</li> <li>• Nakhleh RE, Fitzgibbons PL. Quality Management in Anatomic Pathology. Promoting Patient Safety Through Systems Improvement and Error Reduction. Northfield, IL: College of American Pathologists; 2005.</li> <li>• Novis DA, Zarbo MD. Interinstitutional Comparison of Frozen Section Turnaround Time. A College of American Pathologists Q-Probes Study of 32868 Frozen Sections in 700 Hospitals. <i>Arch Pathol Lab Med.</i> 1997;121:559-567.</li> <li>• Ontario Laboratory Accreditation Requirements and Guidance Information, Version 5.0, December, 2010.</li> <li>• Ozdamar SO, Bahadir B, Ekem TE, et al. Frozen section experience with emphasis on reasons for discordance. <i>Turkish J Cancer.</i> 2006;36(4):157-161.</li> <li>• Raab SS, Grzybicki DM, Zarbo RJ, et al. Anatomic Pathology Databases and</li> </ul>

	<p>Patient Safety. <i>Arch Pathol Lab Med.</i> 2005;129:1246-1251.</p> <ul style="list-style-type: none"><li>• Raab SS, Tworek JA, Sourers BS, et al. The Value of Monitoring Frozen Section-Permanent Section Correlation Data Over Time. <i>Arch Pathol Lab Med.</i> 2006; 30:337-342.</li><li>• Taxy JB. Frozen Section and the Surgical Pathologist. A Point of View. <i>Arch Pathol Lab Med.</i> 2009;133:1135-1138.</li><li>• The Working Group of Histopathology QA Guidelines, Faculty of Pathology. Guidelines for the Implementation of a National QA Programme in Histopathology – Version 3.0. Royal College of Physicians of Ireland. 1-26.</li></ul>
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**Quality Assurance Guideline -  
 Previous Surgical Pathology/ Cytology**

<b>Trigger:</b> Review and correlate previous surgical/ cytology reports with current case.	
<b>Principle/ Purpose</b>	<p>Comparison and correlation of a current case with previous surgical pathology and cytology reports (and, if required, related slides or other material) is an integral component of a quality assurance/ quality improvement program since it may help determine the most appropriate diagnosis for the current case.</p> <p>Additionally, that comparison and correlation may detect report defects or diagnostic discrepancies in the previous surgical pathology and cytology reports.</p>
<b>Policy</b>	<p>As part of the <a href="#">Surgical Pathology Professional Quality Management Plan</a>, there should be a policy that outlines the procedure for correlation of current surgical pathology cases with pertinent previous surgical pathology and cytology cases from the index patient.</p> <p>Only those reports, slides or other materials immediately relevant to a current case need be reviewed in detail. In determination of the relevance of the latter the case pathologist exercises professional discretion.</p> <p>See also <a href="#">Guidelines for Review of Previously Reported Cases</a>, <a href="#">Guidelines for Dealing with Report Defects/ Discrepancies/ Discordances/ Errors</a>, and <a href="#">Guidelines on Classification of Report Defects/ Discrepancies/ Discordances/ Errors</a>.</p>
<b>Exceptions</b>	<p>In some cases it may be that the previous surgical pathology and cytology reports and other materials originate from another institution or professional group. If report defects or other discrepancies are found in such material they should not be included in quality assurance monitoring for the professional group dealing with the current case (they should, however, be brought to the attention of the other institution or professional group, in order that those defects or discrepancies may be part of that other group's quality reporting program).</p>
<b>Practice Type Considerations</b>	<p>This guideline applies to all types of practice.</p>
<b>Responsibilities - Case Pathologist</b>	<p>The case pathologist should review those previous reports and/ or material required to adequately interpret a current case.</p>
<b>Responsibilities - Original Pathologist</b>	<p>When report defects or discordances are revealed, the case pathologist should participate in their investigation and resolution, according to the policies and processes the professional group usually employs.</p>
<b>Monitors</b>	<p>The <a href="#">Surgical Pathology Professional Quality Management Committee</a> should collect and review data on report defect and discordances revealed by review of previous surgical pathology and cytology cases, for the professional group and for each pathologist. As data is collected, it should be compared to established benchmarks and trended over time.</p>

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	<p><b>Minimum Requirements:</b></p> <ul style="list-style-type: none"> <li>• Number of cases where review of previous surgical pathology or cytology reports or materials revealed report defects or diagnostic discordances of various kinds, compared with number of all cases in same time period, for professional group overall</li> </ul> <p><b>Indicator Example:</b></p> <ul style="list-style-type: none"> <li>• % of cases with report defects or diagnostic discordances of various kinds, for professional group overall</li> </ul> <p><b>Optional:</b></p> <ul style="list-style-type: none"> <li>• Number of cases where review of previous surgical pathology or cytology reports or materials revealed report defects or diagnostic discordances of various kinds, compared with number of all cases in same time period, by individual pathologist</li> <li>• Further analysis of the above by specific anatomic site or disease type</li> </ul> <p><b>Indicator Example:</b></p> <ul style="list-style-type: none"> <li>• % of cases with report defects or diagnostic discordances of various kinds, by individual pathologist</li> </ul> <p><b>Frequency:</b></p> <ul style="list-style-type: none"> <li>• Quarterly (or as appropriate to the group)</li> </ul>
<p><b>Associated Documents</b></p>	<ul style="list-style-type: none"> <li>• <a href="#">Surgical Pathology Professional Quality Management Guideline</a></li> <li>• <a href="#">Surgical Pathology Professional Quality Management Committee</a></li> <li>• <a href="#">Foundational Elements</a></li> </ul>
<p><b>References</b></p>	<ul style="list-style-type: none"> <li>• Association of Directors of Anatomic and Surgical Pathology. Recommendations for Quality Assurance and Improvement in Surgical and Autopsy Pathology. <i>Am J Clin Pathol.</i> 2006;126:337-340.</li> <li>• College of American Pathologists Commission on Laboratory Accreditation. Anatomical Pathology Checklist. Northfield, Ill: College of American Pathologists; 2010.</li> <li>• College of American Pathologists Commission on Laboratory Accreditation. Laboratory General Checklist. Northfield, Ill: College of American Pathologists;2010.</li> <li>• Nakhleh RE, Fitzgibbons PL. Quality Management in Anatomic Pathology. Promoting Patient Safety Through Systems Improvement and Error Reduction. Northfield, IL: College of American Pathologists; 2005.</li> <li>• Ontario Laboratory Accreditation Requirements and Guidance Information, Version 5.0, December, 2010.</li> <li>• Raab SR, Grzybicki DM. Quality in Cancer Diagnosis. <i>CA Cancer J Clin.</i> 2010;60:139-165.</li> <li>• Raab SS, Grzybicki DM, Zarbo RJ, et al. Anatomic Pathology Databases and Patient Safety. <i>Arch Pathol Lab Med.</i> 2005; 129: 1246-1251.</li> <li>• Tomaszewski JE, Bear HD, Connally JA, et al. Consensus Conference on Second Opinions in Diagnostic Anatomic Pathology Who, What, and When; <i>Am J Clin Pathol.</i> 2000;114:329-335.</li> </ul>

**Quality Assurance Guideline -  
 Utilization and Compliance**

<b>Trigger:</b> Technical and other supportive services are utilized responsibly.	
<b>Principle/ Purpose</b>	<p>Surgical pathologists should be up-to-date with, and use, the ancillary tests and procedures required for surgical pathologic diagnosis at contemporary standards, and they should be familiar with the standardized reporting requirements of those who use information in surgical pathology reports for patient care.</p> <p>Underuse of ancillary tests and procedures may provide insufficient information for appropriate patient care. Overuse may result in inappropriate costs and resource depletion.</p> <p>Standardization of report format and of the various elements in the surgical pathology reports for varied types of cases will help ensure that all the data elements required for clinical care are included, that the reports are more readily understood, clinically relevant, and suitable for quality monitoring.</p>
<b>Policy</b>	<p>As part of the <a href="#">Surgical Pathology Professional Quality Management Plan</a>, there should be a policy that describes when and how ancillary tests and procedures should be employed for various types of cases, and processes for monitoring same.</p> <p>As part of the <a href="#">Surgical Pathology Professional Quality Management Plan</a>, there should be a policy that describes report formatting, and the various elements expected in the surgical pathology reports for varied types of cases; the plan should include processes for monitoring same.</p> <p>The <a href="#">Surgical Pathology Professional Quality Management Committee</a> should develop, where appropriate, diagnostic algorithms or so-called tissue pathways, based on available “best evidence” that help guide policies for the above.</p>
<b>Exceptions</b>	<p>Cases such as those sent for external consultation and cases that, as part of a group’s standard protocols, may not follow standard work processes may be excluded from analysis by the professional group.</p>
<b>Practice Type Considerations</b>	<ul style="list-style-type: none"> <li>• The required ancillary tests and procedures may not be available to all professional groups. External consultation may be needed to accomplish the required case workup.</li> <li>• The laboratory and professional group providing the ancillary testing in external consult must be appropriately credentialed for this work.</li> <li>• The professional group may choose to monitor specific types of cases and</li> </ul>

