Placing Quality at the Heart of the BC Laboratory Accreditation Standards

College of Physicians and Surgeons of BC Diagnostic Accreditation Program (DAP)

The DAP is a regulatory body:

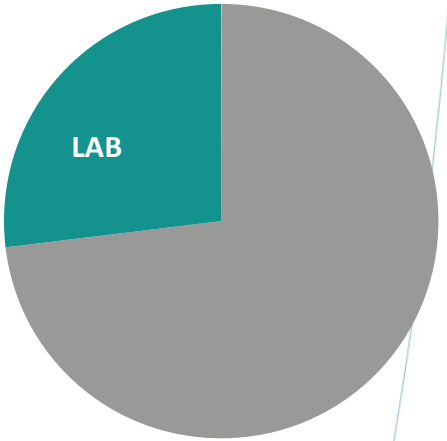
- *Health Professions Act* (rev. September, 2015)
  - College of Physicians and Surgeons of BC Bylaws
  - PART 5, Section B

- DAP Committee established
  - Set performance standards
  - Evaluate actual performance
  - Accredit every diagnostic facility before it can starts a diagnostic service

DAP accreditation programs

The DAP accredits 5 diagnostic services (public and private sector)

- Diagnostic Imaging 202
- Laboratory Medicine 136 + sample collection sites
- Pulmonary Function 94
- Neurodiagnostics 62
- Polysomnography 11
- **TOTAL** **505**



- Done on a four-year cycle 121 per year (3-4 per week)
- Plus initial assessments, focused visits, relocated services

Accreditation awards

- Full accreditation
- Accreditation with report
  - Outstanding mandatory requirements with timeframes for resolution
- Non-accreditation
- Provisional accreditation

Standards development process

Using a defined, document controlled process:

- Draft documents assembled

- Advisory Committee review (8 committees, 40 members)

- Community review (115 laboratorians)

