QUALITY ASSURANCE

IN

DIVISION OF ANATOMIC PATHOLOGY

HEALTH CARE CORPORATION OF ST. JOHN'S

LIST OF CONTENTS

QUALITY ASSURANCE IN ANATOMIC PATHOLOGY

QUALITY ASSURANCE IN ANATOMIC PATHOLOGY

1. Preamble

Division of Anatomic Pathology include the following:
(a) Surgical pathology,
(b) Immunopathology,
(c) Autopsy pathology.

Each of these involve specimen accessioning; gross description, and tissue processing which in turn includes, embedding, cutting, and staining and finally a cognitive process through which conclusions are made.

This last stage involves combination of gross and microscopic description on one hand correlated with clinical data and morphologic findings on the other. The summary of these is in a form of a report communicated to the clinician.

2. Objective of Quality Assurance

Preamble

By application of QI and technological principles, the Anatomic Pathology division shall:
(a) Attempt to contribute to optimal improvement of the patient's total person as early and economically as possible and by so doing,
(b) Assist others in the effective and efficient utilization of our various resources, including knowledge base and clinical resources.
Therefore, the division of Anatomic Pathology shall provide the referring clinician with:

(i) Accurate
(ii) Timely
(iii) Clinically relevant diagnostic report {Zarbo et al}.

The above can only be achieved if diagnosis is made on optimal technical preparation.

In this regard, it must be emphasized that the credibility of the report is as important as its accuracy. {Cowan}

3. Purpose of Design of QA

Any quality assurance must be designed to evaluate each of the above requirements by:

(a) Detecting systematic deficiencies that militate against achievement of the stated objective.
(b) Continuously improving the process by which the objectives are achieved.

4. Scope of Application of this QA

Our quality assurance is for use within:

(i) The division of anatomic pathology.
(ii) The laboratory medicine program.
(iii) Health Care Corporation of St. John's.

5. Personnel Requirements

(a) Pathologists

(i) To be appointed to the post of a pathologist in the division of Anatomic Pathology, a candidate must hold an MD, or MB, BS or a recognized equivalent and have undergone a residency training in Anatomic pathology General pathology / Neuropathology and any of its sub-specialties and thereafter obtained a postgraduate qualification in the respective speciality.

(ii) In pursuit of this objective, such a canadiate shall hold one of the following qualifications; FRCP Canada or its equivalent or deemed suitable by the Lab Medicine Program of HCCSJ must be licensable by the Provincial Medical Board of NL.

5. **Personnel Requirements (Cont'd):**

(b) **Residents**

Residents are those holders of MD, or MB, BS or recognized equivalent who have been accepted in the training program of the Discipline of Laboratory Medicine,Memorial University of Newfoundland.

(c) **Technical Staff**

(i) All technical staff shall hold a RT or acceptable equivalent training.
(ii) Must have completed a prescribed period of training in laboratory medicine including anatomic pathology.

Divisional Manager
Senior Technologist III
Technologists I, II
Technician

The responsibilities of each grade of staff will follow the provisions in the division's job description.

Promotion from one post to another will be according to the provisions in the division's regulations for such technical staff promotions.

6. **Actual Indicators of our Quality Assurance**

The following parameters need to be monitored in pursuit of the excellence required in our laboratory practice:

(a) Receipt and examination of specimen.
(b) Processing and production of adequately sectioned and stained slides.
(c) Arrival at a diagnosis.
(d) Communication of the results.
(e) Systematic Reviews, CME & Proficiency Testing.

Receipt and examination of specimen.
Specimen Identification / Audit Trail / Acceptance.

(i) Specimens brought to the laboratory are to be accompanied by request forms. One or two technical staff is scheduled on receiving each day. When the nurse / porter arrives with the specimen, the technical staff on receiving duties would check the specimen book for proper entry and synchrony of details on the specimen container and those on the request forms.
(ii) If these details agree, then the staff would sign the specimen book.
(iii) When specimen arrives, from other sources without a logbook, similar details are checked on both the specimen container and the request forms.

7. Specimen Handling

The following data are checked:

(i) Date of biopsy. In some instances specimens are procured but left to stand in the Operating theatre for some days before reaching the laboratory. The technical staff on receiving must report this to the supervisor who then calls the theatre supervisor to sort out the reasons for the delay.

