



RÉSEAU DE SANTÉ

Horizon
HEALTH NETWORK

Using ISO 15189's QMS to Achieve
Standardization and Improved Performance
Across Multiple Labs in New Brunswick.

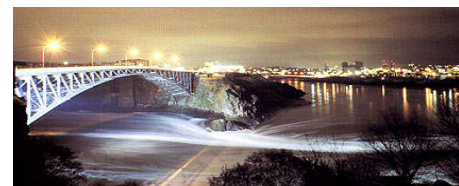
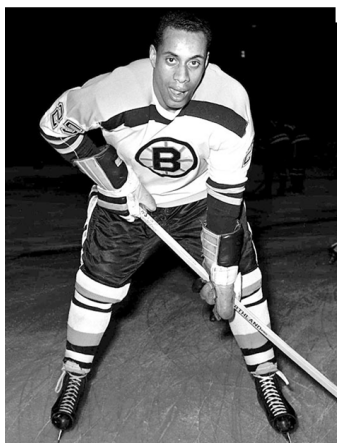
New Brunswick, eh?



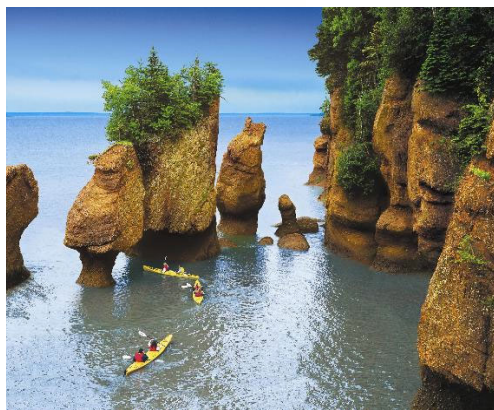
New Brunswick (NB)

- Population ~ 750,000
- Average Temperatures (°F)
 - January Low 4.1 / High 24.8
 - August: Low 54 / High 77
- 27,590 sq mi (roughly same size as West Virginia)
- Only bilingual province in Canada
 - English ~67%
 - French ~33%

NB Notables



World's Longest Covered Bridge - 1282 Feet
Hartland, New Brunswick (Canada)



Question?

- Where does 1/3 of the worlds French Fries come from?
- Where was the first chocolate nut bar produced in North America?
- Only reversing falls in the world is located where?
- Where are the highest tides in the world?
- The “Jackie Robinson” of Hockey grew up in what city?

Answer: New Brunswick!!

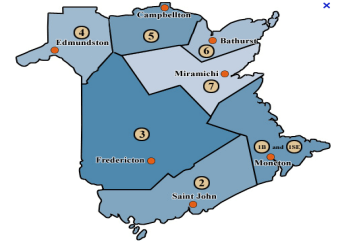
- Where does 1/3 of the worlds French Fries come from?
McCain's, Florenceville NB
- Where was the first Chocolate Nut bar created in North America? Gagnon Brothers, St Stephen, New Brunswick
- Only reversing falls in the world is located where?
Saint John, New Brunswick
- Where are the highest tides in the world?
Bay of Fundy 47.5 to 53.5 feet.
- The “Jackie Robinson” of Hockey grew up in what city?
Willie O'Ree, Fredericton NB

Health Care in NB

- Government funded
- All citizens have access to Medicare
- 2 Regional Health Authorities (RHA)
 - Horizon Health Network (HHN)
 - Working language: English
 - \$1 billion budget
 - Staff of 13,000
 - Service population ~ 500,000
 - Vitalité Health Network (VHN)
 - Working language: French
 - \$660 million budget
 - Staff of 7600
 - Service population ~ 250,000

The Beginning of Horizon Health Network

- NB Healthcare was previously divided into 8 Regional Health Authorities.
- September 1, 2008 Horizon and Vitalité Health Networks were founded: each having 4 former RHA's within.
- HHN was formed with the following 4 previous RHA's:
 - Moncton
 - Fredericton and Upper River Valley
 - Saint John
 - Miramichi



Blue – HHN
Yellow – VHN

Horizon Health Network

- Hospitals – 13
- Over 100 Facilities, clinics and offices
- One of the largest employers in NB: 13,000 Staff
- 3500 Volunteers, auxiliary and alumnae members
- ~ Hospital beds - 1,600
- ~ Admissions - 55,000 (acute, rehab and chronic)
- ~ Inpatient days - 580,000 (acute, rehab and chronic)
- ~ Surgeries completed per year - 45,000
- ~ Extra Mural Program visits annually - 275,000
- ~ Births - 5,400

Horizon Laboratory Network

- 4 Regional Laboratories
- 6 Community Laboratories
- 5 Collection Centers

Horizon Health *Mi*
Laboratory Medicine *Mi*
Program



Saint John Regional
Hospital



Dr Everett Chalmers Regional
Hospital

Saint John Area

Fredericton Area

One Lab Many
Sites

Sussex Health Centre

Charlotte County Hospital

St Joseph's & KV Collection Centres

Oromocto Public Hospital

Upper River Valley Hospital

Hotel Dieu de St Joseph

Tobique Valley & Queens North
Collection Centres

Moncton Area

Miramichi Area

Sackville Memorial Hospital

Jones Lake Collection Centre



The Moncton Hospital



Miramichi Regional Hospital

Laboratory Medicine Program

- One of the largest network of Laboratories in Atlantic Canada
 - 10 Labs and 5 Collection Centers
 - 600 total staff
 - 39 Physicians/Scientists
 - 400 Medical Laboratory Technologists
 - 16,000,000 Procedures annually
 - \$52 M budget