- Final edit, DAP Committee review and approval

Laboratory Medicine Accreditation Standards

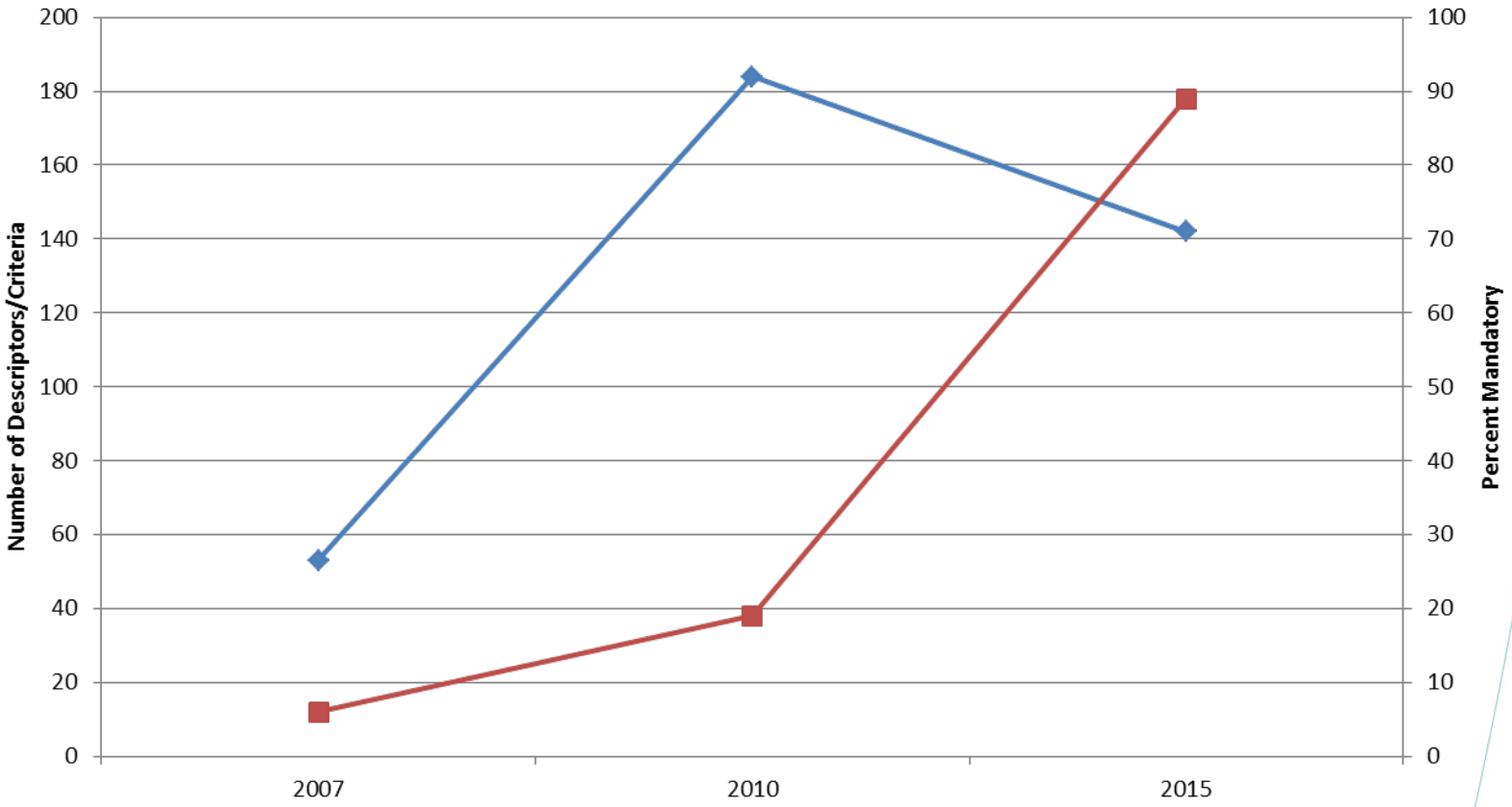
- 20 categories of standards
  - 11 non-discipline specific
    - 55% of total volume
  - 9 discipline specific
    - 45% of total volume

- Laboratory medicine standards accredited by ISQua
- Sent to DAP Committee for approval January 2015
- Made available to sites March 2015

DAP Laboratory Medicine Standards

- 2007 standards
  - 1050 descriptors
  - quality improvement category (4%)
- 2010 standards
  - 2720 descriptors
  - quality improvement category (5%)
- 2015 standards
  - 2504 criteria (8% reduction from 2010)
  - Quality Management Systems category - #2 (6%)

QI/QMS descriptors/criteria



I don’t think we’re in Kansas anymore, Toto

- Wind of change
  - ISO 15189

- 2012 Laboratory Reform Committee
  - Laboratory Services Plan
  - Recommendation 28: Adopt the International Standard Association Quality standard 15189 (ISO 15189) and move to a provincial accreditation program that is ISO 15189 compliant.

Quality Management System Standards

- 1.0 Quality Management
  - Policy, System, Manager and Manual
- 2.0 Documents and Records
  - Document control and standardization and technical records
- 3.0 External Services
  - Referral laboratories & consultants, External Services and materials
- 4.0 Communication and Consultation
  - Communication and feedback,

Quality Management System Standards

- 5.0 Nonconformities and Potential Nonconformities
- 6.0 Quality Management System Improvement
  - Risk management, internal audits, management review
- 7.0 Medical Peer Review

Additions to the standards

- Molecular genetics (pathology)
- Flow cytometry
- Expanded microbiology (TB, virology)
- Cytology including gynecological cytology
- Expanded point-of-care testing

Additions to the standards

- ISO 15189 requirements
  - Clear articulation of general requirements for quality
  - Some challenging areas
  - Some surprises for laboratories