(ii) Name of the patient on the request form must agree with the name on the specimen bottle.

(iii) Hospital or MCP number on the form must also agree with the number on the specimen bottle.

(iv) Ages and sex of the patient must be present on the request form.

(v) Site, number and nature of biopsy must be present on the request form. Clinical data has to be present on the request form.

(vi) Soiled request forms are promptly returned to the originating location and a note is made in the specimen status book.

(vii) When the specimen is returned and is now acceptable, a remark is entered in the specimen status book.

7. Specimen Handling (Cont'd):

(viii) The receiving technical staff has the authority to return such samples but where in doubt the supervisor is contacted.

(ix) Where all details check out, the technical staff on receiving will enter the details of each case in the main surgical logbook. This entry will include assigning a surgical number, which will now be the main identifying number for that case.

(x) This number will be entered in the appropriate section of the request form and also written in red on the cover and the body of the container.

(xi) All specimens received the same day on one request form (one patient), are identified by one surgical number but each sample is sub-labeled numerically as number 1, 2 and onwards.

(xii) Where more than one section is taken additional identifying mark is written on the block in the form of alphabets starting from "A", "B" and onwards.

8. Gross Description:

- The gross examination of the specimen is reflected in the surgical report and as a quality assurance indicator, the quality of this examination is based on the objective criteria for specimen examination.
- Small simple specimen requires less description than big or complicated specimens.
- Residents are instructed how to describe the specimen in simple English language identifying the specimen were possible.
- Pathologists usually teach the art of gross description by doing several cases while the residents watch.

PROCEDURE:

(i) The person doing the gross will ensure that the specimen and details match those on the request form.

(ii) This is achieved in several ways, for example, by directly checking for synchrony of the names and the hospital or MCP numbers as well as the type of specimen as written on the form and the specimen container.

These details must agree before the specimen is considered a match and then described.

(iii) All specimens are identified as organ or part thereof where possible and measured in three dimensions in most cases.

(iv) A two-dimension measurement can be obtained where the specimen is small.

(v) An approximate measurement is made in very small, minute and fragmented samples.

(vi) It is the responsibility of the person doing the gross to examine the specimen thoroughly and take adequate representative sections.

(vii) After the sections are obtained and put in appropriate cassettes bearing the same surgical number as on the request form and the container, the technical staff assisting in the gross cutting takes full responsibility to close the cassettes and put them in 10% buffered formalin preparatory to transferring to the automatic processor.

(viii) Masses such as thyroid nodules, ovarian, testicular or solid tumor masses and breast are also weighed.

(ix) Protocols for gross description of certain specimen such as mastectomy, and colectomy specimen are available.

(x) At the end of the gross description, the residents are required to read through all the description to ascertain that the writer has taken down the dictations accurately.

(xi) When dictated the residents or the pathologist will have to read over the typed gross description and make appropriate corrections.

9. **Processing, Procedure Manuals and Instrument Maintenance**

(i) All samples are transferred to the automatic processor and programmed for 16 hours to be ready for embedding the next day at 6 a.m.

(ii) Tissues that require further fixation may be processed but with a delay mode in the formal alcohol. This is usually achieved by using another processor.

(iii) After embedding, the blocks are distributed to the technical staff for trimming and sectioning.

(iv) Our routine H&E stain is performed automatically by the automatic stainer. This machine has its work manual and a technical staff is assigned to ensure that all levels of the reagents are appropriate.

(v) Reagents are changed weekly and / or when necessary with freshly prepared reagents.

(vi) A technologist is assigned to recheck the pH of all freshly prepared solutions such as bulk formalin.

10. Special Stains

(i) Some special stains such as:
PAS and PAS / ALB
Reticulin
Masson Trichrome
Some are automatically performed on certain specimen where appropriate, such as skin, gastrointestinal tract, liver and testicular biopsies.

(ii) A host of other special stains are performed when and where necessary.

(iii) Each of these stains is done with control tissues on the same slide as the test or the patient's sample.

(iv) A special stain logbook is maintained.
(a) Type of stains performed.
(b) Date of request.
(c) Name of the requesting pathologist.
(d) Name of the technical staff who perform the stain.
(e) Name of the senior technical staff who checked the slides.
(f) Date the slides are passed to the pathologist.