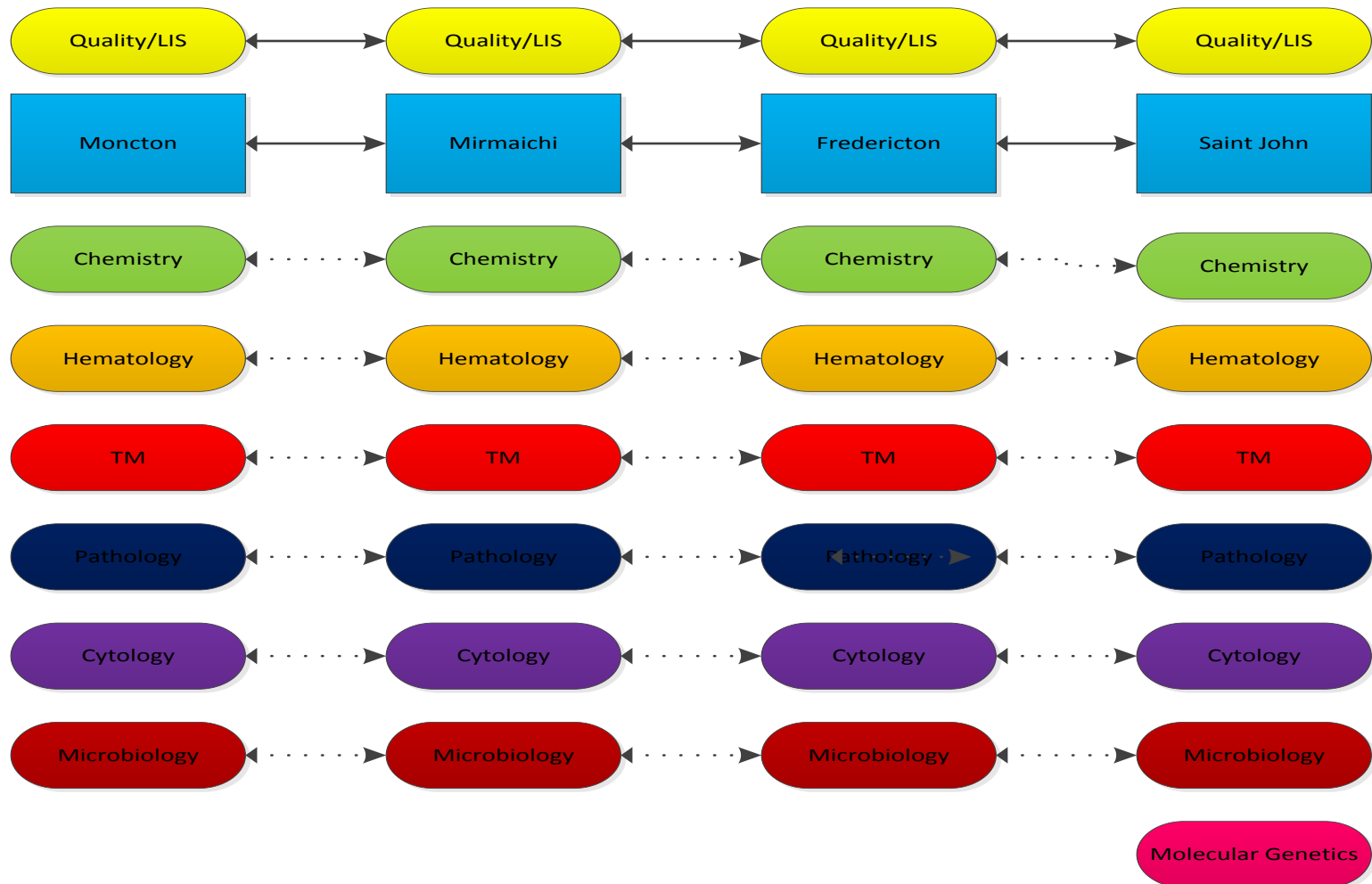
Laboratory Departments

- Anatomical Pathology
- Hematology
- Cytology
- Biochemistry
- Transfusion Medicine
- Microbiology
- Cytogenetics
- Molecular Diagnostics

Specialty Services

- Forensic Pathology
- Toxicology
- Forensic Toxicology
- Stem Cell Laboratory
- Level 3 Laboratory
- Molecular Diagnostics
- HPV Testing
- New born registry

Structure of Work (Prior to June 2013)



Mission, Vision and Values:

- Our mission is to support excellence in patient care through the provision of timely and accurate clinical information
- Our vision is to be an innovative healthcare team; creating high quality laboratory services through Leadership, Education and Research
- Our Values
 - We do our work with:
 - Compassion
 - Accuracy
 - Respect
 - Excellence

One Lab Many Sites

- In 2010 we started moving towards enhanced Regionalization within our lab network using our slogan “One Lab Many Sites”
- In May 2011 it was announced by the provincial DOH that all laboratories in New Brunswick would move towards a standardized Quality Management System

QMS Model of Choice – OLA

- OLA – Ontario Laboratory Accreditation
- Founded in 2000 – Operated through Ontario Medical Association (OMA)
- Based on ISO 15189, ISO 15190, ISO 22870 and the Canadian Standards Association's CSA-Z902
- Peer review process

Why OLA (15189)?

The move to a new accreditation model stemmed from a recommendation (#20) made by Justice Paul S. Creaghan through the Commission of Inquiry into Pathology Services at the Miramichi Regional Hospital in 2008. An ad-hoc group established in April 2009 reviewed various laboratory quality control recommendations made by Creaghan. Based on the weighted criteria, the Ontario Laboratory Accreditation model was unanimously recommended as the best to accredit New Brunswick laboratories in 2011.

Why do we **CARE** about OLA?

- We knew we were a good laboratory service, our Accreditation Canada results validated that.
- BUT we want to be a GREAT service and we knew OLA had a reputation for demanding excellence.

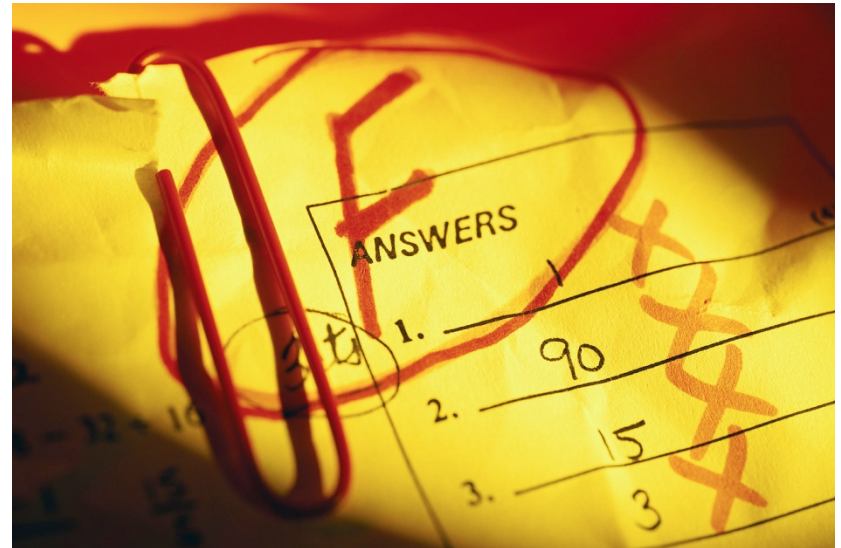
In the beginning of the OLA Journey...

- Fear of the unknown was a BIG driver



The most common phrase's we heard...

