Overview of New Provincial Accreditation Process
Government Authority

The Ministry of Health (MOH) must ensure The Medical Laboratory Licensing Act and Regulations are followed. The MOH contracts The College of Physicians and Surgeons (CPSS) to operate the Laboratory Quality Assurance Program (LQAP).

The LQAP is responsible for the requirements and standards of Medical Laboratories in the Province of Saskatchewan.
Recent Improvements

- In 2014 the LQAP made the decision to do on site assessments at all laboratories in every region.
- In 2016 the LQAP started assessing at all clinics and sites that do POCT as well. No category 1 clinics (Doctor's offices) will be assessed at this time.
- In 2016 the standards were new and this new process was implemented.
LQAP Personnel

- Director of Diagnostic Quality Assurance
- Proficiency Testing Consultant
- Administrative Assistants
- Maintains a pool of Assessors
**LQAP Responsibilities**

- Ensures accuracy and reliability of testing services
- Provides standards of practice and assesses compliance to the standards
- Identifies deficiencies that may affect the quality of testing/services, as well as patient and staff safety
Responsibilities

- Peer review program that provides educational opportunities for both the facility being accredited and the assessment team
- Promotes consistent practice provincially
LQAP
Program Management Committee

- Oversight body for operations and decision making for the program
- Approves processes
- Grants facility accreditation once all evidence of compliance has been received and is satisfactory
Discipline Specific Quality Assurance Committee Duties

- Review standards
- Monitor compliance with standards
- Ensure a consistency process
- Review reports
- Review proficiency testing
- Promote safety and quality
- Respond to inquiries from laboratories
- Maintain policies and guidelines
Accreditation Standards
Western Canadian Diagnostic Accreditation Alliance (WCDAA)
WCDA amalgamation

History

- 2013 – medical laboratory bodies of four western provinces
- Opportunities for diagnostic laboratory accreditation resource sharing and collaboration
- Cross jurisdictional assessor training
- All standards have been approved by the PMC and the QA Committees
Benefits of New Process

- Quality management systems/process based approach

- Compliance with national/international standards (ISO 15189, CAP, CLSI)

- Improved data management, reporting capabilities and tools

- Standards have been accredited by ISQUA (International Society for Quality Healthcare)
Benefits of New Process

- Implementation of a patient/staff risk assessment measure for every standard
- No more pre-assessment questionnaires
- All requirements – no more best practice recommendations
Standard Documents

- General (includes LIS, Safety, POCT)
- Anatomic Pathology
- Chemistry
- Fertility Assessment – Semen Analysis
- Flow Cytometry
- Hematology
- Microbiology
- Molecular Diagnostics and Genetics
- Transfusion Medicine
- Tissue Typing – HC (in development)
Standards – Organization/Sections

- Organization, Management and Personnel
- QMS
- Physical Facilities
- Equipment, Reagents and Supplies
- LIS
- Pre-examination “Policies, Processes, Procedures (PPP)”
- Examination “PPP”
- QA of examination procedures
- Post – examination “PPP”
- Safety
- POCT
Patient and Staff Safety Risks

Each standard has been reviewed and assigned a safety risk category where relevant:

• PS – Patient Safety Risk
  - non-compliance may have direct and/or immediate impact on patient safety

• SS – Staff Safety Risk
  - non-compliance may have direct and/or immediate impact on staff safety
Patient and Staff Safety Risks

Assessors ensure that ALL standards with either a PS/SS are directly assessed at the on-site assessment.

Note that: PS/SS standards are ‘shaded’ for ease of detection.
Description of the Standard Requirement

● This is the actual description of the standard

● When assessing a site this is the part that has to ultimately apply to the non-compliance
Specific References

- Detailed reference citation listing is provided at the end of each standard document.
- References support the content and intent of each standard. All components of cited references may not always be relevant and/or applicable.