(v) Details of each staining procedure are given in the appropriate Procedural Manual.

11. Record Keeping

Record keeping is important in promoting consistently high quality technical preparations in Anatomic Pathology.

- Special Records shall contain:

(i) Number of specimens processed.
(ii) Number of blocks and slides prepared.
(iii) Type and number of special stains.
(iv) Specimens rejected.
(v) Quality of slides and stains produced. How many re-cuts.
(vi) Paraffin blocks / slides are stored for 20 years for adults and 50 years for children.
(vii) Besides specimen preserved for the museum, all other specimens are discarded after a minimum period of 4 weeks from the date of sign out.

12. Pathologic Diagnosis

(a) It is the sole responsibility of the pathologist to render a clear accurate and understandable diagnosis.
(b) Though the basic training in Anatomic Pathology and success at the board or college examinations are the minimum requirement, these may not guarantee accuracy at all times.
(c) Review of large volumes of surgical material as well as peer reviews go a long way to achieve the desired competence.
(d) Adequacy of diagnostic information is a critical measure of our professional responsibility as surgical pathologists. Not only must the information be factually accurate and reported in a timely fashion but it should be clinically relevant and contribute to patient care.
(e) The sign out pathologist must ensure the precision, uniformity, consistency and accuracy of the descriptive information contained within the report. In order to achieve high quality in our surgical pathology services, the following measures are taken:

(i) It is the responsibility of the reporting pathologist to obtain and document the opinion of a second pathologist if the diagnosis is in doubt.

(ii) Intraoperative consultation is an area of surgical pathology practices that underscores the medical responsibility of the pathologist. Comparison of frozen section and final diagnosis is a cornerstone of quality assurance in surgical pathology. A second opinion to be taken if the diagnosis is in doubt.

(iii) A pathologist is assigned to review all frozen sections on a monthly schedule. By this way, all pathologists will rotate through the task of reviewing and comparing the final and frozen section diagnosis.

This does not eliminate the monthly summary of the comparison of permanent section diagnosis with the frozen section diagnosis carried out by the manager.

(iv) Every two months ten random cases are to be selected by the Site Chief or designate and reviewed by a panel of three pathologists.

(v) Appendix, products of conception, epidermal inclusion cysts and lipomas will not be included in this review. The manager is responsible for selecting the review cases.

(vi) Where there is difference of opinion on any case, an inter-institutional consultation may be sort. For tumors in particular, referral to Canadian Cancer Reference Centre Arm Forces Institute of Pathology, or direct consultation to a known authority in the area of the lesion will be carried out.

(vii) A pathologist other than original sign out pathologist will carry out review of cases of neoplasms of breast, colon and stomach which constitute the largest number of big and complicated specimen received in our practice.

The review will include gross description as well as microscopy and the final diagnosis.

Transcription and typographic accuracy must be checked in this review.

13. <u>Turn Around Time (Timely Report)</u>

(a) The working hours at the HCCSJ are from 8 a.m. to 5 p.m. Monday through Friday.
(b) Specimen received on a given day are accessioned, described either by the resident under supervision or by the pathologist and loaded for overnight processing.
(c) The next day that being the second day of the specimen in the laboratory, the tissue is embedded cut and stained by the technical staff.
(d) This means the specimens for microscopic description are divided into urgent, priority and routine.
(e) Owing to other responsibilities of the residents and the pathologist urgent must be reported on the same day, most of the cases may not be reported on that same day.

13. **Turn Around Time (Timely Report) (Cont'd):**

(f) Therefore microscopy and diagnosis of the specimen are made late on the second and on the third day.

(g) Those requiring further fixation, such as bowel or big specimens, will have an additional one-day delay.

(h) The cases that require special stains may not be ready in time for composite microscopy on the same day. As a result of these the following must be our goal.

14. **General Goal for Timely Reporting**

(a) 75% to 80% of all cases in a given day must have their reports typed on the 3rd to 4th day depending on the workload of the secretaries. Those finished reports are dispatched the same day.

(b) All other cases should be reported on the 5th and latest the 7th day of the accession except the decal specimen.