- If we don't... we are going to fail OLA!
- If we don't... we will shut labs, have layoffs..



But we quickly learned

It is all about correcting the non-conformances:
Not pass or fail.

What is Accreditation?

Conformity Assessment

- Standard set
- Process-based assessment
- Seek conformance



5 Phases of the OLA Process

- Phase 1 – Self Assessment
- Phase 2 – (AKA: OMG Phase) – Non conformance correction and standardization
- Phase 3 – The actual OLA assessment
- Phase 4 – Major non-conformance correction and minor action plans
- Phase 5 – Receive OLA certificate ... (and sleep again)

Digging in... Phase 1- The Self Assessment

- The self-assessment used the pivotal OLA checklist of requirements to set a base line of how our current quality program matched up against the OLA standards.



Self Assessment....

- Performed by all laboratories in HHN from December 2011 – February 2012
- Assessed current laboratory practise against OLA requirements (4 different lab practises)
- Performed by laboratory staff in each area led by the area Quality Coordinator
- OLA supplied the Check list and many tools to help aid in the assessment

Self Assessment.... Tools

“The Checklist”



• 11 Tenant's:

- I. Organizational Structure, Personnel Policies and Training, and Laboratory Management
- II. Quality Management System
- III. Physical Facilities
- IV. Equipment, Reagents and Supplies
- V. Pre-analytical Process
- VI. Analytical Process
- VII. Quality Assurance
- VIII Post-analytical Process (Reporting)
- IX. Laboratory Information System
- X. Safety
- XI. Point-of-Care Testing

Self Assessment.... Tools

Decoding ISO 15189



Decoding ISO 15189 Online Education Series

The Decoding ISO 15189™ interactive online education series is designed to help you understand and implement the ISO 15189 standard. The series is highly interactive and allows users to learn at their own pace and on their own schedule. You can refer to modules and the accompanying resource material anytime. The modules vary in length, and each module builds on the next. At the completion of the whole series you will be equipped to begin implementing the ISO 15189 standard for your laboratory and be that much closer to the ultimate goal of Accreditation.

Module	Title	Description	Release Schedule
1	Introducing ISO 15189: World Class Excellence	<ul style="list-style-type: none"> An understanding of the terminology used in the ISO 15189 standard and other quality models A general outline of ISO 15189 and its benefits to medical laboratory professionals Knowledge about the relationships between some common quality models 	November 9, 2011
2	Quality Management: The Essential Cycle	<ul style="list-style-type: none"> An understanding of the four key components of a quality management system Insight into the most common problems medical labs face in implementing a quality 	November 9, 2011
3	Setting the Stage for Change: The Paradigm Shift	<ul style="list-style-type: none"> A 10-step plan to start down the road to ISO 15189 accreditation Practical tips on how to sell the concept of 15189 accreditation to top management Advice on how to sell the concept to staff 	November 9, 2011
4	Document Control: Say What You Do	<ul style="list-style-type: none"> An understanding of the rationale for document control Practical tips on which documents need to be controlled An understanding of the difference between documents and records Information on the advantages and disadvantages of various document control systems 	November 16, 2011
5	The Quality Manual: Your System Roadmap	<ul style="list-style-type: none"> An understanding of what comprises a quality manual Options for a quality manual framework Tips for surviving an audit 	November 16, 2011
6	Process Maps and Procedures: Get the Picture and Develop It	<ul style="list-style-type: none"> Knowledge of the ISO standards on documentation How to create process flow charts Practical advice on writing step-by-step procedures 	November 16, 2011
7	Occurrence Management: The Heart of Quality	<ul style="list-style-type: none"> Tips on how to identify non-conformities A guide to addressing non-conformities through root cause analysis and corrective action Instructions on using cumulative non-conformity data to drive 	November 30, 2011

- 15 Modules decoding everything from managing resources to document control.

NOTE: Extremely valuable tool since this was our first time using the OLA standards

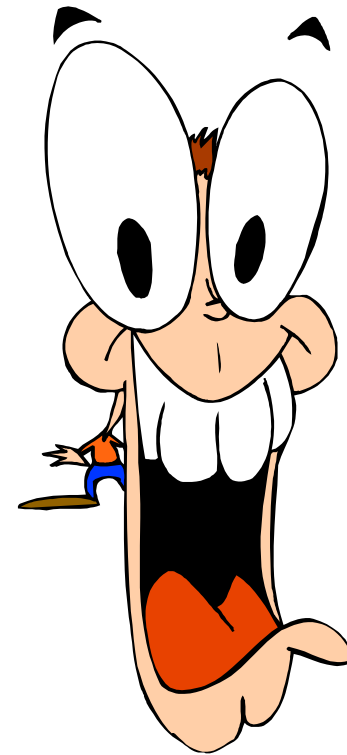
Crossing our fingers.....

- Results were reviewed and sent into OLA on February 21, 2012.
- After a few suggestions from OLA the results were ready, we had our list to start working from...

Phase 2: Results were ready..

That is When...

The enormity
of the project
sunk in for
us!!



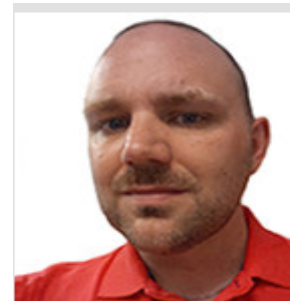
The Results.... EEEEEK

Area	Standards Met	Major Non-Conformances	Minor Non-Conformances	Total Requirements Assessed	Total Non-conformances	% Conformance
Saint John	1209	298	544	2051	842	59%
Moncton*	1151	12	119	1282	131	90%
Fredericton	1870	146	479	2495	625	75%
Miramichi	383	24	67	474	91	81%
Overall	4613	480	1209	6302	1689	73%

NOTE: Moncton Area was previously CAP Accredited for ~20 years

New Addition To The Quality Team: March 2012

- Regional Coordinator for Laboratory Quality, Safety and Process Management hired and introduced to the team March 19, 2012.
- Main responsibility: to help led the 4 Quality Coordinators in the OLA process and to help standardize quality across Horizon Labs.
- Yup he was given a challenge with a deadline of April 2013..
- Thankfully he liked a challenge 😊



March 19, 2012 – The View of the Laboratory Landscape

- 4 areas working together marginally in relation to quality
- 4 different thought processes
- 4 different Quality Manuals
- 4 different document control structures
- Independent divisions within each area



Moving Forward

- A regional excel tracking tool was developed to monitor the management of the non-compliances on a common drive (Maximum distant between any 2 hospitals with HHN~ 350 km /220 miles)
- This proved valuable but stress inducing. Teams attacked the biggest items first, which were the most time consuming and the slowest to “check-off” in the tracking system.

