

**The Manitoba Quality Assurance Program  
(MANQAP)  
ANNUAL REPORT**

**April 1, 2008 to March 31, 2009**

**Manitoba Quality Assurance Program  
(MANQAP)**

## **I. INTRODUCTION**

The objective of the Manitoba Quality Assurance Program (MANQAP) is to establish standards for diagnostic and treatment facilities, to investigate and inspect diagnostic and treatment facilities for accreditation, and to monitor compliance with established standards. Effective August 1, 2007, MANQAP operated pursuant to a Service Purchase Agreement (SPA) between Manitoba Health and the College of Physicians and Surgeons of Manitoba (College).

This is the Annual Report of MANQAP activities for the fiscal year April 1, 2008 to March 31, 2009.

## **II. STRUCTURE**

MANQAP is operated from the College of Physicians and Surgeons of Manitoba offices at 1000-1661 Portage Avenue, Winnipeg, Manitoba R3J 3T7, Telephone Number: 204-774-4344, Fax Number: 204-774-0450.

The College is governed by a Council comprised of physicians and public representatives. For the 2008-2009 fiscal years, the members of the Council were:

- Dr. R. Bhullar
- Dr. M. Burnett
- Dr. N. Carpenter
- Dr. S.D. Chapman
- Dr. H. Domke
- Dr. W. Fleisher
- Ms S. Hrynyk
- Dr. B. Kowaluk
- Dr. B. Kvern
- Dr. D. Lindsay
- Dr. R. Lotocki
- Dr. A. MacDiarmid
- Dr. B. Mackalski, President
- Dr. D. O'Hagan
- Dr. R. Onotera
- Dr. E. Persson
- Ms L. Read
- Dr. D. Sandham
- Dr. K. Saunders, President-Elect
- Mr. W. Shead
- Dr. R. Suss
- Dr. H. Tassi
- Mr. R. M. Toews
- Dr. H. Unruh

Pursuant to *The Medical Act*, Council has established a Program Review Committee which oversees the operation of MANQAP (see Appendix 1).

For the 2008-2009 fiscal year, the Program Review Committee members were:

- Dr. R. Lotocki, Chair, Councillor
- Dr. D. Lindsay, Diagnostic Imaging Physician, Councillor
- Ms L. Read, Public Councillor
- Dr. I. Wilkinson, Manitoba Health
- Dr. J. Naidoo, Laboratory Medicine Physician
- Dr. W.D.B. Pope, Registrar, non-voting ex officio
- Dr. B. MacKalski, President of the College
- Dr. K. Saunders, President-Elect of the College

Dr. W.D.B. Pope, Registrar of the College, has assigned Dr. T. R. Babick, Deputy Registrar of the College, to be responsible for the administration of the Manitoba Quality Assurance Program (MANQAP) within the parameters of the Service Purchase Agreement and pursuant to the direction of the Program Review Committee.

During the 2008-2009 fiscal year, MANQAP had a staff of six led by Mrs. C. Baker, Program Director who reports to Dr. Babick. The staff consists of a Laboratory/Transfusion Accreditation Coordinator and a Diagnostic Imaging Accreditation Coordinator both of whom are under the direction of the Program Director. As the activity level of the Program increased with the addition of the two accreditation coordinators, a third administrative assistant was hired.

### **III. OVERVIEW OF ACCREDITATION**

MANQAP's primary function is to accredit diagnostic facilities and to monitor compliance as well as to ensure that these facilities are encouraged to meet national and international best practice standards which in turn ensure the best outcomes for patients.

Accreditation is meant to:

- Set and measure the achievement of standards by evaluating a diagnostic facility's level of performance in achieving the benchmarked standards.
- Increase public safety and reduce risks associated with injury and infections for patients and staff.
- Increase public confidence in the quality of diagnostic services.

There are several responsibilities that comprise the MANQAP Accreditation Program. These include:

- Review other provincial, national and international organization standards.
- Select best practice standards and incorporate Manitoba best practice evidence, legislative, technical and safety requirements into working standards documents.
- Ensure that standards cover organizational systems, services, quality management and quality improvement.
- Involve stakeholder groups.
- Develop a measurement system to measure compliance with achievement of standards.
- Develop tools such as pre-survey questionnaires, checklists and report templates.
- Train the surveyors.
- Test the standards.
- Implement the standards that are achievable for Manitoba facilities to meet.

### **IV. MANQAP ACTIVITIES**

As MANQAP staff and stakeholders work hard to finalize laboratory and diagnostic imaging standards, the Program continues to utilize Alberta standards for each on-site survey. Copyright permission was obtained from the College of Physicians and Surgeons of Alberta to adapt Alberta's standards to meet Manitoba needs.