2015 Accreditation Standards format

TRM1.3		Specific training for transfusion activities is provided		
TRM1.3.1	**M**	There is a documented training program for all personnel involved in all transfusion activities. There are documented processes for initial and ongoing training.	Z902 4.3.2.1, 4.3.6.2 CSTM 2.12(c)	TM10.3.10 REVISED
TRM1.3.2	**M**	Non-laboratory personnel collecting samples for transfusion medicine examinations are trained and competent in request and labeling requirements.		SCT1.7.1
TRM1.3.3	**M**	All personnel (laboratory or non-laboratory) who participate in the processing, storage or administration of blood components and products are trained and competent in the relevant procedures.	Z902 4.3.2.3, 14.4(b) CSTM 2.12(b), 2.13	NEW
TRM1.3.4	**M**	Personnel involved in the packing and transportation of blood components and products receive specific training. This is documented.	CSTM 5.6.1.2 Z902 9.5.1	TM1.1.1

Standard

Criteria

Reference Document

Link to 2010 Standards

Onsite surveys 2006-2010

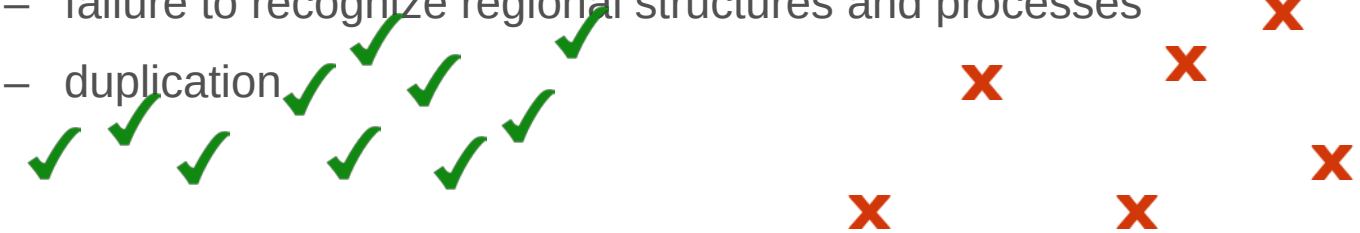
- Used 2007 standards
  - One survey per facility-assessed all descriptors at every site
  - Peer surveyors (up to 10 per site)
  - Paper based protocols
  - MS Word based reports
  - Prolonged turnaround time

Onsite surveys 2010-2015

- Used 2010 standards
  - One survey per facility-assessed all descriptors at every site
  - Staff surveyors (up to 3 per site)
  - E-Accred2 system
  - Electronic protocols using tablets
  - Electronically generated reports
  - Greatly reduced turnaround time

Accreditation assessment

- Previous surveys
  - failure to recognize regional structures and processes
  - duplication



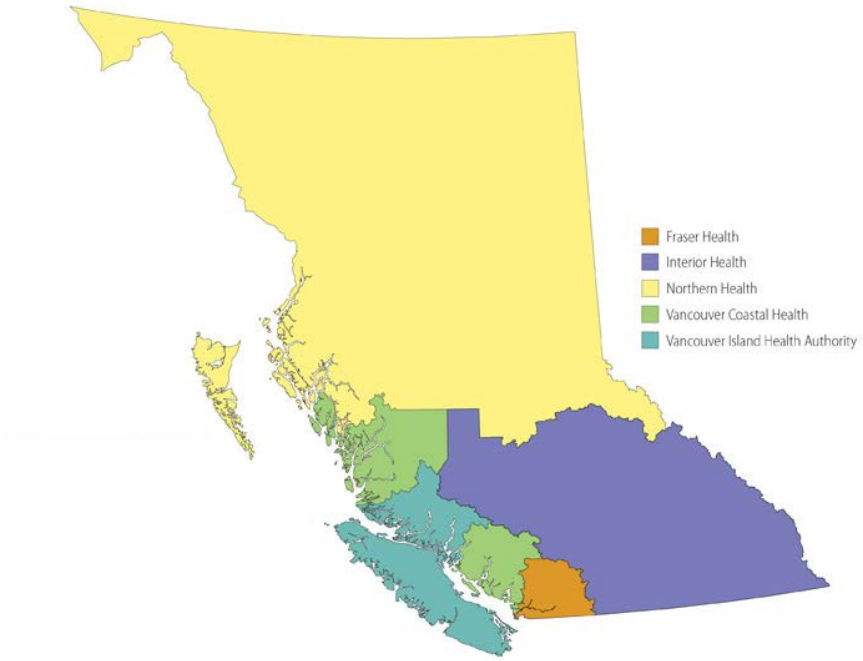
A new approach to assessment:

- Two-step assessment process

Regional assessments

Regional assessment – one per health authority or organization

- Multi-day assessment
- Staff and peer assessors
- Assess high level activities
- Organization
  - Structures
  - Policies
  - procedures
- 69% of criteria



Facility Assessments 2016

Facility assessment – one at each facility

- Done after regional assessment
- One day (typically)
- Staff assessors
- Assess operational processes
  - Records
  - 52% of criteria

Benefits of two-step process

- Don’t need to assess all criteria at each facility
  - Less duplication
- When deficiencies are found in “regional” criteria, only one outstanding mandatory requirement issued
  - Less duplication and evidence submission
- Speaking of evidence submission
  - Less pre-assessment evidence submission

Regional assessment-beta testing

- December 2015 – January 2016 - Interior Health Authority
- Assessment teams
  - Laboratory physician
  - Laboratory administrative director
    - Health authority laboratory medical
    - Director health authority administrative director
  - DAP accreditation assessment officers
    - Health authority laboratory personnel

Current common “deficiencies”

1. Centrifuges
2. Signage
3. Limits of detection studies
4. Consistency of morphological observations
5. Thermometers and temperature monitoring
6. Quarantine areas in transfusion service
7. Instrument and equipment inventories

- Movement toward more quality focused areas in the standards

1. Procedures for referral laboratory/consultant selection, evaluation and monitoring

QMS3.1.1

There is a procedure for the selection, evaluation and monitoring of the quality and competence of referral laboratories and consultants. ISO 15189: 4.5.1a

- The referring laboratory is required to maintain evidence from the referral laboratory or referral consultant that demonstrates competence, such as licensure, certification or accreditation status.
- Referral laboratories and referral consultants working in laboratories that are accredited by the DAP are exempt.

2. Reporting results from a referral laboratory

PRE5.2.1

The referring laboratory is responsible for ensuring that a report of the referral laboratory's examination results is provided to the user unless other arrangements have been documented. ISO 15189 4.5.2

- A referring laboratory not reporting results from a referral laboratory is required to have evidence (e.g. email, letter etc.) that the referring laboratory will report results directly to the user.
- This applies to all referral laboratories.

3. Measurement uncertainty

EXA3.2.1

The laboratory determines measurement uncertainty for each quantitative measurement procedure. ISO 15189 5.5.1.4

- Measurement uncertainty is reviewed at a defined frequency
- Measurement uncertainty is provided to users upon request
- Measurement uncertainty is considered when interpreting measured quantitative values

Resources for measurement uncertainty:

- ISO/IEC Guide 98-3
- CLSI EP29-A Expression of Measurement Uncertainty in Lab Medicine
- Local chemistry resources

4. Biological Safety Cabinets

SAF4.2.5

BSCs are used for handling organisms considered highly contagious by airborne routes and for setting up samples that may potentially contain these organisms. ISO 15190 16, CLSI GP17-A 3.5.1.1

- This is a general safety item, not exclusive to microbiology

5. Comparability

QUA3.1.1

There are procedures to establish the comparability of procedures, equipment and methods used, and establishing the comparability of results for patient samples. This is applicable to the same or different procedures, equipment, different sites or all of these. ISO 15189 5.6.4

- Comparability studies must be performed twice per year
- Comparability studies must be performed within a site and at different sites
- Proficiency testing does not demonstrate comparability
- Patient samples are preferred to QC samples