Day 1

Time (1 year)

April 2013

Working together

- We tried to seize the opportunity and continue to build on the regionalization that had been our top priority since 2008.
- Our motto of “One Lab many Sites” was about to have its first real challenge.

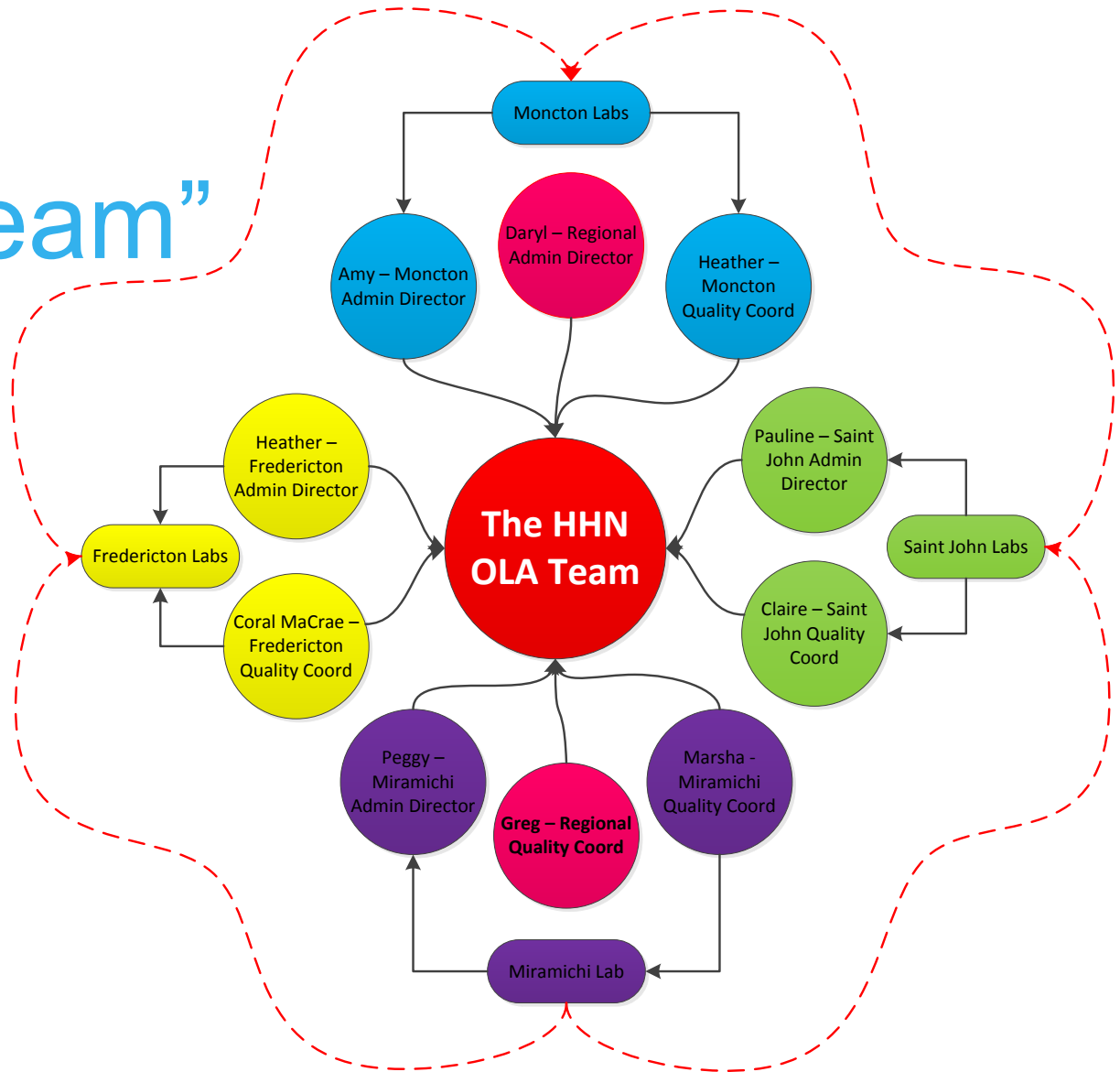
Local Teams

- Represented all parts of the Laboratory and integrated Laboratory Clinicians into the process whenever possible/required.
- Each was chaired by the Clinical Chief but managed by the Quality Coordinator.
- Each local team reported to the Regional Team

Regional Team

- Chaired by the Regional QSPM Coordinator
- The Administrative Directors and Quality Coordinators were the Regional Team and worked to drive the process forward in each area
- October 2012 - The Regional team and other laboratory employees (total 25) participated in OLA assessor training, gearing us up for the big day