- Compliance is expected with WCDAA standard, not the reference standard.
Interpretation Guidance

- This is not present for all standards

- Can be found in the Reference/Guidance section of the standards

- Assists with the interpretation of the standard
Assessment of Compliance (AOC) Questions

- Provide specific guidance and practical direction for the evaluation of compliance with the standard.
- AOC questions address key evidence required to meet the intent of each standard; however, are not meant to be the only criteria to assess compliance.
- There may be other evidence that demonstrates compliance with the standard.
- AOC are a guide.
Compliance Category (CPEN)

CPEN

- C – meets requirement and intent of standard
- P – in progress
- E – exceeds requirement of standard
- N – does not meet intent and/or requirements of standard
Observation Recording Field

- This is an area for making notes
- Can be used by the facility or the assessors
<table>
<thead>
<tr>
<th></th>
<th>Procedures are available for the decontamination, cleaning, and disinfection of each piece of equipment.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Are procedures available for the decontamination, cleaning, and disinfection of each piece of equipment in each of the following situations:</td>
</tr>
<tr>
<td></td>
<td>• in case of accidents or spills that result in biological, chemical, or radioactive contamination?</td>
</tr>
<tr>
<td></td>
<td>• prior to being serviced?</td>
</tr>
<tr>
<td></td>
<td>• prior to repair?</td>
</tr>
<tr>
<td></td>
<td>Is there evidence of compliance with the decontamination / cleaning/disinfection procedures?</td>
</tr>
<tr>
<td></td>
<td>Are transport boxes cleaned:</td>
</tr>
<tr>
<td></td>
<td>• on a routine basis / at defined intervals?</td>
</tr>
<tr>
<td></td>
<td>• when there is evidence of a spill?</td>
</tr>
<tr>
<td></td>
<td>Observation:</td>
</tr>
</tbody>
</table>

|   | C □ P □ E □ N □ N/A □ |
Terms and Definitions

- A glossary of applicable terms and definitions are provided at the end of each document.
- Encompasses general terms used in all documents.
- Not discipline specific.
Version Control and Review

- Comprehensive review of reference documents occurs annually
  - A new version is released each time a change is made to a document.
  - A summary of changes is provided to all health regions.

- Supporting references are reviewed and updated annually as well
Revision Process

There is a process for submission of stakeholder request for revisions to current standards

- Form...on CPSS website

- Must provide supporting references for the revision to be considered
Distribution Process

- Standards are no longer on website

- A complete SECURE version of all standards is provided directly to laboratory regional consultants:
  - Ensure compliance/facilitate on-going self assessment
  - Further distribution within the organization/facility is at the discretion of the regional consultant (This is usually the most responsible Laboratory leader)
  - One representative from each region
Customized Standards

- LQAP provides customized standards to facilities and assessors prior to the on-site assessment
  - Tailored to scope of testing
  - Non-applicable sections are removed
Customized Standards Benefits

- These are intended to be used as a tool for Laboratory personnel:
  - Preparation for assessment
  - Self assessment/internal audit
  - Facilitate constant state of readiness
Customized Standards

- These are intended to be a tool for CPSS assessors:
  - Pre-assessment preparation
  - On-site assessment
  - Recording observations
The Assessment Process
Assessment Initiation

- LQAP notifies region of their assessment

- There is a 4 year rotation, so if you were assessed in 2015 you will be assessed again in 2019
Months before the Assessment

- LQAP in collaboration with the regional supervisor determines specific assessment dates.

- Now that we do every testing site in a region the assessment process may take several weeks.
Assessment Team Training

- Mandatory prior to every assessment cycle
  - 2-4 weeks prior to on-site assessment
- Encompasses
  - overview of process and standards documents
  - general assessment guidance techniques
  - confidentiality, honorarium, expenses
- Competency assessment exam
  - In development
Before the Assessment

- LQAP prepares and distributes customized assessment supporting documents for each assessor:
  - Previous inspection report
  - 4 year summary of EQA performance
  - Customized facility specific standards (reflecting assessor focus)
  - Interview templates if required
  - Copy of General standards
Assessment Team

- Team leader
- Discipline specific assessors
- LQAP staff
Team Leader

- Represent LQAP
- Spokesperson at opening and summation conferences
- Conducts interviews (LQAP staff may do interviews)
- Mitigates and resolves conflicts if required
- Acts as a resource for the team
- Promotes and ensures consistency
- Assists in report and response review
Assessment Team

- Based on scope of laboratory services
- Experience
- Availability
- Possibility for using out of province assessors
- Confidentiality and Conflict of Interest forms are signed by each assessor prior to each regional assessment
- Assessor pool maintained by LQAP
Assessor Preparation

- Review customized standards documents
- Review previous citations
- Review EQA summary
Documentation Available On site for Assessors and Team Leader

- Printed copy of General standards
- Printed copy of EQA summary
- Printed copy of previous inspection report
- Access to a copy of all standards
- Facility test menu
- Interview Schedule
Assessment Day

- Usually the team meets the night before for a short meeting to discuss logistics and if there are any questions or concerns.