	<p>diagnostic algorithms/ 'tissue pathways' depending on clinical needs, perceived issues, or changes in practice.</p>
<p><b>Responsibilities - Case Pathologist</b></p>	<p>The case pathologist should ensure that appropriate diagnostic algorithms/ tissue pathways are followed and that appropriate ancillary tests/ procedures are employed, or requested in external consultation.                  The case pathologist should ensure that the formatting of their surgical pathology reports is at the standard defined by their professional group, and that the various elements expected in them are included.</p>
<p><b>Monitors</b></p>	<p>The <a href="#">Surgical Pathology Professional Quality Management Committee</a> should collect and review data on compliance with diagnostic algorithms/ tissue pathways, ancillary test/ procedure utilization, and on report formatting and completeness, for the professional group and for each pathologist. As data is collected, it should be compared to established benchmarks and trended over time.</p> <p><b>Minimum Requirements:</b></p> <ul style="list-style-type: none"> <li>• Number of cases where selected ancillary tests/ procedures defined by various protocols were used, compared with number of all cases in same time period, for professional group overall</li> <li>• Number of cases where selected report type had appropriate format and was complete, compared with number of all cases in same time period, for professional group overall</li> </ul> <p><b>Indicator Examples:</b></p> <ul style="list-style-type: none"> <li>• % of cases where selected ancillary tests/ procedures defined by various protocols were used, for professional group overall</li> <li>• % of cases where selected report type had appropriate format and was complete, for professional group overall</li> </ul> <p><b>Optional:</b></p> <ul style="list-style-type: none"> <li>• Number of cases where selected ancillary tests/ procedures defined by various protocols were used, by individual pathologist</li> <li>• Number of cases where selected report type had appropriate format and was complete, compared with number of all cases in same time period, by individual pathologist</li> <li>• Further analysis of the above, determined by needs of the professional group</li> </ul> <p><b>Indicator Examples:</b></p> <ul style="list-style-type: none"> <li>• % of cases where selected ancillary tests/ procedures defined by various protocols were used, by individual pathologist</li> <li>• % of cases where selected report type had appropriate format and was complete, by individual pathologist</li> </ul> <p><b>Frequency:</b></p> <ul style="list-style-type: none"> <li>• Quarterly (or as appropriate for the group)</li> </ul>

<b>Associated Documents</b>	<ul style="list-style-type: none"><li>• <a href="#">Surgical Pathology Professional Quality Management Guideline</a></li><li>• <a href="#">Surgical Pathology Professional Quality Management Committee Terms of Reference</a></li><li>• <a href="#">Foundational Elements</a></li></ul>
<b>References</b>	<ul style="list-style-type: none"><li>• Cook IS, McCormick D, Poller DN. Referrals for second opinion in surgical pathology: implications for management of cancer patients in the UK. PubMed Abstract. <i>Eur J Surg Oncol.</i> 2001;27:589-594.</li><li>• Howard D, Anderson D. Patient Safety: Demand for Change in Anatomic Pathology. <i>Washington Healthcare News.</i> 2009;4:1-4.</li><li>• Jambhekar NA, Chaturvedi AC, Madur BP. Immunohistochemistry in surgical pathology practice: A current perspective of a simple, powerful, yet complex tool. Review Article. <i>Indian J Pathol&amp; Micro.</i> 2008;51:2-11.</li><li>• Price C. Evidence-based Laboratory Medicine: Supporting Decision-Making. <i>Clinical Chemistry.</i> 2000;46:1041-1050.</li><li>• Zhao JJ, Liberman A. Pathologists' Roles in Clinical Utilization Management. A Financing Model for Managed Care. <i>Am J Clin Pathol.</i> 2000;113:336-342.</li></ul>

**Quality Assurance Guideline -  
 External Review**

<b>Trigger:</b> Previously finalized cases are reviewed externally in a variety of circumstances.	
<b>Principle /Purpose</b>	<p>External reviews occur when there is a request by a pathologist, clinician, institution (e.g. cancer clinic), or patient to have a case reviewed by a laboratory or pathologist/s external to the one in which the case was originally reported.</p> <p>External reviews may be required to clarify information for patient treatment or may be a <i>pro forma</i> requirement of an institution. They may also be requested by a clinician or patient as a second opinion.</p> <p>External review is distinguished from “external consultation” (see <a href="#">QA Guideline – External Consultation</a>) which occurs in a variety of circumstances; external consultation occurs before a final case report is issued, while external review occurs after a final diagnosis is rendered and a final case report issued.</p>
<b>Policy</b>	<p>As part of the <a href="#">Surgical Pathology Professional Quality Management Plan</a>, there should be a policy that outlines the processes for handling requests for review of cases by an external pathologist including the documentation and review of those results.</p> <p>When the results of an external review are received the original report should be reviewed and compared with it.</p> <p>The external review may be documented in the report of the case in question – if so, most often this will require an addendum report. After an external review the case pathologist determines whether new clinically relevant information is available as a result, and determines if an addendum report is required.</p> <p>The professional group should have tracking and audit processes, to ensure that external reviews are sent, and that the related review reports are received, documented, and retained. Monitoring for outstanding cases should occur on a regular basis.</p> <p>For quality assurance purposes, the external review should be forwarded to the case pathologist for review, whether or not the original pathologist finalizes the report.</p> <p>See also <a href="#">Guidelines for Review of Previously Reported Cases</a>, <a href="#">Guidelines for Dealing with Report Defects/ Discrepancies/ Discordances/ Errors</a>, and <a href="#">Guidelines on Classification of Report Defects/ Discrepancies/ Discordances/</a></p>

	<a href="#">Errors.</a>
<b>Exceptions</b>	None
<b>Practice Type Considerations</b>	This guideline applies to all types of practice.
<b>Responsibilities-Case Pathologist</b>	<ul style="list-style-type: none"> <li>• When a request for an external review is received the case pathologist should review the original material and determine the appropriate slides and/ or blocks and/ or other material to be sent for external review.</li> <li>• When the external review is returned the case pathologist should review the consultant's opinion and document that review. In most cases this will require an addendum report.</li> <li>• When report defects or discordances are revealed, the case pathologist should participate in their investigation and resolution, according to the policies and processes the professional group usually employs.</li> </ul>
<b>Monitors</b>	<p>The <a href="#">Surgical Pathology Professional Quality Management Committee</a> should collect and review data on report defect and discordances revealed by external reviews, for the professional group and for each pathologist. As data is collected, it should be compared to established benchmarks and trended over time.</p> <p><b>Minimum Requirements:</b></p> <ul style="list-style-type: none"> <li>• Number of cases where external review revealed report defects or diagnostic discordances, compared with number of all cases in same time period, for professional group overall</li> </ul> <p><b>Indicator Example:</b></p> <ul style="list-style-type: none"> <li>• % of cases with report defects or diagnostic discordances, for professional group overall</li> </ul> <p><b>Optional:</b></p> <ul style="list-style-type: none"> <li>• Number of cases where external review revealed report defects or diagnostic discordances, compared with number of all cases in same time period, by individual pathologist</li> <li>• Further analysis of the above by specific anatomic site or disease type</li> </ul> <p><b>Indicator Example:</b></p> <ul style="list-style-type: none"> <li>• % of cases with report defects or diagnostic discordances, by individual pathologist</li> </ul> <p><b>Frequency:</b></p> <ul style="list-style-type: none"> <li>• Quarterly (or as appropriate for the group)</li> </ul>

<p><b>Associated Documents</b></p>	<ul style="list-style-type: none"> <li>• <a href="#">Surgical Pathology Professional Quality Management Guideline</a></li> <li>• <a href="#">Surgical Pathology Professional Quality Management Committee Terms of Reference</a></li> <li>• <a href="#">Foundational Elements</a></li> <li>• <a href="#">QA Guideline – External Consultation</a></li> </ul>
<p><b>References</b></p>	<ul style="list-style-type: none"> <li>• Association of Directors of Anatomic and Surgical Pathology. Recommendations for Quality Assurance and Improvement in Surgical and Autopsy Pathology. <i>Am J Clin Pathol.</i> 2006;126:337-340.</li> <li>• Azam M, Nakhleh RE. CAP Laboratory Improvement Programs. Surgical Pathology Extradepartmental Consultation Practices. A College of American Pathologists Q-Probes Study of 2746 Consultations From 180 Laboratories. <i>Arch Pathol Lab Med.</i> 2002;126:405-412.</li> <li>• College of American Pathologists Commission on Laboratory Accreditation. Anatomical Pathology Checklist. Northfield, Ill: College of American Pathologists; 2010.</li> <li>• College of American Pathologists Commission on Laboratory Accreditation. Laboratory General Checklist. Northfield, Ill: College of American Pathologists; 2010.</li> <li>• Nakhleh RE, Fitzgibbons PL. Quality Management in Anatomic Pathology. Promoting Patient Safety Through Systems Improvement and Error Reduction. Northfield, IL: College of American Pathologists; 2005.</li> <li>• Raab SR, Grzybicki DM. Quality in Cancer Diagnosis. <i>CA Cancer J Clin.</i> 2010;60:139-165.</li> <li>• Raab SS, Grzybicki, DM, Mahood LK, et al. Effectiveness of Random and Focused Review in Detecting Surgical Pathology Error. <i>Am J Clin Pathol.</i> 2008;130:905-91.</li> <li>• Renshaw AA, Gould EW. Measuring the Value of Review of Pathology Material by a Second Pathologist, <i>Am J Clin Pathol.</i> 2006;125:737-739.</li> <li>• The Royal College of Pathologists of Australasia. Provision of Second and Subsequent Opinions with Particular Reference to Histopathology Cytology &amp; Specimens for Morphological Examinations. Revised March 2007. Number 2/1999.</li> <li>• Tomaszewski JE, Bear HD, Connally JA, et al. Consensus Conference on Second Opinions in Diagnostic Anatomic Pathology Who, What, and When; <i>Am J Clin Pathol.</i> 2000;114:329-335.</li> <li>• Troxel, DB. Error in Surgical Pathology. <i>Am J Surg Pathol.</i> 2004;28:1092-1095.</li> </ul>