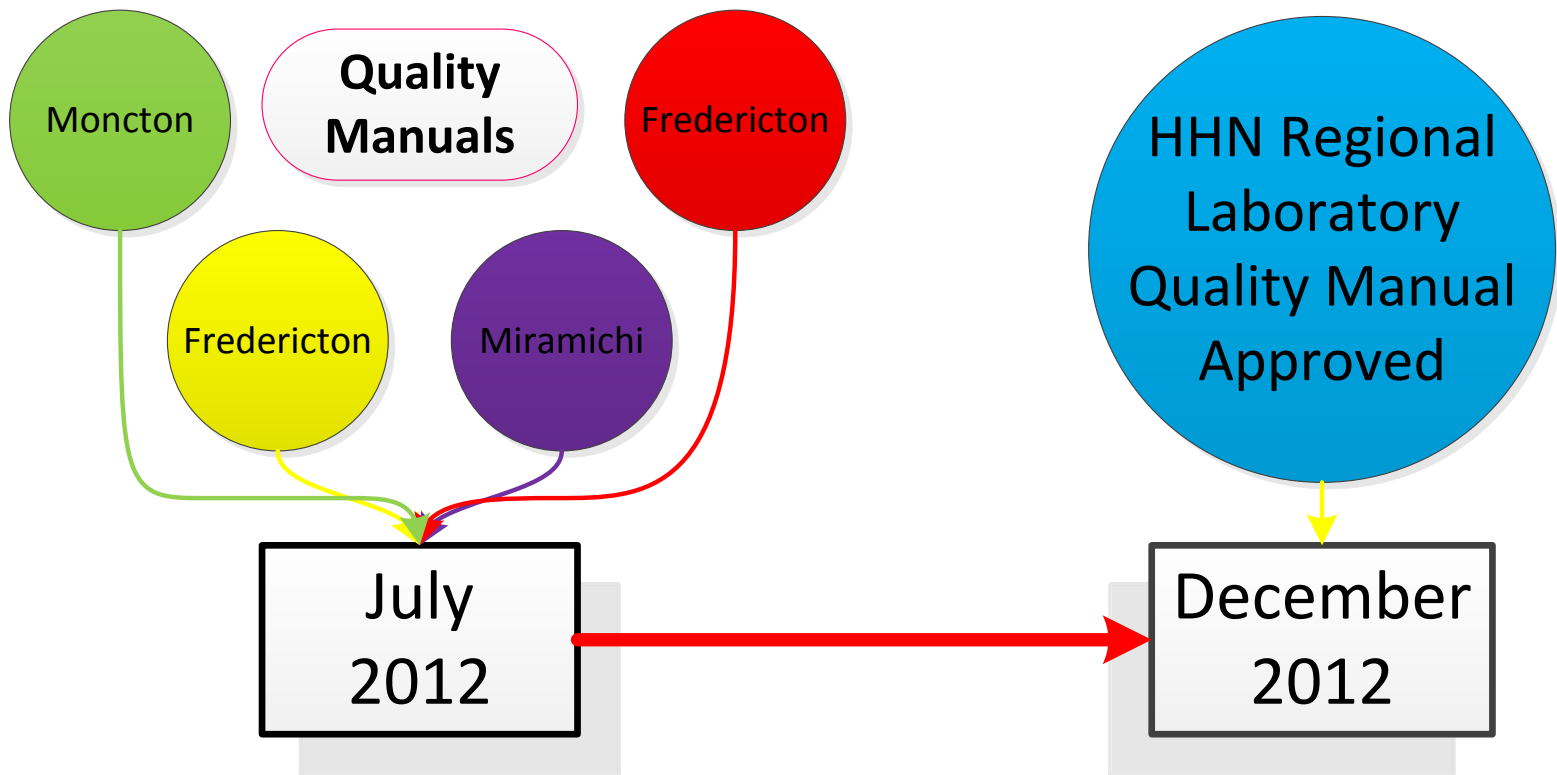
The “Team”



The “92 Page Document”

- AKA the Regional Quality Manual was signed and introduced in December 2012.
- Describes in details the quality outlines for how we do our laboratory business while taking into consideration the OLA requirements and how we address the standards.

The Quality Manual




The Regional Quality Manual

- A common Regional Quality Manual was a key element in standardizing our quality program

This document applies to:		<input checked="checked" type="checkbox"/> All Horizon	<input type="checkbox"/> Z-1 Moncton	<input type="checkbox"/> Z-2 Saint John
		<input type="checkbox"/> Z-3 Fredericton	<input type="checkbox"/> Z-3 Upper River Valley	<input type="checkbox"/> Z-7 Miramichi

Horizon Health Network



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Regional Laboratory Quality Manual

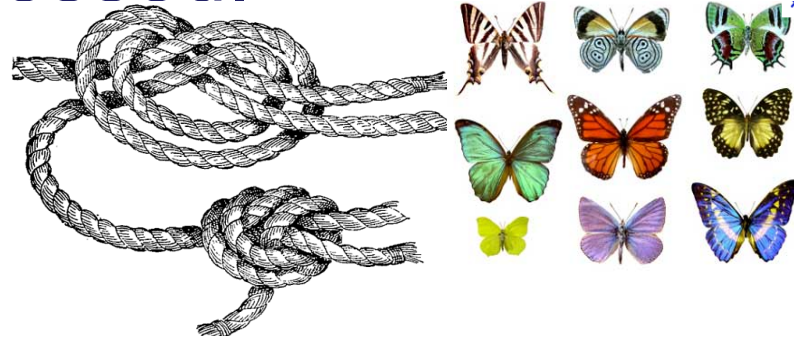
NOTE: This is a CONTROLLED document. Any document appearing in paper form is not controlled and should ALWAYS be checked against the electronic version prior to use. Printed on: 04/04/2019

Policy Number:	RQG-LIS-02-001	Draft Date:	December 21 2012
Section:	Laboratory Information	Original Date:	March 16 2010
Issued by:	Reg Quality and Safety Committee	Revision Details:	N/A
Approved by:	Reg Clinical Directors		Page 1 of 68

January 1, 2013

Once the Calendar flipped to 2013, we knew we this “OLA Thing” was real as we were only 4 months away from our first sites being assessed.

That's when the
Started to sink in...



Next Big step in our standardization progress..

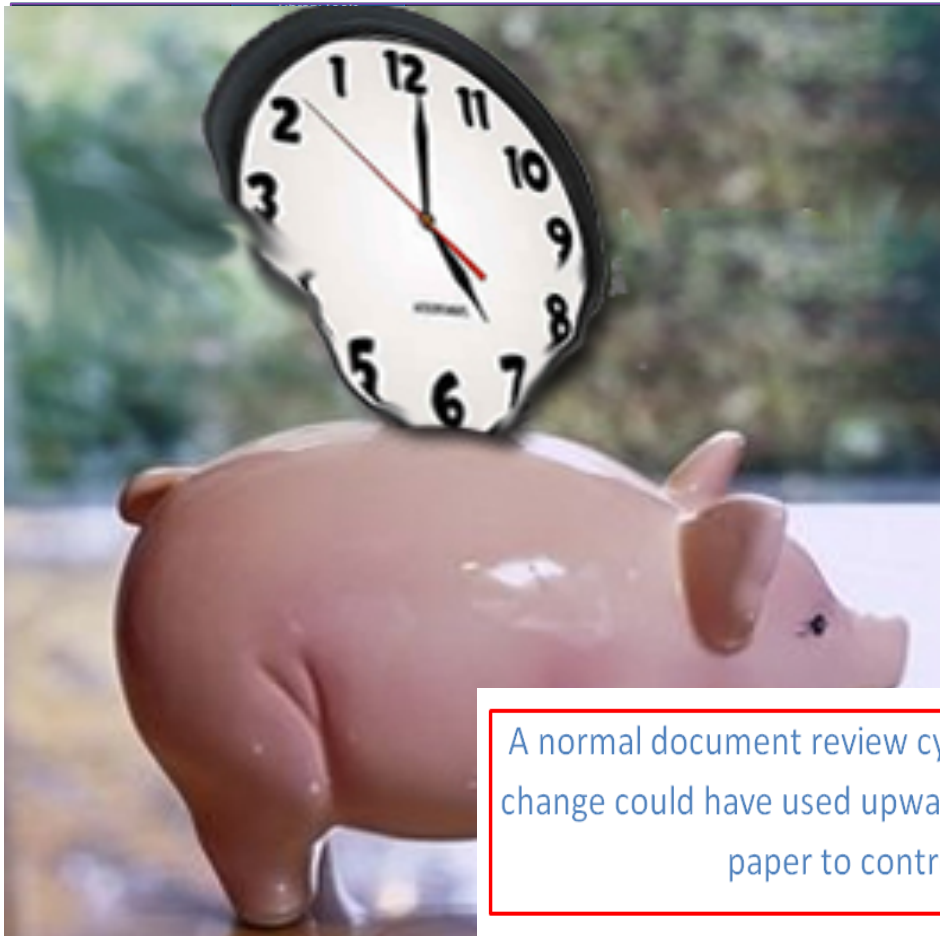
- So we had this great regional quality manual, but where does it live? How do staff access it? How do we keep it document controlled? So many questions... so little time.
- All 4 area's used a Sharepoint product to manage **viewing** of documents, but we continued to exist as 4 separate silo's....
 - Different Sharepoint versions/platforms
 - Could not view each others documents
 - Different functionality used
 - 3 areas used paper to manage document control but used Sharepoint to view documents (we bought a car but we were pushing it around)