(c) Cases for immunoperoxidase and immunofluorescence should be reported on the 5th or latest the 6th day but where possible a preliminary report is relayed verbally or in writing to the clinician by the pathologist. All verbal reports to the clinician be documented in the report.

(d) Bone tissues, which require decalcification, must be completed by the 10th day.

(e) Urgent cases must be marked with the word "urgent" on the request form if possible in red ink. The pathologist will call and give a verbal report to the clinicians. Depending on how urgent these cases are, a 6 hour processing can be done on the new processor.

(f) Clinicians are encouraged to phone the secretaries who may relay the results of ONLY signed reports on the phone. Ascertaining the identity of the clinician on the other end of the phone has remained a concern but so far, no problem has arisen from such a practice.

(g) A previous biopsy relevant to a current biopsy shall be reviewed by the current sign out pathologist and such a review shall form part of the current report.

(h) Where a significant information relevant to patient care and which could have led to a different diagnosis were omitted in the previous report, the current sign out pathologist shall inform the sign out pathologist of the reviewed case who shall then review the case and the report.

If a difference of opinion exits the case be referred to an outside centre.

(i) Where such a relevant omission is established an amendment or addendum report shall be issued.

15. Complaints and Redress

Despite all genuine efforts to provide timely, accurate and clinically relevant reports,there may still be some lapses or some dissatisfied clinician. The procedure for sorting these cases out is simple and straight.

(a) The clinician should call or visit the sign out pathologist and review the case with him or her.

(b) Where the clinician is not satisfied, he / she can inform the sign out pathologist of his / her wish to request for a second opinion either within the division or outside the HCCSJ.

(c) In either case, the clinician should collect a second opinion from the clerks and complete the relevant details.

(d) The sign out pathologist should have over the cases with the request form to any of the pathologists unless the clinician wishes a particular pathologist to review the case. In that situation, the case is handed over to the clinician's choice.

(e) The second opinion pathologist shall give his opinion in writing and such a report shall be made known to the sign out pathologist.

(f) Copies of the second opinion report shall be attached to the original report and filed in the division and the patient's file in the medical records. A copy shall be given to the requesting clinician.

(g) No pathologist shall review and give a second opinion on his colleague's cases without a formal request for second opinion.

16. Continuing Medical Education and Proficiency Testing

Pathologists and the senior technical staff have the privilege to attend conferences in any part of the world. Popular ones include ASCP, CAP, and IAP.

- Workshops and seminars in these meetings are very instructive besides providing good teaching materials.

- The division is enrolled in the PIP (Performance Improvement Program) from College of American Pathologists (CAP), ASCP Check Path & ASCP Check Samples.

- This program has been on for three years and performance has remained at over 85% average score on the diagnosis and questions.

- The following other activities form part of the CME program of the division.

- Slides and case reviews are carried out with the clinicians when requested.
- Daily slides and case reviews with the residents are carried out.
- Monthly Pathology Med-Path Round
- Regular slides and case reviews with the clinician, neurosurgeons / neurologists.
- Regular slides and case reviews with the nephrologists.
- Weekly Surgical Pathology and Quality Control Conference.
- Weekly Lymphoma Pathology conference
- Weekly Oncology Conference
- Monthly Gyn. Path Rounds
- Bi-weekly Lymphoma Rounds with Hematology Division
- MOOMP
- Weekly Mammogram Pathology Review
- Surgical Pathology Review Committee.

17. Responsibilities

(a) The Site Chief / Division Manger are responsible for QA in the Division.

(b) However, this responsibility needs to be shared in order to achieve the desired goal.

(c) The Quality Control Manager and pathologists shall bear full responsibility for QA in their professional practice following the guidelines above.

(d) The measures stated above shall enable the manager of the division to co-ordinate the QA in the division.

(e) The manager shall be responsible for all QA in all technical activities and shall ensure the quality of all diagnostic materials reaching the pathologists.

(f) This responsibility may be delegated to the senior technologist or any other technologist as the manager may wish.

(g) The manager shall also be responsible for assembling all cases that require reviews for QA purposes according to the provisions in this QA document.

(h) Logbooks are maintained for both pathologists and technologists at both Sites to monitor technical quality and recommendation.