## **1. Laboratory**

Laboratory discipline modules have been written and these standards will be forwarded to the Program Review Committee and the Council of the College for review and approval. Once approved, they will then be posted on the College website.

Presently, these modules are:

- Anatomic Pathology
- Clinical Biochemistry
- Clinical Microbiology
- Equipment
- Hematology
- Laboratory Information System
- Manuals
- Phlebotomy
- Quality Management System
- Safety
- Urinalysis

All of the laboratory modules benchmark the internationally accepted standards entitled:

- ISO 15189–Medical laboratory–Particular requirements for quality and competence
- ISO 15190–Medical laboratory–Requirements for Safety

MANQAP staff is working with laboratorians to author standards relevant to Manitoba laboratory practices while currently using the College of Physicians and Surgeons of Alberta Standards.

## **2. Diagnostic Imaging**

Diagnostic Imaging is a field that is advancing rapidly as new innovative imaging applications are introduced. New computerized technology significantly impacts quality management requirements. MANQAP ensures the quality control procedures are performed as required for all equipment and related components to systematically evaluate optimal performance and establish best practices. MANQAP benchmarks the Health Canada Safety Code 35, Radiation Protection Services and the College of Physicians and Surgeons of Alberta standards.

MANQAP staff is working with radiologists to author standards relevant to Manitoba imaging practices while currently using the College of Physicians and Surgeons of Alberta Standards.

The following modules have been written and are currently under review:

- Qualifications and Definitions
- Organization and Management
- Safety (Radiation, WHMIS, Electrical, Infection Control and General Safety including Risk Management)
- Quality Management, General Duty Radiography, Ultrasound, Computed Tomography, Magnetic Resonance Imaging and Nuclear Medicine

The Radiation Safety Section is benchmarked to the current Health Canada Safety Code 35, Radiation Protection in Radiology – Large Facilities. This document was released in November 2008.

### **3. Transfusion Medicine**

The American Association of Blood Banks (AABB) is the gold standard universally accepted by blood bank specialists. MANQAP reviews all public blood bank facilities against AABB standards. The AABB standards are updated every 18 months.

Health Canada will eventually be introducing the document “Canadian Standards Association (CSA) Z902, Blood and Blood Components”. The requirement will be for all Canadian transfusion services to meet these standards. The document is a response to the findings of the Krever Inquiry.

### **4. Cytology**

The Canadian Society of Cytology Guidelines for Practice and Quality Assurance in Cytopathology was the template used to create the Manitoba Cytology Standards. The Manitoba Cytology Standards have recently been updated to include recent changes.

Cytology facilities follow Bylaw 3A requirements of an on-site inspection on a 5 year rotation.

### **5. Investigation and Inspection for Accreditation**

#### **i. Process**

Pursuant to the Service Purchase Agreement with Manitoba Health and Health Living (MHHL), MANQAP accredits the public laboratories, transfusion medicine and diagnostic imaging facilities in the province of Manitoba specified on a schedule to the SPA. Each year comprehensive surveys are conducted at specified facilities, as agreed between Manitoba Health and MANQAP. All public facilities included within the scope of the SPA will be surveyed on a five year cycle. Privately owned facilities will also be surveyed on a five year cycle.

The survey process for public and private facilities includes completion of pre-survey questionnaires before the facility is surveyed. Following the on-site inspection, a debriefing meeting is held and an interim report which summarizes the survey team findings is left at the facility. A comprehensive report is then prepared and forwarded to the Program Review Committee which determines accreditation status. If the survey team uncovers an unsafe practice during the survey, the Diagnostic Facility Medical Director is immediately notified of the need to modify/correct the unsafe practice.

There are three types of accreditation:

- Full Accreditation – a facility is compliant with all current standards.
- Conditional Accreditation – a facility has not yet fulfilled all required current standards but is working towards compliance.
- Intent to Withdraw Accreditation – pursuant to significant concerns, the Program Review Committee will advise the Diagnostic Facility Medical Director/Owner of its intent to withdraw accreditation.

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It is important to note that there will always be facilities with some non-conformity, but in no case is conditional accreditation granted when the non-conformity is of such a nature that the public is at risk. Any matter of public safety is addressed on an immediate and direct basis.

Where a facility does not achieve full accreditation, the specific requirements to achieve full accreditation are made known to the Diagnostic Facility Medical Director/Owner. MANQAP monitors a conditionally accredited facility's progress in making the appropriate changes to achieve full accreditation as noted in the paragraph below.

Once accreditation status has been granted by the Program Review Committee, the comprehensive report is sent to the Diagnostic Facility Medical Director and owners as applicable. Where conditional accreditation is granted, time frames are established for compliance with the recommendations. Once the recommendations have been satisfactorily addressed, the facility is granted full accreditation by the Program Review Committee. Validation surveys are conducted when there is a need for a re-inspection prior to the 5 year cycle.