Regional Sharepoint

- End of February 2013 a Regional Sharepoint site was unveiled with:
 - Standard electronic functionality
 - Met standards set out by accreditation
 - We could finally view each others documents
 - Regional Section created for standard documents (including Quality Manual)

Regional Sharepoint



A normal document review cycle with a minor change could have used upwards of 6 pieces of paper to control



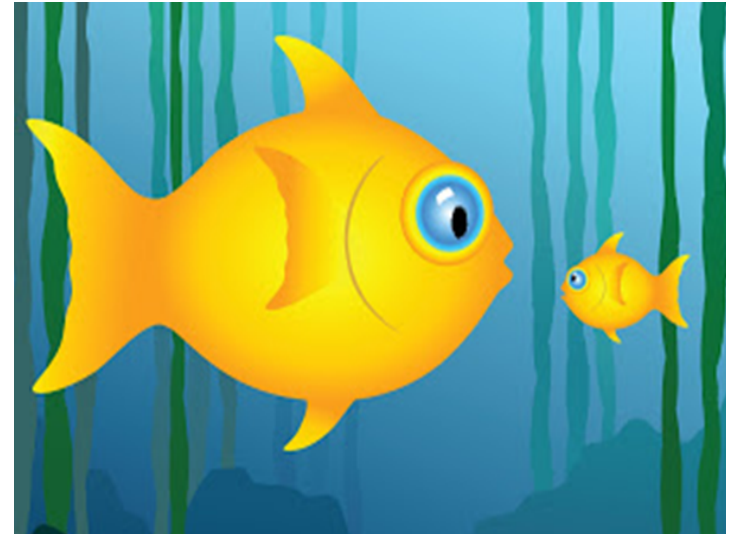
Onwards... upwards.

- We finally had some standardized tools implemented for all 4 areas.
- Now what... PHASE 3 maybe?

THE OLA ASSESSMENT!

So it begins, the VISIT's

- We felt like small fish in a big sea. Our big cousins from Ontario were coming to go through our underwear drawer. Being from a small province we know its not about size, but it was a bit intimidating: Ontario had been doing OLA for 10+ years!!!



The “Visits”

- At first we thought it sounded familiar, like the Accreditation Canada survey we had been through in the past.
- We were wrong! The Ontario peer team moved into our laboratories for several days/weeks and were very detailed.
- They checked processes, measured temperatures, dug into our records, questioned staff and clients at a level of detail we had never imagined

The “Visit”



- Although very respectful, the assessors were relentless in their pursuit of Plan-Do-Check-Act
- Over and over they wanted to see the policy, see the action, see the evidence, see the monitoring and see the correction.

The “Visits”

- From April 8th to May 24th OLA Assessor’s were hard at work assessing our 4 Regional Labs, 6 Community Hospitals, and 5 collection centers
- A grueling 6+ weeks, a few sleepless nights and some tears of joys later....

The Final “Visit”

- The green light did not start to fix non-conformances until the last site was assessed. Naturally this was my site in the Miramichi, so the pressure was on to have a good push to the finish.



- After each area visit staff were given feedback from the assessor team through a plenary meeting. Ten days after each area was assessed we received the list of major and minor non-compliances and had 90 days to repair the majors and develop an action plan for the minors.

The Assessor Results Are In

Area	Standards Met	Major Non-Conformances	Minor Non-Conformances	Total Requirements Assessed	Total Non-conformances	% Conformance
Saint John	1801	79	254	2134	333	84%
Moncton	927	21	118	1066	139	87%
Fredericton	1816	52	315	2168	367	84%
Miramichi	398	13	61	470	74	85%
Overall	4942	165	748	5838	913	85%

Pre/Post: Lets Compare

Area	Pre-Assessment (%)	Assessment (%)	% Change
Saint John	59	84	25
Moncton	90	87	-3
Fredericton	75	84	9
Miramichi	81	85	4
Overall	73	85	12

POC – The Battle Continues.