- CPSS name tags are provided

- Closed toe shoes and appropriate clothing is required
Assessment Day

Make sure to have ready for Assessors:

- a separate room for assessment team and possibly an interview room
- Lunch (if requested) and water/coffee and tea
- PPE for the assessors to wear in the laboratory (eg: Lab Coats)
Assessment Day

- Travel together to facility
- Team Leader holds opening meeting
- All staff and assessment team are introduced.
- Tour of laboratory for assessors and Team Leader
Assessment Day

- Team leader (or LQAP staff) conducts interviews either in person or by phone.
- Assessment team assesses specific discipline.
Assessment Day

Interviews

- Done by Team Leader (or LQAP Staff)
  - examples – laboratory director, quality manager, pathologists, client physician, nurse manager, laboratory supervisor, safety personnel, POCT manager
    - specific templates are used
    - interview summaries are included in the final report

- May need a separate room to conduct the interviews
Assessment Day
Assessment process

- Verifying compliance with the intent of the accreditation standard
- Follow up on previous areas of concern
- Interaction with laboratory staff at all levels
- Assessors will need to talk to Nursing staff for TML and POCT
Assessment Day
Assessment process

- Review of documents
- Look at Quality Manual
- Look at Safety Manual
- Review QC records
- Look at Procedures
- Look around for any safety concerns
Assessment Day
Use of Tools

- Each assessor utilizes both the General standards and the discipline specific.

- The General standards include all standards common to all disciplines.

- The discipline specific standards include only those specific and relevant to each discipline.

- Example – general quality control, proficiency testing, calibration, validation and procedure manual standards are not repeated in each discipline specific standard.
Assessment Day
Assessment of Compliance (AOC)
Questions

- Provide specific guidance and practical direction for the evaluation of compliance with the standard.

- AOC questions address key evidence required to meet the intent of each standard; however, are not meant to be the only criteria to assess compliance.

- There may be other evidence that demonstrates compliance with the standard.

- AOC are a guide.
Assessment Day

- Where AOC state “all of the following” compliance with all elements is expected
- Assessors and Team Leader apply their own expertise when determining compliance with each standard
- Compliance may be assessed by review of documents, records, observation, interviews or a combination
Assessment Day

“Process Based” Model

- It is not possible to directly assess every individual standard for the entire scope of the laboratory operations

- Process based

- Focus on areas of highest and lowest test volumes, likely problem areas, and highest test results with highest impact on patient care

- Mindful of time management
Assessment Day

- Directly assess all standards with either a PS or SS designation
- Verify that previous citations have been addressed
- Verify system with non-conformances examples: document control, procedures
Assessment Day
Objective Evidence

- Review of policies, processes and procedures and records
- Random selection of documents and records
- Will not rely solely on those selected by the facility
- Documents housed outside the laboratory (POCT/TML)
- Regional documents
Assessment Day

- Ask open ended questions (what, where, when, who, how)
- Engage with all staff
- Compare observed activities with policies, processes and procedures
- Use techniques such as:
  - Tracer method – follow a sample through pre-examination, examination and post-examination
  - Drill down – further investigate areas of concern
  - Show/teach me – staff describes a procedure as they perform
  - If not able to directly observe activities – ask to describe
Assessment Day
Determine the Scope and Nature of Potential Citations:

- Are there policies, processes, and procedures
  - Are they in compliance with the standard
  - Are they being followed as written

- Is there evidence of training/competency assessment for the activity
- Is there documentation of the activity
- Is there required review
Assessment Day

- Always seek verification of findings and evaluate for significance
- Discuss all potential deficiencies with facility representatives
- Citations for insufficient space must relate to safety concerns
- May need to take photographs
Assessment Day

