

# **The role of ISO 15189 in Canada**

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**IQMH, Canada**

# **ISO 15189 – A Canadian National Standard**



# Regulation of Medical Laboratories in Canada



# ISO 15189



# Two Signatory Canadian Accreditation Bodies



Standards Council of Canada  
Conseil canadien des normes



Institute for Quality  
Management in Healthcare

# **ISO 15189 Accreditation Bodies in Canada**

***Similar, yet different...***



# ISO 15189 Accreditation - The Canadian Landscape



# Ontario





Quebec





# Newfoundland and Labrador



New Brunswick

# British Columbia





Institute for Quality  
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Centre for Accreditation



# Engagement

# Rigour

Confidence. *Elevated.*

# **IQMH - ISO 15189 Requirements**

- I Organization, Personnel & Management (34)**
- II Quality Management System (62)**
- III Physical Facilities (13+2)**
- IV Equipment, Reagent and Supplies (35+1)**
- V Pre-Analytical Process (55)**
- VI Analytical Process (14)**
- VII Quality Assurance of Laboratory Examinations (26+1)**
- VIII Post-analytical Process [Reporting] (36)**
- IX Laboratory Information System (46)**
- X Safety (116)**
- XI Point-of-care Testing (59)**

# **IQMH - ISO 15189 Requirements**

## **Discipline Application Guidance**

• <b>Anatomical Pathology</b>	<b>30</b>
• <b>Chemistry</b>	<b>9</b>
• <b>Cytology</b>	<b>32</b>
• <b>Genetics</b>	<b>41</b>
• <b>Hematology</b>	<b>28</b>
• <b>Flow Cytometry</b>	<b>27</b>
• <b>Maternal Serum Screening</b>	<b>10</b>
• <b>Microbiology</b>	<b>36</b>
• <b>Molecular Diagnostics</b>	<b>32</b>
• <b>Transfusion Medicine</b>	<b>108</b>