Resource document:

- CLSI EP31-A-IR Verification of Comparability of Patient Results Within One Health Care System

6. Potential nonconformities

QMS5.2.1

There are procedures for reviewing laboratory information and data to determine where potential nonconformities exist, identifying the cause(s) of potential nonconformities, and evaluating the need for preventive action. ISO 15189 4.11a-c

- Not in response to a nonconformity
- If discovered, preventative action is
  - Defined
  - Implemented
  - Recorded
  - Reviewed

7. Management review

QMS6.4.1

There is a periodic management review of the documents and records of the QMS. ISO 15189 4.15.1

- evaluations of assessment of user feedback
- internal audits
- use of quality indicators
- results of participation in proficiency testing and alternative assessment
- performance of suppliers
- monitoring and resolution of complaints
- follow-up actions from previous management reviews
- personnel and premises that affect the QMS
- personnel suggestions
- risk management
- reviews by external organizations
- results of continual improvement including corrective actions and preventive actions
- identification and control of nonconformities
- changes in the volume and scope of work
- recommendations for improvement, including technical requirements

8. “Users”

User

- Physicians and others who order diagnostic examinations and/or receive diagnostic information and reports from laboratories.
- Standards often use the term “patients and users”
- **Synonyms:** authorized requestor, ordering physician, clinical personnel

QMS4.1.4

The laboratory solicits information relating to user perception as to whether the service has met the needs and requirements of users. Records of information collected and actions taken are maintained. ISO 15189 4.14.3

9. Point-of-care authority

POC1.1.6

A health professional group such as the medical advisory committee (in consultation with administration and the laboratory director or designate) is responsible to the governing body for defining the scope of POCT available. ISO 22870 4.1.1

- Governing body

POC1.2.1

The laboratory director or designate is assigned responsibility for appointing a multidisciplinary POCT management group with representation from the laboratory, administration, and clinical programs including nursing, to advise on the provision of POCT. ISO 22870 4.1.2.2

- Roles and responsibilities of POCT management group
  - Define authorities,
  - Review proposals, assist in evaluation and selection of equipment

10. Equipment reagents and supplies

QMS3.3.1

There are procedures for the selection and purchase of external services, equipment, reagents and consumables that affect the quality of examinations. ISO 15189 4.6, 5.3.2.1, 5.3.1.1

ERS1.1.2

Suppliers are selected and approved based on their ability to supply services, equipment, reagents and consumables in accordance with the laboratory's requirements. ISO 15189 4.6

ERS1.1.4

The performance of suppliers is monitored to ensure that purchased services or items meet stated criteria. ISO 15189 4.6

11. Risk Management

QMS6.2.2 There are documented processes to report and review personnel and patient risk. A risk register of all identified risks is maintained. ISQua 4.2

- Potential risks may include:
  - Improper patient identification
  - Sample handoffs
  - Recognized QC failure after reporting
  - Reporting errors
  - PPE use
  - Hand hygiene

12. Medical peer review

QMS7.1

There is an established medical peer review program

QMS7.2

The medical peer review program includes defined elements

- 2014 Medical Peer Review Advisory Group established:
  - Criteria
  - Evidence for fulfillment

What have we learned?

- Collaborative approach (external and internal)
  - Produces better standards
  - Clarity for DAP and laboratories
  - Improved laboratory satisfaction and buy-in

- Reliance on source documents
  - Produces better standards
  - Clarity
  - Improved laboratory satisfaction and buy-in

What's Next?

- Movement from "big bang" to minor explosions
  - Keep current with source document releases
  - Remove the need for major change documents
  - Issues with maintenance
- Different versioning of standards

- Next version of standards in 2016

Questions and Resources

- DAP.org
- DAP.org – 2010 & 2015 Standards – FAQs
- laboratorymedicine@cpsbc.ca or dapinfo@cpsbc.ca