The following is a breakdown of the number of sites and type of modalities surveyed in 2008-2009. Sixty-three (63) surveys were performed from April 1, 2008 to March 31, 2009. Of the 63 surveys performed:

Full accreditation was granted to:

- 5 laboratory sites
- 2 diagnostic imaging sites
- 2 transfusion medicine sites

Conditional accreditation was granted to:

- 12 laboratory sites
- 33 diagnostic imaging sites
- 8 transfusion medicine sites

Closed sites

- 1 diagnostic imaging site has discontinued services due to staff shortages

**ii. Surveyors**

Surveyors are a vital component of the accreditation process as they bring a wealth of knowledge, experience and expertise and provide significant benefits to each diagnostic facility being surveyed. Surveying provides opportunities to observe and disseminate best practice guidelines and standards as well as to identify areas that may affect patient or staff safety.

The MANQAP Program Director, Laboratory/Transfusion Medicine Accreditation Coordinator and the Diagnostic Imaging Accreditation Coordinator each have certification with the College of American Pathologists as accredited surveyors and College of American Pathologists Accredited Survey Team Leader status.

A Quality Management System (QMS) is a critical component of the accreditation process. The nationally accepted ISO 15189 – *Medical Laboratories – Particular Requirements for Quality and Competence* relates all laboratory activities to the QMS. Surveyors must be aware of the QMS model and provide education as necessary. Diagnostic imaging has also adopted the QMS model and surveyors follow the same educational strategy for imaging surveys.

**iii. Monitoring Compliance**

External Proficiency Testing (EPT) – Laboratory Medicine

EPT is one of the cornerstones of a well defined laboratory quality management system. In addition to the internal quality controls performed daily, EPT provides a powerful tool allowing comparisons with similar laboratories in order to verify the accuracy and reliability of their test results.

The purpose of external proficiency testing is to ensure continued quality improvement in the laboratory. One of the major benefits of external proficiency testing is to provide an external tool for identifying overall performance. Another benefit is enabling laboratories to monitor their tests results over time. Longer time trends can be identified and any necessary action implemented.

Director Response – Action and Feedback

If a result is outside 2 standard deviations, the Diagnostic Facility Medical Laboratory Directors must investigate and comment in writing to MANQAP within a designated time-frame.

The Program Director and Laboratory Accreditation Coordinator thoroughly review all external proficiency testing results to monitor non-conformities and trends.

Progress Reports - Action and Feedback

All facilities which received conditional accreditation are required to provide continual progress reports on a schedule mandated by the Program Review Committee until all non-conformances have been addressed. It must be noted that any non-conformance that may affect patient or staff safety is addressed immediately at the time of the survey. This process applies to all disciplines.

**iv. Laboratory Medicine**

**Positive Trends:**

- Technologists are working very hard to meet the increased demands in laboratory testing due to the “Baby Boomer” retirements from the workforce. Annual workloads continue to increase.
- Closer monitoring of external proficiency testing reports is being undertaken by laboratory personnel.
- Laboratories are adhering to Workplace Safety and Health<sup>1</sup> in regards to routine practices, such as wearing of gloves, safety goggles, and following appropriate disinfecting protocols.

**Inconsistencies:**

- Clerical errors such as results not correctly transcribed and incorrect unit values are ongoing.
- Equipment calibration and maintenance needs to be more consistent.
- Policy and procedure manuals are not written in a standardized format and require updating to meet the new Quality Management Standard.

**v. Transfusion Medicine**

**Positive Trends:**

- The second edition of the “Manitoba Transfusion Quality Manual for Blood Banks” was developed under the direction of the Manitoba Provincial Blood Coordinating Office. This standardized comprehensive document is an excellent tool for every blood bank facility in Manitoba that issues blood and blood products. This project, funded by Manitoba Health, had brought expertise to the table by allowing knowledgeable technologists to brainstorm and collaborate.
- The survey teams noted that blood bank refrigerators displayed the desired temperature for storage of blood and blood products.

**Inconsistencies:**

- Inconsistent equipment calibration.
- With ongoing retirements from the workforce, it has become evident that orientation training and competencies are very important tools for educating new employees. Currently, orientation training and standardized processes need to be more consistent.
- The comprehensive documentation processes as stated in the 2<sup>nd</sup> edition of the “Manitoba Transfusion Quality Manual for Blood Banks” must be extended to all Manitoba blood banks.