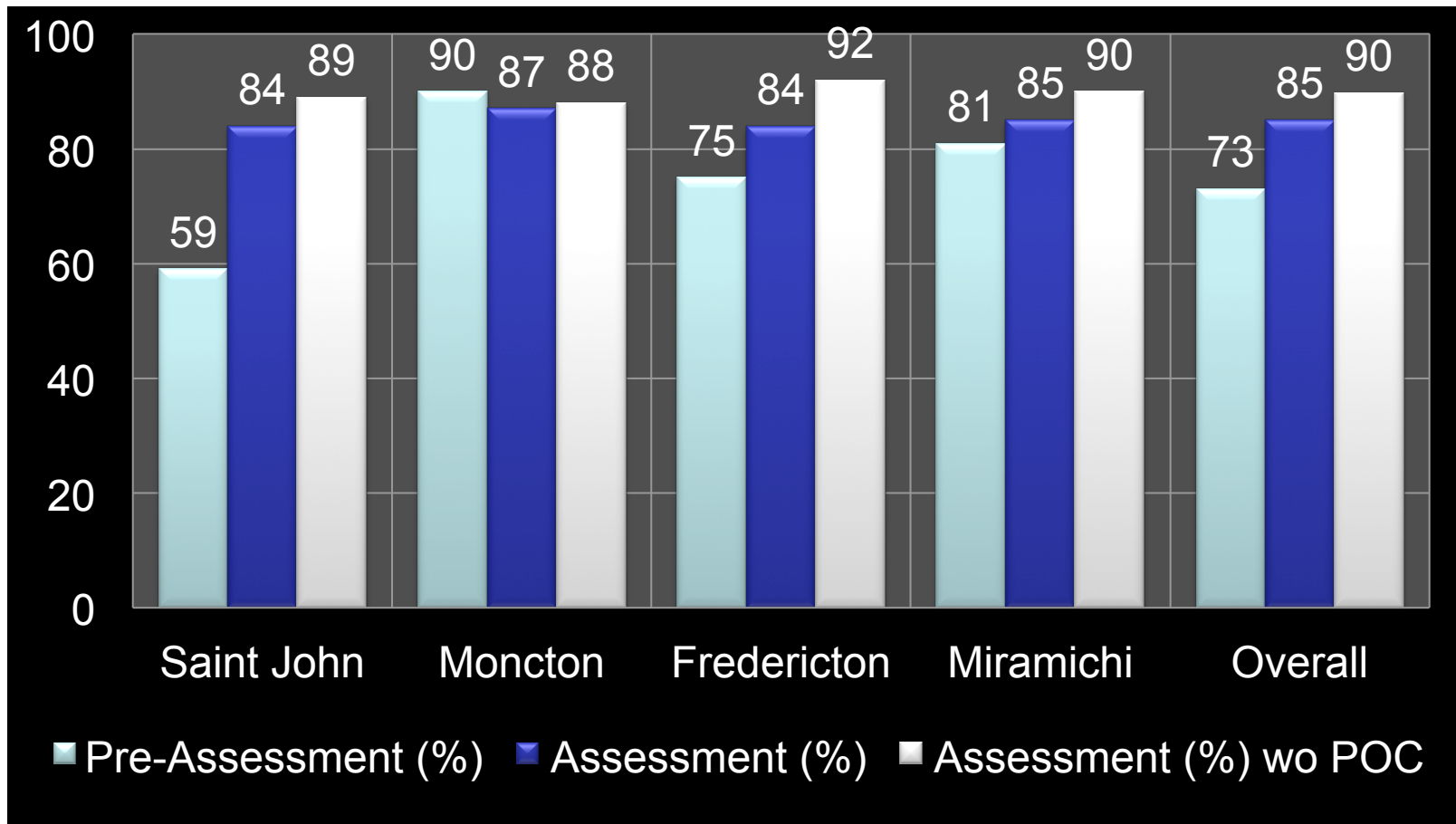
- Point of Care was the hardest hit section, but we were aware of this prior to the OLA assessment.
- He have amazing dedicated POC Coordinators, but we know that POC involves more than lab.
- We knew we didn't have time to correct all of our POC non conformances from the Self assessment and we wanted to build a foundation that would allow us to be successful with POC: So we took a hit
- We started working towards a Regional POC Committee late in 2012 and held the first meeting June 2013.

POC – The Battle Continues

Area	Assessment (%) with POC	Assessment (%) wo POC	Change (%)
Saint John	84	89	5
Moncton	87	88	1
Fredericton	84	92	8
Miramichi	85	90	5
Overall	85	90	5

NOTE: 42.7% of non-conformances were from POC

Moving in the right direction...



Day 1 of 90: May 24, 2013

- First working day after OLA assessment.. The light turned Green
- Physically and mentally exhausted
- But the party must go on... we only have 89 more days
- Corrective action Deadline: August 23



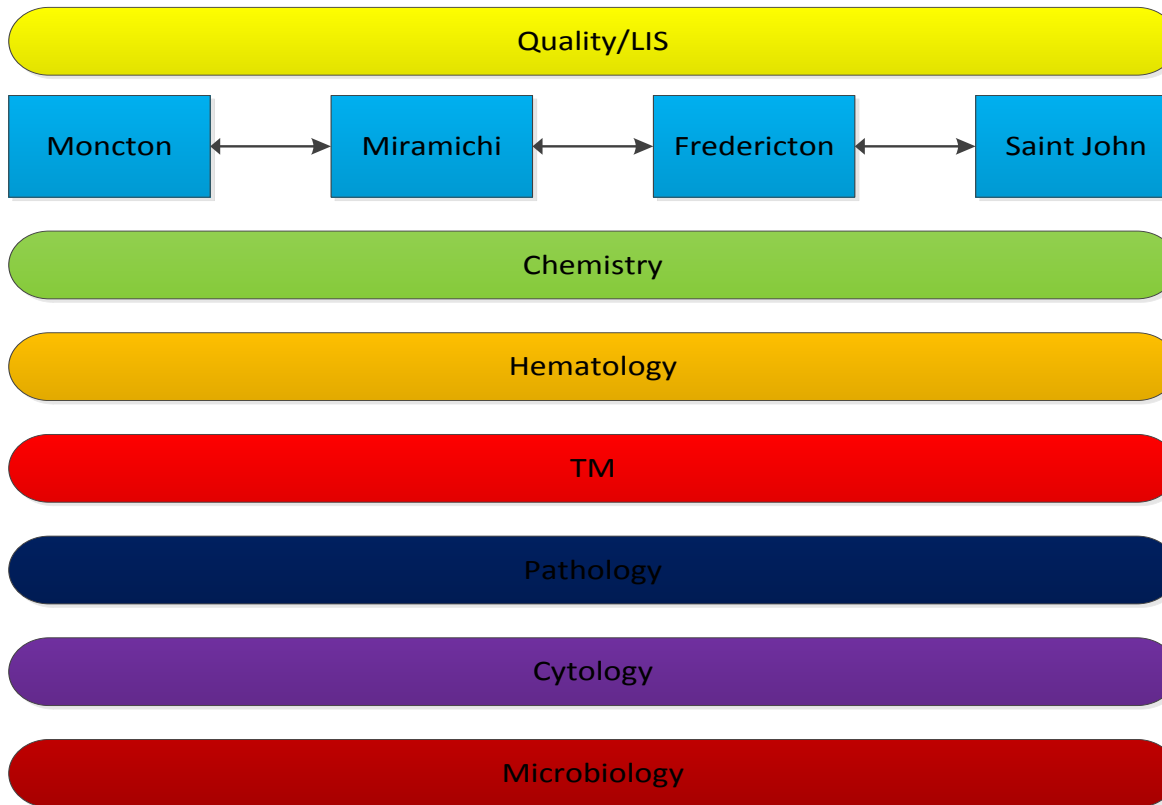
90 Day Challenges

- June/July/August – prime summer vacation months in NB
- Exhausted staff – low morale due to recent workforce adjustment and new structure to operate lab Medicine
- Staff facing OLA burn out
- Keep staff motivated
- Where do we start the process....