**Quality Assurance Guideline -  
 Addendum Reports, including Those Documenting  
 Revisions and Corrections**

<b>Trigger:</b> Addendum reports are issued, including those documenting report revisions and corrections.	
<b>Principle/ Purpose</b>	<p>After case sign-out, new information may become available that should be documented in the report for future reference, or some other revision or correction in the original report may be required.</p> <p>The requirement for an addendum report may be anticipated at the time of case sign-out, or may be unanticipated.</p> <p>By monitoring the rates of unanticipated addendum reports (especially those issued for revisions or corrections) and the reasons for same, quality improvement opportunities can be identified and implemented to decrease those rates.</p> <p>In some professional groups, and sometimes dictated by the information system used, addendum reports may be referred to by other names (e.g. supplemental reports or similar).</p> <p>In some professional groups, revised or corrected reports may be referred to by other terminology (e.g. amended reports or similar).</p> <p>In any case the principles outlined below should apply – of paramount importance is that the users of the reports in question are clear about the meaning/ implications of, and the processes related to, the issuing of such reports.</p>
<b>Policy</b>	<p>As part of the <a href="#">Surgical Pathology Professional Quality Management Plan</a>, there should be a policy that outlines the criteria for issuing addendum reports, the processes for issuing them, the documentation required when they are issued, and related follow-up quality assurance actions.</p> <p>Addendum reports should be issued if:</p> <ul style="list-style-type: none"> <li>• New information becomes available (for instance, as a result of the immunohistochemistry, external consultation, etc.) which was anticipated/ planned at the time of issuing the original report:             <ul style="list-style-type: none"> <li>• With this form of addendum report, it is preferable that at the time of original report sign-out the anticipated addendum report is described and referred to in the diagnosis.</li> <li>• In some instances it will be appropriate to indicate a degree of uncertainty with respect to the diagnosis in the original report if</li> </ul> </li> </ul>

	<p>further investigations are being performed.</p> <ul style="list-style-type: none"><li>• The case is discussed with a clinician after issuing the original report.</li><li>• New information becomes available after issuing the original report (for instance, as the result of provision of further history, as the result of external review, as the result of a case conference, etc.) which was not planned for or anticipated at the time of the original report verification.</li></ul> <p>In some of the various circumstances that addendum reports are issued there will be circumstances when the originally rendered diagnosis requires revision or correction, either because the diagnosis (or some other element of the report) was known to be incomplete at the time the original report was issued, or because new information becomes available which was not anticipated at the time the original report was issued.</p> <p>As part of its <a href="#">Surgical Pathology Professional Quality Management Plan</a>, the professional group should have a policy that outlines the criteria for revising or correcting reports, including those in which diagnoses are revised or corrected. This policy should include definitions of the terms employed by the group for such reports, criteria for their use, the procedures and documentation required to issue them, and related follow-up quality assurance actions.</p> <p>If a diagnosis is revised or corrected, this should be clearly indicated in the addendum report, preferably with an explanation of the background for the revision or correction.</p> <p>An addendum report containing a revision or correction should be issued as soon as possible. It should be explained clearly in the report that it is replacing a previously generated report. This should apply to all paper reports as well as to data that are displayed in laboratory information systems or other clinical information systems.</p> <p>Computer records should allow for the retention of the original and addendum reports. In the event that computer system cannot capture amendments, an audit log may be used, and its existence referred to in the addendum report.</p> <p>The original report shall not be erased, made illegible or deleted from the record. The original report will be kept in such a way as to ensure that it is not confused with the revised or corrected report.</p> <p>In those cases where a report revision or correction might impact patient care, impact the reputation of the professional group, or confuse the clinician, it will be appropriate to directly inform the responsible clinician of the revision or correction (e.g. by verbal communication), and to document that communication in the addendum report.</p>
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	<p>An important part of the policies governing issuing revised and corrected reports should be defined policies and procedures for notification of the Laboratory Director (or depending on a group’s policies, the Chair of the SPPQMC), and through the Laboratory Director (or Chair, SPPQMC) initiation of critical incident and similar reporting where appropriate.</p> <p>Remedial, corrective, and/or preventative action should be implemented, if required.</p> <p>Based on the host organization’s incident reporting process, revised or corrected reports may also have to be documented for risk management, root cause analysis and quality improvement purposes via that organization’s processes.</p> <p>See also <a href="#">Guidelines for Review of Previously Reported Cases</a>, <a href="#">Guidelines for Dealing with Report Defects/ Discrepancies/ Discordances/ Errors</a>, and <a href="#">Guidelines on Classification of Report Defects/ Discrepancies/ Discordances/ Errors</a>.</p>
<b>Exceptions</b>	None
<b>Practice Type Considerations</b>	This guideline applies to all types of practice.
<b>Responsibilities - Case Pathologist</b>	The pathologist follows the professional group’s policy for issuing addendum reports, including those with revisions and corrections, including communicating with the clinician, completing all related documentation, and following all related quality assurance processes.
<b>Monitors</b>	<p>The <a href="#">Surgical Pathology Professional Quality Management Committee</a> should collect and review data on addendum reports that include corrections and the reasons for the corrections, for the professional group and for individual pathologists. As data is collected, it should be compared to established benchmarks for the professional group and trended over time.</p> <p><b>Minimum Requirements:</b></p> <ul style="list-style-type: none"> <li>• Number of addendum (e.g., corrected) reports of various kinds, compared with number of all cases in same time period, for professional group overall</li> </ul> <p><b>Indicator Example:</b></p> <ul style="list-style-type: none"> <li>• % of corrected reports of various kinds, for professional group overall</li> </ul> <p><b>Optional:</b></p> <ul style="list-style-type: none"> <li>• Number of addendum (e.g., corrected) reports of various kinds, compared with number of all cases in same time period, by individual pathologist</li> <li>• Further analysis of the above by specific anatomic site or disease type, or for other attributes</li> </ul>

	<p><b>Indicator Example:</b></p> <ul style="list-style-type: none"> <li>• % of corrected reports of various kinds, by individual pathologist</li> </ul> <p><b>Frequency:</b></p> <ul style="list-style-type: none"> <li>• Monthly (or as appropriate for the group)</li> </ul>
<p><b>Associated Documents</b></p>	<ul style="list-style-type: none"> <li>• <a href="#">Surgical Pathology Professional Quality Management Guideline</a></li> <li>• <a href="#">Surgical Professional Quality Management Committee Terms of Reference</a></li> <li>• <a href="#">Foundational Elements</a></li> </ul>
<p><b>References</b></p>	<ul style="list-style-type: none"> <li>• CAP Laboratory Patient Safety Plan; Updated August 10, 2009. <a href="http://www.cap.org/apps/cap.portal? nfpb=true&amp;cntvwrPtlit_actionOverride=%2Fportlets%2FcontentViewer%2Fshow&amp; windowLabel=cntvwrPtlit&amp;cntvwrPtlit{actionForm.contentReference}=patient_safety%2Flaboratory_patient_safety_plan.html&amp; state=maximized&amp; pageLabel=cntvwr">http://www.cap.org/apps/cap.portal? nfpb=true&amp;cntvwrPtlit_actionOverride=%2Fportlets%2FcontentViewer%2Fshow&amp; windowLabel=cntvwrPtlit&amp;cntvwrPtlit{actionForm.contentReference}=patient_safety%2Flaboratory_patient_safety_plan.html&amp; state=maximized&amp; pageLabel=cntvwr</a></li> <li>• Clinical Pathology Accreditation (UK) Ltd. Standards for the Medical Laboratory. PD-LAB-Standards v2.01. Mar 2009.1-58. <a href="http://www.cpa-uk.co.uk/files/PD-LAB-Standards_v2.01_Mar_09.pdf">http://www.cpa-uk.co.uk/files/PD-LAB-Standards_v2.01_Mar_09.pdf</a></li> <li>• College of American Pathologists Commission on Laboratory Accreditation. Laboratory General Checklist. Northfield, Ill: College of American Pathologists; 2010.</li> <li>• Hilborne, L. Examining amended reports in surgical pathology. <i>Arch Pathol Lab Med.</i> 1998;122:303-309.</li> <li>• Kempson R., Rosai J. Standardization of the Surgical Pathology Report. ASACP. <i>Am J Surg Pathol.</i> 1992;16:84-86 and <i>Mod Pathol.</i> 1992;5:197-199.</li> <li>• Meier FA, Zarbo RJ, Varney RC, et al. Amended Reports. Development and Validation of Taxonomy of Defects. <i>Am J Clin Pathol.</i> 2008;130:238-246.</li> <li>• Nakhleh RE, Gephardt G, Zarbo RJ. Necessity of Clinical Information in Surgical Pathology. A College of American Pathologist Q-Probes Study of 771,475 Surgical Pathology Cases from 341 Institutions. <i>Arch Pathol Lab Med.</i> 1999;123:615-619.</li> <li>• Nakhleh RE, Zarbo RJ. Amended Reports in Surgical Pathology and Implications for Diagnostic Error Detection and Avoidance. A College of American Pathologists Q-Probes Study of 1,667,547 Accessioned Cases in 359 Laboratories. <i>Arch Pathol Lab Med.</i> 1998;122:303-309.</li> <li>• Nakhleh RE. What is quality in surgical pathology? <i>J Clin Pathol.</i> 2006;59:669-672.</li> <li>• Nakhleh, RE, Fitzgibbons PL, editors. Quality Management in Anatomic Pathology – Promoting Patient Safety Through Systems Improvement and Error Reduction. College of American Pathologists. 2005.</li> <li>• Novis DA, Konstantakos G. Reducing Errors in the Practice of Pathology and Laboratory Medicine. An Industrial Approach. <i>Am J Clin Pathol.</i> 2006;126:S30-S35.</li> <li>• Ontario Laboratory Accreditation Requirements and Guidance Information July 2008, Version 4.1.</li> <li>• Shahram S, Snyder S. Laboratory Medicine Quality Indicators, A Review of the Literature. <i>Am J Clin Pathol.</i> 2009;131:418-431.</li> <li>• The Working Group of Histopathology QA Guidelines, Faculty of Pathology. Guidelines for the Implementation of a National QA Programme in Histopathology – Version 3.0. Royal College of Physicians of Ireland. 1-26.</li> </ul>