- If assessors encounter any situation that, in their judgement, represents potential for significant immediate harm to staff or patients they are directed to bring it to the attention of:
  - laboratory personnel for immediate action
  - Team leader who may notify LQAP
Assessment Day
Compliance Categories

○ CPEN

▪ C – meets requirement and intent of standard
▪ P – in progress
▪ E – exceeds requirement of standard
▪ N – does not meet intent and/or requirements of standard
Assessment Day
“P” Scenarios

- Renovations actively underway but incomplete
- Replacement instrumentation ordered but not received or fully implemented
- TM clinical protocol recently developed but not fully implemented
Assessment Day
“E” Scenarios

- Excellent process/forms for facilitation of handling and rotating of multiple EQA survey amongst staff
- TM areas have excellent checklists for infusion and transfusion reaction investigations
- Excellent internal audit forms
- User friendly safety checklist
Assessment Day

- It is an educational approach rather than a consultant approach.
- The goal of the assessment is laboratory improvement.
- Be conscious of the sites workload, staffing, assessment schedules and obligations.
Assessment Day
Pre-Summation Meeting

- Conducted by the team leader
- Verbal report with all findings stated.
- Review of all findings with assessment team before doing the Summation Meeting
Assessment Day
Summation Conference

- Conducted by the Team Leader
- Takes place at each facility
- Encompasses:
  - Verbal report of all assessment findings
  - Commendable findings
  - Acknowledgement of laboratory personnel for their cooperation
  - Time for questions
Post-Assessment
Post-Assessment Final Report

- Team leader and LQAP staff ensures submission of complete citation and interview summaries
- Final report is completed by LQAP in consultation with the Team Leader
- Completed report is based on the citation summaries and the completed interview forms
- Nothing is added after the verbal report is completed
Post-Assessment Final Report

- LQAP ensures consistent:
  - Application of standards based on observations
  - Wording of requirements
Post-Assessment Final Report

- Discipline specific and Program Management Committee reviews the reports. This review/revision/approval of reports is to:
  - Eliminate bias
  - Ensure consistent application of standards
  - Ensure standards reflect best practice
Post-Assessment Final Report

- Final report is distributed by LQAP to regional supervisor, medical director and CEO
- Usually 3-4 weeks from the final assessment in the region
<table>
<thead>
<tr>
<th>Standard #</th>
<th>Safety Risk</th>
<th>Compliance Assessment Category</th>
<th>Standard Description</th>
<th>Objective Evidence</th>
<th>Requirement</th>
<th>Evidence of Compliance (EOC) Required</th>
<th>Timeline for submission of EOC</th>
</tr>
</thead>
<tbody>
<tr>
<td>G.10.9.4</td>
<td>SS</td>
<td>N</td>
<td>Procedures are available for the decontamination, cleaning, and disinfection of each piece of equipment.</td>
<td>No evidence that transport boxes are being cleaned and no SOP.</td>
<td>Transport boxes must be cleaned on a routine basis. This must be documented. There must be an SOP available to all staff.</td>
<td>Provide a copy of tote SOP and checklist to LQAP.</td>
<td>30 Days</td>
</tr>
</tbody>
</table>

**Facility Response:**
- SOP for Cleaning Totes.pdf
- Tote Cleaning Checklist.pdf

**LQAP Committee Response:**
Post-Assessment Final Report

Evidence Of Compliance (EOC) is required either 30 or 60 days after receiving the final report.

A significant safety issue would require a 30 day response. All other EOC is due in 60 days.

Final reports are formatted to include a section for the facility response to each non-conformance.
Post-Assessment Feedback Surveys

- Distributed to assessors and facility
- Submitted to Kim.Skrypnyk@cps.sk.ca
- Evaluates assessment process
- Assesses customer satisfaction
- Changes to process implemented as appropriate based on feedback
Post-Assessment Facility Response

Accreditation decisions of the LQAP are approved by PMC.

LQAP issues new ‘full’ accreditation certificates once all requirements and EOC are deemed acceptable.

PMC determines any outstanding non-conformances would substantiate a reversion to “probationary” accreditation.
Website

- CPSS/LQAP
  - Laboratory guidelines
  - Microbiology Guidelines
  - LQAP accreditation program guide
  - Standard revision form

Reminder: No standards on website
Questions???