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<sup>1</sup> Manitoba Workplace Safety and Health Act and Regulations, Chapter W210, 10/02 (includes January 2006 amendment)

**vi. Diagnostic Imaging**

**Positive Trends:**

- Preventative maintenance requirements and equipment repair are generally performed in a timely manner.
- Registered radiology technologists continue to produce good quality images and consistently improve quality through a reject discard image analysis process.
- Facilities are cognizant and comply with the Personal Health Information Act (PHIA).
- A new contrast media policy is now available.

**Inconsistencies:**

- Current policy and procedure manuals as well as radiation safety manuals are not generally in place.
- Facilities utilizing wet processing equipment may not have quality tools to perform sensitometry and densitometry to maintain image integrity and quality.
- There appears to be x-ray equipment in the province which is greater than 30 years of age. Newer equipment offers a lesser dose of irradiation.

**V. ANNUAL REVIEW FORMS AND DATABASE**

Annually, all laboratories and diagnostic imaging facilities are required to notify MANQAP of any changes to staffing, changes in equipment, procedures, external proficiency providers (laboratory and transfusion medicine), specimen collection sites and changes in directorship. A copy of the latest Radiation Protection Report is also required for diagnostic imaging facilities. These forms are distributed to the survey team in order to review compliance during the on-site survey process.

**VI. CANADIAN COALITION FOR QUALITY IN LABORATORY MEDICINE**

The Canadian Coalition for Quality in Laboratory Medicine (CCQLM) provides a national structure for quality management in medical laboratories across the provinces and the territories. It promotes implementation of national and international standards (where appropriate), creates and maintains an effective centralized forum for the exchange of information, promotes national educational initiatives and collaborates with other national/international agencies.

At the CCQLM Executive Committee meetings, it was agreed that CCQLM would embark on a strategic planning exercise to reevaluate the coalition to ensure it is meeting member needs. The direction of CCQLM will be confirmed or revised to reflect what its members and stakeholders require, including a revised organizational structure (e.g. executive committee and working groups). To that end, the Executive Committee conducted an environmental analysis to identify member needs.

The June meeting focused on the results of the environmental analysis. There was agreement that the coalition provides a national networking platform through which provincial expertise can be shared. There was limited satisfaction with the current coalition and the format of the current annual general meeting. There was also a desire expressed for clear goals, obtainable objectives, and effective communication tools.

Key decisions were:

- That the current working group structure be disbanded.
- That the CCQLM web site be used as the primary communication tool.
- That there continue to be annual meetings of the membership.
- That the membership be limited to those organizations with designated provincial responsibility for laboratory quality management.

The CCQLM Executive agreed to develop a revised strategic plan and propose relevant by-law amendments for consideration by the membership.

Manitoba will host the 19<sup>th</sup> Annual CCQLM Conference in Winnipeg in September 2009.

## **VII. PARTNERS**

MANQAP partners with organizations that are equally as committed to quality and patient safety. MANQAP staff is actively involved with the following organizations:

- American Association of Blood Banks (AABB)
- Cadham Provincial Laboratory
- Canadian Coalition for Quality in Laboratory Medicine (CCQLM)
- Canadian Association of Medical Radiation Technologists (CAMRT)
- Canadian Association of Radiologists (CAR)
- Canadian Blood Services (CBS)
- Canadian Society of Medical Laboratory Sciences (CSLMS)
- College of American Pathologists (CAP)
- College of Medical Laboratory Technologists of Manitoba (CMLTM)
- College of Physicians and Surgeons of Alberta (Accreditation Program)
- College of Physicians and Surgeons of Saskatchewan (Laboratory Quality Assurance Program)
- Diagnostic Accreditation Program of British Columbia (DAP)
- Diagnostic Services of Manitoba (DSM)
- Manitoba Blood Programs Coordinating Office
- Manitoba Workplace, Safety and Health
- Ontario Laboratory Accreditation (OLA)
- Radiation Protection Services
- Red River College
- Standing Committee on Diagnostic Services (SCODS)
- Winnipeg Fire Services
- Winnipeg Regional Health Authority (WRHA)

## **VIII. CONCLUSION**

During the coming year, MANQAP will be focusing on field testing accreditation standards for laboratories and diagnostic imaging. Development will continue on accreditation standards for diagnostic imaging modalities and will include nuclear medicine. The survey process for laboratory and diagnostic imaging will continue on a five-year cycle.

MANQAP strives to explore new avenues in the accreditation process always mindful of patient safety as a priority.

The Program Director and staff would like to extend our sincere thank you to the Registrars and Council of the College of Physicians and Surgeons of Manitoba, the members of the Program Review Committee as well as our many partners who assist us in our commitment to improve the quality of diagnostic services provided to Manitoba citizens.

MANQAP ORGANIZATIONAL CHART