	<ul style="list-style-type: none"><li>• Zarbo RJ, D'Angelo R. Patient Safety &amp; Diagnostic Error in Surgical Pathology. Ontario Association of Pathologist 68th Annual General Meeting, Collingwood, Ontario. 2006;1-6.</li></ul>
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**Quality Assurance Guideline -  
 Critical Diagnoses/ Results**

<p><b>Trigger:</b>                  Some diagnoses or results may seriously affect patient outcome, and require immediate communication to the clinician.</p>	
<p><b>Principle/                  Purpose</b></p>	<p>Critical diagnoses/ results (may variably be referred to as critical values, alert values, significant pathologic findings, or critical pathologic findings) in surgical pathology are those which require expedited notification of the most responsible physician or delegate since urgent patient management may be needed to prevent morbidity or mortality.</p> <p>Critical diagnosis/ result reporting can impact clinical decision making, patient safety and operational efficiency.</p> <p>A clearly defined process for critical diagnosis/ result notification will improve the quality of patient care and enhance patient safety.</p>
<p><b>Policy</b></p>	<p>As part of the <a href="#">Surgical Pathology Professional Quality Management Plan</a>, there should be a policy that outlines the types of diagnoses/ findings which are considered critical in the practice/s of physicians served by a surgical pathology group.</p> <p>There should be a defined procedure for timely communication of these diagnoses/ findings to the physician most responsible for the care of the patient involved.</p> <p>In general critical diagnoses/ results are those which will potentially require urgent/ emergent clinical care, may be ‘missed’ or go un-noticed by the clinician because they are unexpected, or may result in an untoward clinical outcome if not dealt with promptly.</p> <p>Not all situations appropriate for consideration as a critical diagnoses/ results can be anticipated in this guideline. The criteria for defining critical diagnoses/ results should be done with input from the organization’s clinical staff and clients. On a case by case basis, the discretion of the pathologist is necessary.</p> <p>Critical diagnoses/ results should be communicated directly by a method appropriate for the situation (verbal, fax, encrypted or secure electronic communication) to the appropriate individual. It should be ensured that the message was received correctly.</p> <p>The communication of these results should be documented. The documentation should include the date and time of the communication, method</p>

	<p>of communication and to whom the communication was made. The documentation should be included in the pathology report or in laboratory files.</p> <p>The communication and documentation processes for critical diagnoses/ results should be standardized within the department.</p>
<b>Exceptions</b>	None
<b>Practice Type Considerations</b>	<ul style="list-style-type: none"> <li>• Pathologists in all organizations should reach consensus with their clinical colleagues about what types of diagnoses are deemed critical, and policy development should be based on the organization’s clinical service needs and best practice.</li> <li>• The method of direct communication may vary among organizations but, if methods other than verbal communication are used, mechanisms should be in place to ensure that the communication is compliant with privacy regulations and is received by an appropriate individual.</li> </ul>
<b>Responsibilities – Case Pathologist</b>	The discretion of the pathologist is necessary to determine additional diagnoses/findings that should be communicated to the physician.
<b>Monitors</b>	<p>The <a href="#">Surgical Pathology Professional Quality Management Committee</a> should collect and review data on reporting of critical diagnoses/ results, for the professional group and for each pathologist. As data is collected, it should be compared to established benchmarks and trended over time.</p> <p><b>Minimum Requirements:</b></p> <ul style="list-style-type: none"> <li>• Number of cases where critical diagnoses/ results were reported, compared with number of all cases in same time period, for professional group overall</li> <li>• Period of time elapsed before critical diagnoses/ results were reported, for professional group overall</li> </ul> <p><b>Indicator Examples:</b></p> <ul style="list-style-type: none"> <li>• % of cases where critical diagnoses/ results were reported, for professional group overall</li> <li>• Mean time to critical diagnoses/ results reporting, by professional group overall</li> </ul> <p><b>Optional:</b></p> <ul style="list-style-type: none"> <li>• Number of cases where critical diagnoses/ results were reported, compared with number of all cases in same time period, by individual pathologist</li> <li>• Period of time elapsed before critical diagnoses/ results were reported, by individual pathologist</li> <li>• Further analysis of the above by specific anatomic site or disease type, or for other attributes</li> </ul> <p><b>Indicator Examples:</b></p> <ul style="list-style-type: none"> <li>• % of cases where critical diagnoses/ results were reported, by individual pathologist</li> <li>• Mean time to critical diagnoses/ results reporting, by individual</li> </ul>

	<p>pathologist</p> <p><b>Frequency:</b></p> <ul style="list-style-type: none"> <li>• Quarterly (or as appropriate for the group)</li> </ul>
<b>Associated Documents</b>	<ul style="list-style-type: none"> <li>• <a href="#">Surgical Pathology Professional Quality Management Guideline</a></li> <li>• <a href="#">Surgical Pathology Professional Quality Management Committee Terms of Reference</a></li> <li>• <a href="#">Foundational Elements</a></li> <li>• <a href="#">Post-interpretative Patient Safety Checklist</a></li> </ul>
<b>References</b>	<ul style="list-style-type: none"> <li>• Association of Directors of Anatomic and Surgical Pathology. Recommendations for Quality Assurance and Improvement in Surgical and Autopsy Pathology. <i>Am J Clin Pathol.</i> 2006;126:337-340.</li> <li>• Coffin CM, Spilker K, Lowichik A, et al. Critical Values in Pediatric Surgical Pathology. Definition, Implementation, and Reporting in a Children’s Hospital. <i>Am J Clin Pathol.</i> 2007;128:1035-1040.</li> <li>• College of American Pathologists Commission on Laboratory Accreditation. Anatomical Pathology Checklist. Northfield, Ill: College of American Pathologists; 2010.</li> <li>• LiVolsi VA. Critical Values in Anatomic Pathology. How Do We Communicate? <i>Am J Clin Pathol.</i> 2004;122:171-172.</li> <li>• LiVolsi VA, Leung S. Communicating Critical Values in Anatomic Pathology. <i>Arch Pathol Lab Med.</i> 2006;130:641-644.</li> <li>• Masoud M. How do surgical pathologists evaluate critical diagnoses (critical values)? <i>Diag Pathol.</i> 2008;3:30.</li> <li>• Nakhleh RE. What is quality in surgical pathology? <i>J Clin Pathol.</i> 2006;59:669-672.</li> <li>• Nakhleh RE, Fitzgibbons PL. Quality Management in Anatomic Pathology. Promoting Patient Safety Through Systems Improvement and Error Reduction. Northfield, IL: College of American Pathologists; 2005.</li> <li>• Ontario Laboratory Accreditation Requirements and Guidance Information, Version 5.0, December, 2010.</li> <li>• Pereira TC, Liu Y, Silverman JF. Critical Values in Surgical Pathology. <i>Am J Clin Pathol.</i> 2004;122:201-205.</li> <li>• Personal Health Information Protection Act 2004 S.O. 2004, Chapter 3. Schedule A.</li> <li>• Shahram S, Synder S. Laboratory Medicine Quality Indicators. A Review of the Literature. <i>Am J Clin Pathol.</i> 2009;131:418-431.</li> <li>• Silverman JF, LiVolsi V, Fletcher CD, et al. Critical Diagnoses (Critical Values) in Anatomic Pathology. Association of Directors of Anatomic and Surgical Pathology Ad Hoc Committee Report.</li> <li>• Silverman JF, Pereira TC. Critical Values in Anatomic Pathology. <i>Arch Pathol Lab Med.</i> 2006;130:638-640.</li> <li>• Silverman JF, Pereira TC. The Concept and Application of Critical Diagnoses (Critical Values) in Anatomic Pathology. Abstract. <i>Pathol Case Rev.</i> 2009;14:66-68.</li> <li>• The Working Group of Histopathology QA Guidelines, Faculty of Pathology. Guidelines for the Implementation of a National QA Programme in Histopathology – Version 3.0. Royal College of Physicians of Ireland. 1-26.</li> <li>• Visscher D. What Values Are Critical? <i>Am J Clin Pathol.</i> 2008;130:681-682.</li> <li>• Zarbo RJ, D’Angelo R. Patient Safety &amp; Diagnostic Error in Surgical Pathology; Ontario Association of Pathologists 68th Annual General Meeting, Collingwood, Ontario. 2006;1-6.</li> </ul>