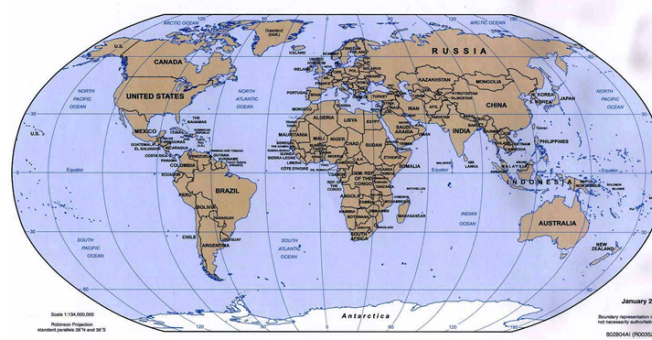
Phase 4: Back to Tracking

- A tracking system (simple excel tool) was developed and used to manage the corrective actions, monitor the progress.
- Each facility had to fix major non conformances and have action plans for minor non conformances
- The quality coordinator in each area was responsible to direct the traffic, while keeping in mind regional solutions for regional non conformances
- With the recent WFA and organizational change – Laboratory Divisions were create to manage divisions of work

Divisions and Structural Change



The Map




- We mapped out all non conformances to know where we need to start tackling regional non-conformances

Tenant	Req # (Do not use this filter)	X Major • Minor	7024 DECH	7025 HDSJ	7026 QNCH C	7027 OPH	7028 TVCH C	7029 URVH	7021 MH	7022 JLC	7023 SMH	7015 SJRH	7016 SJRH SC	7017 CCH	7018 SJH	7019 SHC	7020 KVHC	7030 MRH
1	1.B.10	The facility shall evaluate staff skills to perform assigned tasks following training and periodically thereafter. Records shall be	X	X	X	X	X	X	X	—	X	X	—	X	X	X	•	•
1	1.B.11	The laboratory shall provide training for personnel prior to the performance of duties without direct supervision.	—	—	—	—	—	—	—	—	—	—	—	—	—	•	—	—
1	1.B.11.2	The personnel training program shall include training in quality assurance/quality management.	—	—	—	—	—	—	—	—	—	—	•	—	—	—	—	—
1	1.B.14	The laboratory management shall conduct and maintain records of periodic performance evaluations for all staff.	—	—	—	—	—	—	—	—	—	—	—	—	—	•	—	—
1	1.B.4	The laboratory shall have a job description readily available for each personnel position that includes educational and professional qualifications and defines duties and responsibilities.	—	—	—	—	—	—	—	—	—	•	—	—	—	—	—	—
2	2.A.3	The quality management system shall be communicated to and understood by all personnel. The related policies, processes and procedures shall be readily available to appropriate staff.	•	•	•	•	•	•	•	•	•	•	•	—	•	•	•	—

Example of Regional Problem + Solution

- I.B.10 Major: The facility shall evaluate staff skills to perform assigned tasks following training and periodically thereafter. Records shall be maintained. Major - TM111
 - There is no evidence of ongoing training for staff involved in blood component/product administration, and there is no evidence of a formal program to assess skills in transfusion-related activities for staff involved in these activities.
- Non- Conformance was noted in 12/15 facilities
- Regional TM Division was able to successfully implement “bloody easy” program from ORBCON.

Keeping Score



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OLA STATUS DASHBOARD						Regional-Major		53.9%
						Regional - Minor		17.5%
TMH		SMH		JLC		MRH		
Major	18.2%	Major	20.0%	Major	NA	Major	61.5%	
Minor	6.9%	Minor	7.7%	Minor	33.3%	Minor	6.6%	
DECRH		URVH		OPH		QNCHC		
Major	88.9%	Major	88.9%	Major	88.9%	Major	100.0%	
Minor	6.9%	Minor	5.4%	Minor	6.7%	Minor	3.1%	
TVCHC		HDSJ		SJRH		SJH		
Major	100.0%	Major	88.9%	Major	26.9%	Major	60.0%	
Minor	3.1%	Minor	4.8%	Minor	32.0%	Minor	100.0%	
SHC		CCH		KVHC		SJRH SC		
Major	31.6%	Major	30.0%	Major	100.0%	Major	0.0%	
Minor	36.7%	Minor	44.4%	Minor	42.1%	Minor	0.0%	

August 23 2013

- All 15 corrective action reports were submitted at 13:02
- 2 hours and 58 minutes to spare 😊

Where are we Today?

- Phase 5 Receive OLA certificate ... (and sleep again)
- Expect to receive OLA Certificates mid to late October 2013
- Several of our team members have been asked to survey other labs, which is a measure in the quality of our resources.
- Went through a successful Accreditation Canada Survey last week (September 23-26)

What Next?

- Receive OLA Certificate in late October
- Continue to build and standardize the divisions and entire program
- We are sitting on the edge of great, but need to take the next leap forward
- OLA check up in August/September 2014
- Next self assessment – Late 2014
- Next OLA assessment – Late 2015
 - Improve on conformance % and leap to GREAT!

What have we learned?

- We can and will move from good to great but it will require:
 - Teamwork
 - Unity
 - Standardization
 - Commitment
 - Perseverance
 - Determination

What would we tell others

- **Do not underestimate the process.** It is long, complicated and difficult (but very rewarding).
- **Do not underestimate the value.** It is immense, for the clinician, the laboratorian, and most importantly the patient.
- **Do not underestimate your staff.** We are in awe of what our staff have accomplished in less than a 2 year cycle.

Lessons Learned:

- Would have educated staff earlier about the OLA process and ISO 15189 background
- Would have had more staff engagement and given out more projects and tasks
- Would have had OLA assessor training prior to self assessment**
- Started earlier with Regional Quality Manual production and implementation (Should have been first step)
- Have Quality Coordinators act as a regional audit team (would not audit own respective are)
- Have bench staff do more auditing to introduce the standards and process (this way it doesn't look like a "management thing")

Lessons Learned:

- Need to get better at collecting and analyzing metrics regionally (introduction within our next strategic plan FY14-15)
- Establish and measure more pre OLA indicators so that baselines are established and progress can be tracked.
- Have a well planned out attack so that it is evenly distributed.
- Make sure all staff are aware of the work that is taking place in the background

Never Stop Reaching for the Horizon