**Quality Assurance Guideline -  
 Retrospective Reviews**

<b>Trigger:</b> Previously finalized cases may reviewed retrospectively in a variety of circumstances.	
<b>Principle/ Purpose</b>	<p>Retrospective reviews occur after cases have been signed-out. Retrospective reviews occur in a variety of circumstances, and serve a variety of purposes.</p> <p>A benefit of retrospective focused reviews is that evaluation of case sets may produce more data and identify previously unrecognized areas of discrepancy.</p> <p>Retrospective reviews in this circumstance are distinguished from “external consultations” (see <a href="#">QA Guideline – External Consultation</a>) and “external reviews” (see <a href="#">QA Guideline – External Review</a>) which refer respectively to the review of individual cases, prospectively and retrospectively. In the context of the guideline here, “retrospective reviews” refers to the review of groups or sets of cases.</p>
<b>Policy</b>	<p>As part of the <a href="#">Surgical Pathology Professional Quality Management Plan</a>, various types of retrospective case review should be performed, and their documentation and reporting for quality management purposes should be described.</p> <p>Retrospective reviews may be performed in a number of circumstances and by various methods:</p> <ul style="list-style-type: none"> <li>• As part of formal and planned reviews for quality assurance purposes, for example:             <ul style="list-style-type: none"> <li>• A set percentage of a group or a pathologist’s cases.</li> <li>• A focused review of a group of cases of predetermined case type or diagnosis.</li> </ul> </li> <li>• In the setting of various forms of case conference, for example:             <ul style="list-style-type: none"> <li>• Multidisciplinary case conferences.</li> <li>• Intra-departmental consensus conferences.</li> </ul> </li> <li>• As part of activities related to test development or validation, and similar.</li> <li>• As part of research protocols or projects, and similar.</li> </ul> <p>See also <a href="#">Guidelines for Review of Previously Reported Cases</a>, <a href="#">Guidelines for Dealing with Report Defects/ Discrepancies/ Discordances/ Errors</a>, and <a href="#">Guidelines on Classification of Report Defects/ Discrepancies/ Discordances/ Errors</a>.</p>
<b>Exceptions</b>	<p>Discrepancies may occur because a retrospective review employs diagnostic material or techniques not available at the time of the original case sign-out (e.g. additional recut slides, additional immunohistochemistry, or other ancillary studies).</p>

<b>Practice Type Considerations</b>	Institutions/ groups with resource limitations of various kinds (e.g. numbers of pathologists, lack of specialty training of their pathologists) may have to consider external assistance to perform some forms of retrospective review intended for quality assurance or other purposes.
<b>Responsibilities – QA Pathologist</b>	<ul style="list-style-type: none"> <li>● When retrospective reviews are part of formal and planned reviews for quality assurance purposes:                     <ul style="list-style-type: none"> <li>● Case selection criteria will be predetermined to maximize the random nature of the case selection.</li> <li>● Case/ report elements that will be assessed, and the criteria against which they will be compared will be predetermined.</li> <li>● Particularly, as part of the above, criteria for determination of concordance/ discordance will be predetermined.</li> <li>● Where possible, the reviews will be performed blindly, with the identifiers for the original sign-out pathologist masked.</li> <li>● Where possible, the reviews will not be performed by the pathologist originally responsible for case sign-out.</li> <li>● The policies and processes the professional group usually uses for dealing with any revealed report defects or discordances should be employed.</li> </ul> </li> <li>● In the setting of retrospective reviews for case conferences or similar:                     <ul style="list-style-type: none"> <li>● The policies and processes the professional group usually uses for dealing with any revealed report defects or discordances should be employed.</li> </ul> </li> <li>● In the setting of retrospective reviews for test development or validation, or as part of research protocols or projects, and similar:                     <ul style="list-style-type: none"> <li>● There should be a predefined policy about whether patients will or will not be identified if significant new information is revealed.</li> <li>● The policies and processes the professional group usually uses for dealing with any revealed report defects or discordances should be employed.</li> </ul> </li> </ul>
<b>Responsibilities – Case Pathologist</b>	When report defects or discordances are revealed, the case pathologist should participate in their investigation and resolution, according to the policies and processes the professional group usually employs.
<b>Monitors</b>	<p>The <a href="#">Surgical Pathology Professional Quality Management Committee</a> should collect and review data on report defect and discordances revealed by retrospective reviews, for the professional group and for each pathologist. As data is collected, it should be compared to established benchmarks and trended over time.</p> <p><b>Minimum Requirements:</b></p> <ul style="list-style-type: none"> <li>● Number of cases where retrospective review revealed report defects or diagnostic discordances of various kinds, compared with number of all cases in same time period, for professional group overall</li> </ul>

	<p><b>Indicator Example:</b></p> <ul style="list-style-type: none"> <li>• % of cases with report defects or diagnostic discordances of various kinds, for professional group overall</li> </ul> <p><b>Optional:</b></p> <ul style="list-style-type: none"> <li>• Number of cases where retrospective review revealed report defects or diagnostic discordances kinds, compared with number of all cases in same time period, by individual pathologist</li> <li>• Further analysis of the above by specific anatomic site or disease type, or for other attributes</li> </ul> <p><b>Indicator Example:</b></p> <ul style="list-style-type: none"> <li>• % of cases with report defects or diagnostic discordances of various kinds, by individual pathologist</li> </ul> <p><b>Frequency:</b></p> <ul style="list-style-type: none"> <li>• Monthly (or as appropriate for the group)</li> </ul>
<p><b>Associated Documents</b></p>	<ul style="list-style-type: none"> <li>• <a href="#">Surgical Pathology Professional Quality Management Guideline</a></li> <li>• <a href="#">Surgical Pathology Professional Quality Management Committee Terms of Reference</a></li> <li>• <a href="#">Foundational Elements</a></li> <li>• <a href="#">QA Guideline – External Consultation</a></li> <li>• <a href="#">QA Guideline – External Review</a></li> </ul>
<p><b>References</b></p>	<ul style="list-style-type: none"> <li>• Association of Directors of Anatomic and Surgical Pathology. Recommendations for Quality Assurance and Improvement in Surgical and Autopsy Pathology. <i>Am J Clin Pathol.</i> 2006;126:337-340</li> <li>• Azam M, Nakhleh RE. CAP Laboratory Improvement Programs. Surgical Pathology Extradepartmental Consultation Practices. A College of American Pathologists Q-Probes Study of 2746 Consultations From 180 Laboratories. <i>Arch Pathol Lab Med.</i> 2002;126:405-412.</li> <li>• College of American Pathologists Commission on Laboratory Accreditation. Anatomical Pathology Checklist. Northfield, Ill: College of American Pathologists. 2010.</li> <li>• Frable WJ. Surgical Pathology–Second Review, Institutional Reviews, Audits, and Correlations. What’s Out There? Error or Diagnostic Variation? <i>Arch Pathol Lab Med.</i> 2006;130:620-625.</li> <li>• Foucar E. Error in Anatomic Pathology. <i>Am J Clin Pathol.</i> 2001;116(Suppl 1):S34-S36.</li> <li>• Gatcliffe TA, Coleman RL. Tumour Board: More Than Treatment Planning – A 1-Year Prospective Survey. <i>J Cancer Educ.</i> 2008;23:235-237.</li> <li>• Leong S-Y, Leong SB, Bhagwandeem B. Diagnostic “errors” in anatomical pathology: relevance to Australian laboratories. <i>Pathology.</i> 2006;38:490-497.</li> <li>• Malami SA, Iliyasu Y. Local Audit of Diagnostic Surgical Pathology as a Tool for Quality Assurance. <i>Nigerian Journal of Medicine.</i> 2008;17:186-190.</li> <li>• Meier FA, Zarbo RJ, Varney RC, et al. Amended Reports. Development and Validation of a Taxonomy of Defects. <i>Am J Clin Pathol.</i> 2008;130:238-246.</li> <li>• Nakhleh RE, Fitzgibbons PL. Quality Management in Anatomic Pathology.</li> </ul>

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**Quality Assurance Guideline -  
 Turnaround Times**

<b>Trigger:</b> Turnaround times are monitored.	
<b>Principle/ Purpose</b>	Turnaround times are key indicators of surgical pathology work processes, as they reflect the efficiency of the surgical pathology service, and the professional group's and individual pathologist's ability to report cases in a timely fashion.
<b>Policy</b>	<p>As part of the <a href="#">Surgical Pathology Professional Quality Management Plan</a>, there should be a policy that outlines the processes for monitoring turnaround times on a regular basis.</p> <p>Overall surgical pathology turnaround times should be measured from the time the laboratory receives the specimen to the time the final report is issued; those turnaround times may analyzed further, according to constituent work processes, e.g., those portions which are the responsibility of technical and other support staff and those that are the direct responsibility of the surgical pathologists involved.</p> <p>It should be specified whether turnaround times are measured in calendar or working hours or days.</p>
<b>Exceptions</b>	Cases such as those sent for external consultation and cases that, as part of a group's standard protocols, may not follow standard work processes may be excluded from analysis by the professional group.
<b>Practice Type Considerations</b>	<ul style="list-style-type: none"> <li>• Turnaround times may vary due to a number of factors such as: case volume and type, concurrent urgent and routine requests, number of laboratory staff and pathologists, subspecialty expertise, availability of intra-departmental tests and expertise, the available information technology, geographical location, and the need for resident training.</li> <li>• Depending upon the complexity of an individual case, additional time may be allowed for adequate acquisition of clinical information, reviewing previous reports and materials, ensuring adequate fixation, employing special techniques or testing, or obtaining external consultation.</li> <li>• The professional group may choose to monitor specific types of cases depending on clinical needs and perceived issues/ changes in their practice.</li> </ul>
<b>Responsibilities - Case Pathologist</b>	Delays that may impact patient care should be communicated to the clinician, and that communication documented.
<b>Monitors</b>	The <a href="#">Surgical Pathology Professional Quality Management Committee</a> should collect and review data on turnaround times, for the professional group and for

	<p>each pathologist. As data is collected, it should be compared to established benchmarks and trended over time.</p> <p><b>Minimum Requirements:</b></p> <ul style="list-style-type: none"> <li>• Times from specimen receipt to case sign-out, for professional group overall</li> <li>• Cumulative number of cases signed out by professional group, by day after specimen receipt</li> </ul> <p><b>Indicator Examples:</b></p> <ul style="list-style-type: none"> <li>• Mean turnaround time, for professional group overall</li> <li>• Cumulative percent of cases signed out by professional group, by day after specimen receipt</li> </ul> <p><b>Optional:</b></p> <ul style="list-style-type: none"> <li>• Times from specimen receipt to case sign-out, by individual pathologist</li> <li>• Cumulative number of cases signed out by individual pathologist, by day after specimen receipt</li> <li>• Times from when cases available to pathologists to case sign-out, for professional group overall</li> <li>• Times from when cases available to pathologist to case sign-out, by individual pathologist</li> </ul> <p><b>Indicator Examples:</b></p> <ul style="list-style-type: none"> <li>• Mean turnaround times, for professional group overall</li> <li>• Mean turnaround times, by individual pathologist</li> <li>• Cumulative percent of cases signed out by individual pathologist, by day after specimen receipt</li> </ul> <ul style="list-style-type: none"> <li>• Further analysis of the above by specific anatomic site or disease type, or by other attributes</li> </ul> <p><b>Frequency:</b></p> <ul style="list-style-type: none"> <li>• Quarterly (or as appropriate for the group)</li> </ul>
<p><b>Associated Documents</b></p>	<ul style="list-style-type: none"> <li>• <a href="#">Surgical Pathology Professional Quality Management Guideline</a></li> <li>• <a href="#">Surgical Pathology Professional Quality Management Committee Terms of Reference</a></li> <li>• <a href="#">Foundational Elements</a></li> </ul>
<p><b>References</b></p>	<ul style="list-style-type: none"> <li>• Association of Directors of Anatomic and Surgical Pathology. Recommendations for Quality Assurance and Improvement in Surgical and Autopsy Pathology. <i>Am J Clin Pathol.</i> 2006;126:337-340.</li> <li>• College of American Pathologists Commission on Laboratory Accreditation. Anatomical Pathology Checklist. Northfield, Ill: College of American Pathologists. 2010.</li> <li>• College of American Pathologists Commission on Laboratory Accreditation. Laboratory General Checklist. Northfield, Ill: College of American Pathologists. 2010.</li> </ul>

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**Quality Assurance Guideline -  
 Service Satisfaction**

<b>Trigger:</b> Service satisfaction is monitored.	
<b>Principle/ Purpose</b>	<p>Communication with, and feedback from, those who use surgical pathology services clinically should provide a continuing framework for understanding user needs, implementing appropriate improvement initiatives, and determining overall service satisfaction.</p> <p>Monitoring is particularly helpful before, during and after implementing changes or new services related to surgical pathology.</p>
<b>Policy</b>	<p>As part of the <a href="#">Surgical Pathology Professional Quality Management Plan</a>, there should be a policy that outlines the processes that will be employed to monitor and improve service satisfaction. The SPPQMC should identify the current and future needs and expectations of stakeholders, including objective measures of service satisfaction.</p> <p>Service satisfaction may be monitored through surveys, the monitoring of complaints and compliments, and other sources of feedback.</p> <p>Various aspects of surgical pathology may be rated and monitored, including:</p> <ul style="list-style-type: none"> <li>• Professional interaction for consultation.</li> <li>• Clerical and technical staff interaction/ attitude.</li> <li>• Perception of diagnostic accuracy and report usefulness.</li> <li>• Surgical pathologist’s responsiveness to questions and concerns.</li> <li>• Surgical pathologist’s accessibility for intra-operative consults.</li> <li>• Tumor board and case conference presentations.</li> <li>• Teaching conferences and courses.</li> <li>• Notification of critical diagnoses/ results.</li> <li>• Timeliness of reports.</li> </ul> <p>Open-ended questions should be included in surveys, to gain more information regarding services.</p> <p>Satisfaction surveys may be expanded beyond the organization and used on a regional basis, if appropriate.</p>
<b>Exceptions</b>	None
<b>Practice Type Considerations</b>	An effective way of obtaining user/ stakeholder feedback when pathology resources are limited may be to develop focused surveys. Surveys may be targeted to a subset of user/ stakeholder groups, based on specific requirements, expectations and/ or associated risks.

<b>Responsibilities – Case Pathologist</b>	The pathologist should take the opportunity to understand users/ stakeholders concerns about service. They should participate in monitoring and managing user/ stakeholder expectation by informing, educating and obtaining feedback on an ongoing basis, while working towards service improvement.
<b>Monitors</b>	<p>The <a href="#">Surgical Pathology Professional Quality Management Committee</a> should collect and review data on service satisfaction, for the professional group and for each pathologist. As data is collected, it should be compared to established benchmarks and trended over time.</p> <p><b>Minimum Requirements:</b></p> <ul style="list-style-type: none"> <li>• A log of positive comments and complaints to the professional group, and of suggestions for improvement</li> <li>• An annual survey to adequately understand user needs, improvement opportunities, and determine overall service satisfaction.</li> </ul> <p><b>Optional:</b></p> <ul style="list-style-type: none"> <li>• Focused surveys of the satisfaction of specific user groups or of satisfaction with the reports for specific anatomic sites or disease types</li> </ul> <p><b>Frequency:</b></p> <ul style="list-style-type: none"> <li>• Annual (or as appropriate for the group)</li> </ul>
<b>Associated Documents</b>	<ul style="list-style-type: none"> <li>• <a href="#">Surgical Pathology Professional Quality Management Policy</a></li> <li>• <a href="#">Surgical Pathology Professional Quality Management Committee Terms of Reference</a></li> <li>• <a href="#">Foundation Elements</a></li> </ul>
<b>References</b>	<ul style="list-style-type: none"> <li>• Association of Directors of Anatomic and Surgical Pathology. Recommendations for Quality Assurance and Improvement in Surgical and Autopsy Pathology. <i>Am J Clin Pathol.</i> 2006;126:337-340.</li> <li>• Azam M, Nakhleh RE. CAP Laboratory Improvement Programs. Surgical Pathology Extradepartmental Consultation Practices. A College of American Pathologists Q-Probes Study of 2746 Consultations From 180 Laboratories. <i>Arch Pathol Lab Med.</i> 2002;126:405-412.</li> <li>• College of American Pathologists Commission on Laboratory Accreditation. Laboratory General Checklist. Northfield, Ill: <i>College of American Pathologists</i>; 2010.</li> <li>• GP22-A2 - Continuous Quality Improvement: Integrating Five Key Quality Components; Approved Guideline-Second Edition. NCCLS.</li> <li>• Jones BA, Walsh MK, Ruby SG. Hospital Nursing Satisfaction With Clinical Laboratory Services. A College of American Pathologist Q-Probes Study of 162 Institutions. <i>Arch Pathol Lab Med.</i> 2006;130:1756-1761.</li> <li>• Nakhleh RE. Core Components of a Comprehensive Quality Assurance Program in Anatomic Pathology. <i>CAP Companion Society Meeting at USCAP 2009. Quality Assurance, Error Reduction, and Patient Safety in Anatomic Pathology.</i> 2009.</li> <li>• Nakhleh RE. What is quality in surgical pathology? <i>J Clin Pathol.</i> 2006;59:669-672.</li> <li>• Nakhleh RE, Fitzgibbons PL. Quality Management in Anatomic Pathology. Promoting Patient Safety Through Systems Improvement and Error Reduction. Northfield, IL: College of American Pathologists; 2005.</li> <li>• Oja PI, Kouri TT, Pakarienen AJ. From customer satisfaction survey to corrective</li> </ul>

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## SECTION 6 GLOSSARY

TERM	DEFINITION	REFERENCE
<b>Academic practice</b>	Professional practice carried out in an institution that is attached to a university/ teaching centre. This type of practice is often subspecialty based and a referral centre .	
<b>ADASP</b>	Association of Directors of Anatomic and Surgical Pathology.	Association of Directors of Anatomic and Surgical Pathology
<b>AP</b>	Anatomic Pathology.	
<b>Blinded review</b>	A review that takes place without knowledge of clinical information or previous opinions.	
<b>CAP</b>	College of American Pathologists.	
<b>Case</b>	A pathology specimen or group of specimens from a single patient procured at the same diagnostic or operative procedure	
<b>Case Pathologist</b>	The pathologist most responsible for a case	
<b>Case conference</b>	A conference where cases are reviewed. In the context of surgical pathology a case conference usually involves reviewing material with colleagues, often using a multi-headed microscope or image projection.	
<b>CLSI</b>	Clinical And Laboratory Standards Institute.	
<b>Correlation</b>	Pathologic findings are within the same category of interpretation (e.g., grading of a tumour, or assessment of a margin, or the diagnoses agree or match). Correlation can involve separate interpretations on the same specimen or initial and subsequent material from the same patient.	
<b>Consensus</b>	An opinion or position reached by a group as a whole.	

<b>Consulting pathologist</b>	The pathologist whose opinion is sought by the case pathologist. This pathologist can be internal or external to the organization. Also referred to as Review Pathologist.	
<b>Critical diagnoses</b>	In surgical pathology, critical diagnoses are those that require expedited notification of the most responsible physician or delegate, as urgent patient management may be needed to prevent morbidity and mortality. (Synonyms include: critical value, alert value, significant pathologic findings, critical pathologic findings).	
<b>Cytohistologic discrepancies</b>	A difference in interpretation with respect to cytologic and histologic specimens from the same patient.	
<b>Deferral</b>	A diagnosis is not provided and is deferred until after subsequent testing.	
<b>Deferral rate</b>	The number of cases with a deferred diagnosis compared to the total number of cases in the same group.	
<b>Deferral rate - appropriate</b>	The number of cases with a deferred diagnosis where this deferral was considered an appropriate course of action, compared to the total number of cases within the same group.	
<b>Deferral rate - inappropriate</b>	The number of cases with a deferred diagnosis where a more definitive interpretation could have been rendered, compared to the total number of cases within the same group.	
<b>Disagreement</b>	A difference of opinion as to the interpretation of a case.	
<b>Discrepancy/ discrepant</b>	Description of a difference between the original interpretation and that after a second review.	Patient Safety In Anatomic Pathology. Measuring Discrepancy Frequency and Causes. Stephen S. Raab
<b>External consult</b>	External consultation occurs when a case pathologist seeks an opinion from a pathologist external to the case pathologist's professional group.	
<b>External review</b>	External review occurs when there is a request by a pathologist (other than the	

	case pathologist), clinician, or patient for case review by a pathologist external to the case pathologist’s professional group.	
<b>False negative</b>	A negative test result for patient or specimen that is positive for the condition or constituent in question.	MM4-A. CLSI
<b>False-positive</b>	A positive test result for a patient or specimen that is negative for the condition or constituent in question.	MM4-A. CLSI
<b>Frozen section</b>	One form of an intra-operative consultation that includes rapid microscopic interpretation of pathology material that is frozen quickly to produce the tissue section for microscopy.	
<b>Guideline</b>	A consensus recommendation for best practice that should be used if an advanced level of practice is desired.	NPAAC
<b>Internal audit</b>	A review of cases or results within a professional group.	
<b>Interpretation</b>	A professional opinion or diagnosis.	
<b>Inter-departmental case conference</b>	A conference that involves clinicians or other health care professionals external to the surgical pathology department.	
<b>Intra-departmental consultation</b>	When a pathologist seeks an opinion from another pathologist in their professional group. This may involve either a direct request from one pathologist to another to review all or selected slides from a case. It may also involve review of all or selected slides during a case conference.	
<b>Intra-operative consultation (IOC)</b>	A rapid consultation by a pathologist (often while the patient is still in the operating room) that may include gross evaluation of the specimen, frozen section, examination of cytology preparations (e.g., touch imprints), or sampling of the specimen for special studies (e.g. molecular pathology techniques, flow cytometry).	
<b>Intra-operative Consultation Pathologist</b>	Pathologist performing/ responsible for an intra-operative consultation.	
<b>Laboratory Director</b>	A licensed physician who is a suitably qualified specialist in laboratory medicine who is responsible for the administration	

	of the scientific and technical operation of a laboratory, including the supervision of tests and the reporting of results of the tests.	
<b>LAP</b>	Laboratory Accreditation Program of the CAP.	
<b>LIS</b>	Laboratory Information System.	
<b>MAC</b>	Medical Advisory Committee.	
<b>Minimum requirements</b>	These are basic or baseline monitors or indicators that should be used or in place. Depending on the type of practice/ scenario additional monitors or indicators may be employed.	
<b>Misidentification</b>	The identity of the patient or the type of specimen is incorrect.	
<b>MOHLTC</b>	Ministry of Health and Long Term Care	
<b>OLA</b>	Ontario Laboratory Accreditation	
<b>Original pathologist</b>	The pathologist who previously finalized a case that is being reviewed.	
<b>Optional requirements</b>	Additional actions that may be performed in addition to minimum requirements.	
<b>Patient Safety Checklist</b>	A listing of actions to be performed in a given clinical setting, in order decrease the risk of adverse events by fostering a patient safety mindset and encouraging communication.	
<b>Peer review</b>	Review of a case by laboratory physicians within the same type of practice.	
<b>Preliminary diagnosis</b>	An interpretation that contains some but not all of the information required in the final report.	
<b>Preventive action</b>	A proactive process for identifying opportunities for improvement rather than reaction to the identification of problems or complaints (i.e., non-conformances). In addition to review of the operational procedures, preventive action might involve analysis of data, including trend and risk analysis, external quality assurance, and the monitoring of quality indicators.	Standards for the Medical Laboratory. Clinical Pathology Accreditation (UK) Ltd

<b>Quality assurance</b>	A set of activities intended to establish confidence that quality requirements will be met. It is one part of quality management.	
<b>Quality control</b>	A set of procedures intended to ensure that a product or performed service adheres to a defined set of quality criteria.	
<b>Quality improvement</b>	Anything that enhances an organization's ability to meet quality requirements. It is one part of quality management.	
<b>Quality management</b>	All activities of the overall management function that determine quality policy objectives and responsibilities, and implement them by means such as quality planning, quality control, quality assurance, and quality improvement within the system. Quality management is focused not only on final quality, but also the means to achieve it.	
<b>QA Pathologist</b>	A pathologist responsible for carrying out and reviewing a quality assurance (QA) activity and its results.	
<b>QMP - LS</b>	Quality Management Program - Laboratory Services	
<b>Referring pathologist</b>	A case pathologist who requests a second opinion on a case, usually from an external consultant.	
<b>Regional/community practice</b>	Professional practice carried out in a regional or community based organization/ laboratory.	
<b>Report defect</b>	An error or omission in a report.	
<b>Requirement</b>	Need or expectation that is stated, generally implied or obligatory.	Standards for the Medical Laboratory. Clinical Pathology Accreditation (UK) Ltd - from ISO 9000:2000
<b>Retrospective review</b>	A review that occurs after a case has been finalized.	
<b>Review</b>	An activity undertaken to ensure the suitability, adequacy, effectiveness and efficiency of the subject matter to achieve established objectives.	Standards for the Medical Laboratory. Clinical Pathology Accreditation (UK) Ltd - based on ISO 9000:2000

<b>Review pathologist</b>	A pathologist who is reviewing or giving a second opinion on a case.	
<b>Revision</b>	Introduction of all necessary changes to the substance and presentation of a document to ensure its continuing suitability, adequacy, effectiveness to achieve established objectives.	Standards for the Medical Laboratory. Clinical Pathology Accreditation (UK) Ltd
<b>Risk management</b>	Clinical and administrative activities undertaken to identify, evaluate, and reduce the risk of injury to patients.	
<b>Service satisfaction</b>	The degree to which lab services meet or surpass the expectations of physicians, clinical personnel and patients.	
<b>SPPQMC</b>	Surgical Pathology Professional Quality Management Committee.	
<b>Standard</b>	The minimum requirement for a procedure, method, staffing resource, or laboratory facility that is required before accreditation can be attained.	NPAAC
<b>Subspecialty expertise</b>	Focused or additional expertise in a specific area of medicine/ pathology.	
<b>Turnaround time</b>	The time taken to accomplish a task – in the context of a surgical pathology practice, the time between receipt of a specimen to the time the report and diagnosis are available for clinical use. Turnaround time (TAT) may be further analyzed for its constituent work processes, e.g., the portion of overall TAT that is under direct control of, for instance, the surgical pathologist. The units used to measure TATs should be specified, e.g., calendar or working hours or days.	

## **APPENDIX 1**

### **PROCESS AND RESULTS OF CONSULTATION WITH LABORATORY PHYSICIANS IN ONTARIO**

Central to the principles guiding the Standards2Quality project was the desire for active consultation and transparency. Laboratory physicians were made aware of the work of Path2Quality, and its efforts to draft quality assurance guidelines for professional practice in the area of surgical pathology, on multiple occasions and via a number of methods. For instance, this work was described at the Annual General Meetings of the Ontario Medical Association (OMA) Section on Laboratory Medicine and the Ontario Association of Pathologists (OAP). It was highlighted in a number of preparatory emails directed to each of those associations' members.

Once the Guidelines were available in draft form they were circulated in hard copy to all laboratory physicians in the OMA database. Excluded were laboratory physicians who do not practice in Ontario, and those who have retired their College of Physicians and Surgeons of Ontario license to practice in Ontario.

A total of 495 laboratory physicians were sent the Guidelines (it is estimated that about 420 of these individuals practice either surgical pathology or cytopathology). Included with the Guidelines was a brief questionnaire about the Guidelines, and an opportunity to provide free text comments. Addressed return envelopes with prepaid postage were provided. Responses were in confidence, and physicians desiring to respond anonymously did so.

Eighty (80) questionnaire responses were received. The response rate was, as a result, at least 16.2% (some responses received were submitted on behalf of groups of physicians, so the total number of individual physicians responding is not fully known). Seventy (70) percent of the responses included free text comments.

The questionnaire consisted of nine statements about the Guidelines and an agreement rating was requested for each statement. The rating choices included: "1 (strongly disagree)", "2", "3", "4", or "5 (strongly agree)" for each statement. The following describes the aggregate of the questionnaire ratings (compiled by the Standards2Quality project's secretariat/ technical support):

Survey Statement About Circulated Draft Guidelines	Mean Response	Median Response	Mode Response
Purpose is clearly defined	4.6	5	5
Well organized & easy	4.4	5	5
Complete - no gaps	4.0	4	5
Consistent with literature	4.2	4	5
Appropriate for Ontario	4.1	4	5
Clearly distinguished requirements	3.9	4	5
Sufficient information to develop a plan	4.1	4.5	5
I would use them	4.3	5	5
I would recommend them	4.2	5	5

Standards2Quality project’s secretariat/ technical support also compiled the free text comments provided by respondents. These comments were anonymized and reviewed in detail by the Path2Quality Executive. While some respondents had reservations about portions of the document, virtually all respondents expressed a positive interest in the work, and most a recognition that the Guidelines would likely be useful to them in their own practices and/ or at the provincial level.

The comments received about the Guidelines ranged from suggestions for formatting and typographic improvements to others of a more substantive nature. In some cases the latter highlighted issues (e.g., the resource implications of the Guidelines) considered out of scope by the Path2Quality Executive. Where possible, the comments provided were used to enhance the Guidelines currently being circulated to other stakeholders. All comments and responses have been made available for review by any interested laboratory physicians in the Province.

## APPENDIX 2 NATIONAL AND INTERNATIONAL EXPERTS CONSULTED

The Path2Quality Executive approached each of these individuals listed below and requested their comments on the draft Guidelines. The group represents a selection of national and international experts with an interest in, and knowledge of, the various quality management programs in place for surgical pathologists - in Canada or in other jurisdictions. Honoraria were provided to these individuals, to recognize the considerable time commitment required to review the Guidelines.

In general the comments provided by these experts were laudatory and supportive. Where possible, the comments provided were used to enhance the Guidelines currently being circulated to other stakeholders. Some comments will have to await the next phase of this project before they are dealt with.

Diponkar Banerjee, MBChB, FRCPC, PhD  
Chair, Section of Patient Safety and  
Quality Assurance, CAP-ACP  
Executive Medical Director, Provincial Health  
Services Authority Laboratories, Vancouver  
Clinical Professor, Department of Pathology and  
Laboratory Medicine, University of British  
Columbia

Brett Delahunt ONZM KStJ, BSc (Hons), MBChB,  
BMedSc, MD, FRCPA, FFSc, FRCPath, AFNZIM  
Chair, Cancer Control New Zealand  
Research Advisory Committee  
Deputy Chair, Medical Sciences Council  
of New Zealand  
Professor of Pathology and Molecular Medicine,  
Wellington School of Medicine and Health  
Sciences, University of Otago

Paul R McKenzie MBBS, FRCPA, Dip.  
Cytopathology  
President, Royal College of Pathologists of  
Australasia  
Senior Staff Specialist, Tissue Pathology and  
Diagnostic Oncology, Royal Prince Alfred  
Hospital  
Clinical Associate Professor, Central Clinical  
School, University of Sydney

Raouf E Nakhleh, MD  
Professor of Pathology  
Mayo Clinic Florida  
Jacksonville, Fl.

Conor O'Keane, BSc MB BCh BAO FFPATH,  
FRCPI  
Dean, Faculty of Pathology, Royal College of  
Physicians of Ireland  
Consultant Histopathologist, Department of  
Histopathology, Mater Misericordiae University  
Hospital, Dublin  
Associate Clinical Professor of Pathology,  
University College, Dublin

Andrew Renshaw, MD  
Staff Pathologist, Baptist Hospital,  
Miami, FL  
Medical Director of Laboratories,  
Homestead Hospital, Homestead, FL

Kieran Sheahan, MB, BCh., BAO B.Sc. MRCPI,  
FRCPI, FFPATH, FRCPath  
Chair, Histopathology Working Group, Faculty of  
Pathology, RCPI  
Consultant Histopathologist, St. Vincent's  
University Hospital, Ireland

Niall Swan, MB, MCh, BAO (NUI), FFPATH  
Consultant Histopathologist, St. Vincent's  
University Hospital, Ireland

Michael Wells, BSc(Hons), MD, FRCPath,  
FRCOG  
President, European Society of Pathology  
Chair, Specialty Advisory Committee on  
Histopathology, Royal College of Pathologists,  
UK  
Honorary Consultant Histopathologist,  
Sheffield Teaching Hospitals, UK  
Professor of Gynaecological Pathology,  
University of Sheffield, UK

## APPENDIX 3 PATH2QUALITY EXECUTIVE

C. Meg McLachlin, MD FRCPC  
Chair, OMA Section on Laboratory  
Medicine;  
Co-Chair Path2Quality;  
Deputy Chief of Pathology, London Health  
Sciences Centre;  
Professor, Department of Pathology,  
University of Western Ontario

J Brendan M. Mullen, MD FRCPC  
Past-Chair, OMA Section on Laboratory  
Medicine;  
Deputy Director, Department of Pathology  
and Laboratory Medicine, Mount Sinai  
Hospital;  
Associate Professor, Departments of  
Laboratory Medicine and Pathobiology,  
Urology and Anaesthesia, University of  
Toronto

Victor A. Tron, MD FRCPC  
Secretary-Treasurer, OMA Section on  
Laboratory Medicine;  
Professor, Head, and Pathologist-in-Chief  
Department of Pathology and Molecular  
Medicine, Queen's University, Kingston  
General Hospital and Hotel Dieu Hospitals

Virginia M. Walley, MD FRCPC  
Chair, OMA Section on Laboratory Medicine  
Tariff Committee;  
Ontario Medical Director, LifeLabs;  
Adjunct Professor, Department of Pathology  
and Molecular Medicine, Queen's University

John R. Srigley, MD, FRCPC  
President, Ontario Association of  
Pathologists;  
Co-Chair Path2Quality;  
Head, Pathology and Laboratory Medicine  
Program, Cancer Care Ontario;  
Chair, National Pathology Standards  
Committee, Canadian Partnership Against  
Cancer;  
Pathologist, Credit Valley Hospital;  
Professor, Department of Pathology and  
Molecular Medicine, McMaster University

Katherine A. Chorneyko, MD FRCPC  
Vice-President, Ontario Association of  
Pathologists;  
Medical Director, Laboratory Services  
Brantford Community Healthcare Services;  
Associate Professor, Department of  
Pathology and Molecular Medicine,  
McMaster University

Suhas B. Joshi, MD FRCPC  
Past-President, Ontario Association of  
Pathologists;  
Chief of Department of Laboratory Medicine  
and Regional Director of Laboratories,  
Niagara Health System

Christina M. MacMillan, MD FRCPC  
Secretary-Treasurer, Ontario Association of  
Pathologists;  
Staff Pathologist, Pathology and Laboratory  
Medicine, Mount Sinai Hospital, Toronto;  
Assistant Professor, Department of  
Laboratory Medicine and Pathobiology,  
University of Toronto

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