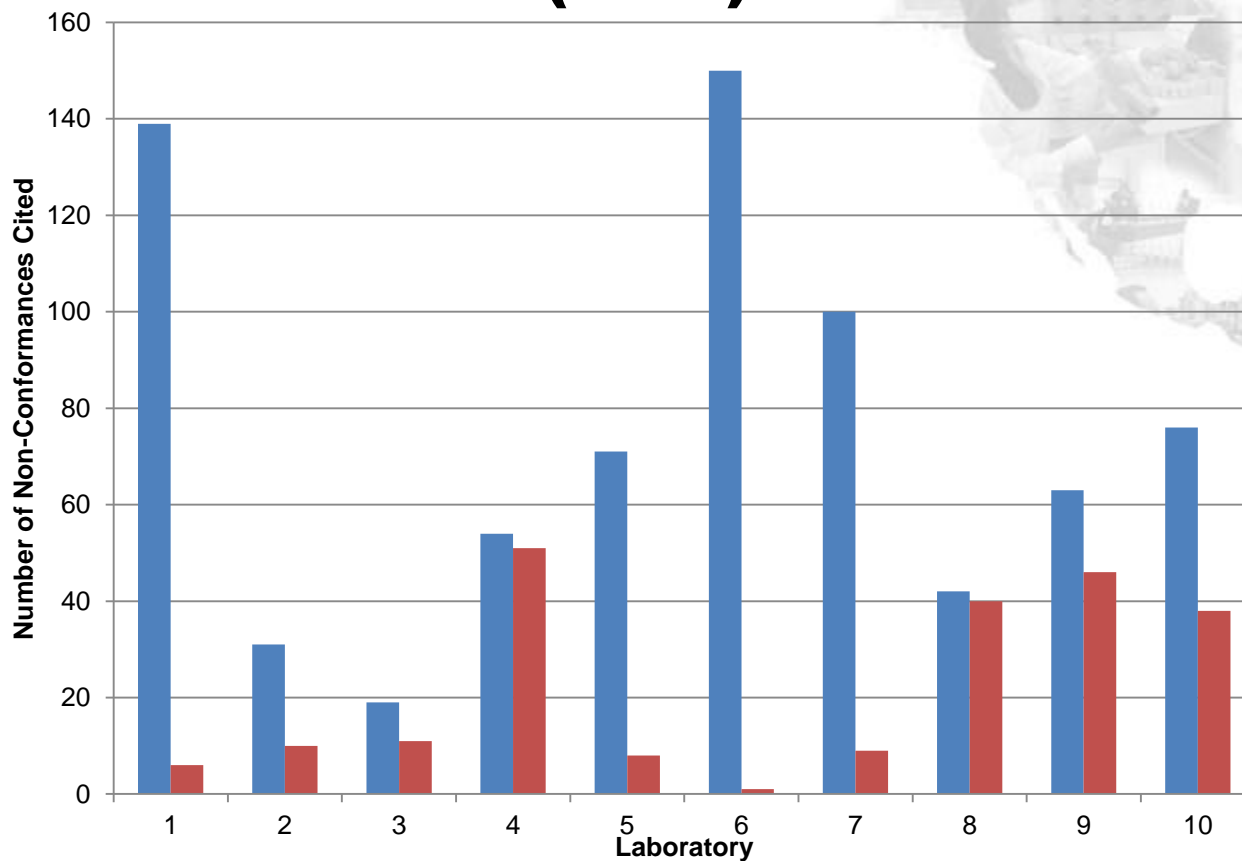


# Confidence. *Elevated.*



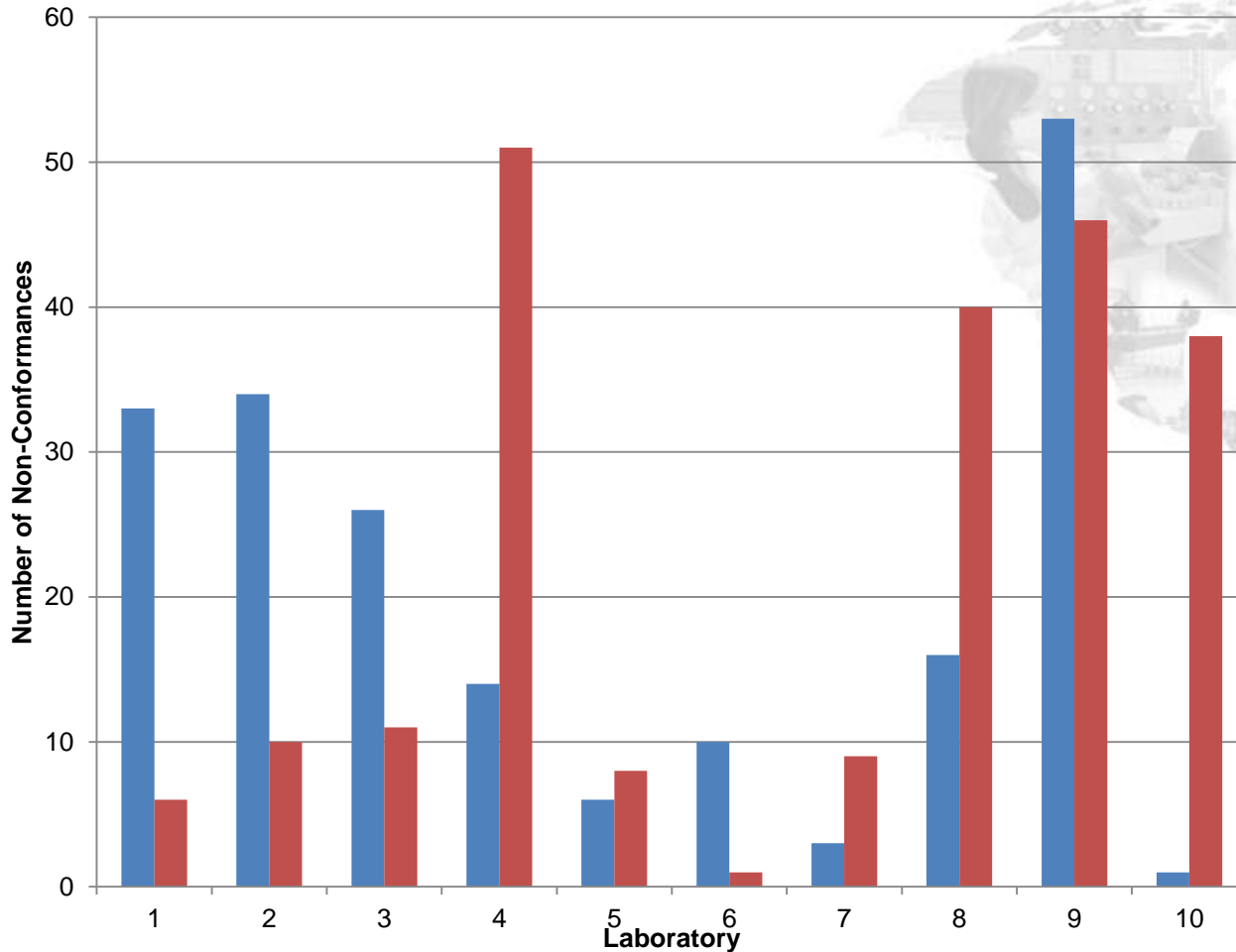
# Performance of Ten Random Laboratories 2004 - 2011

## 1st Event (Blue) to Latest Event (Red)



# Performance of Ten Random Laboratories 2008-2011

## Self (Blue) to Peer (Red)



# Conformance to ISO15189 – a Provincial Cohort 2010 - 2014

Self assessment (gap analysis to ISO 15189)	First Visit	1-yr Surveillance Visit	Mid-cycle Surveillance Visit
<b>62%</b>	<b>81%</b>	<b>86%</b>	<b>90%</b>

2010

2014



# ISO 15189 in Canada – Unexpected Benefits



# 1. Transformational Change

*When the ... requirements were first delivered to us, they sat on a desk collecting dust. We thought this was just another quality initiative that would just fizzle out and go away.*

*Luckily for our profession the exact opposite happened and everyone in the province embraced the opportunity to make a difference for the patients we serve.*

— Sue Randell, Ross Memorial Hospital, Lindsay, ON

## 2. Patient Safety

*In the past, when colleagues asked me if I'm sure that the results of their lab tests are correct I always used to say 'yes', and hope I was correct. Now I still say 'yes' but I know they are correct.*

— Dr. Robert Lannigan, London Health Sciences Centre

### **3. New Career Niche for Lab Professionals**

*In addition to raising the bar in quality and service excellence, this program has in essence, created a niche market for laboratorians wishing to pursue a career in quality management and leadership.*

- Judy Sherman-Jones, Oshawa ON

*Never in my 22-year career have I been more proud to be a Laboratory Technologist.*

— Pamela Calverley, Orillia

## 4. Lab as Respected Advisors

*... requirements have been used as the 'Gold Standard' for the way things must be done in my hospital.*

— Dr. Douglas Gornall, Toronto East General Hospital

*Lab Technologists are now sought after throughout the hospital for our expertise.*

— Pam Calverley

*I am often asked to help in creating corporate policies, teaching others about document control and helping to implement a functional quality management system in their areas.*

— Lorraine Hart, EORLA, Ottawa



## 5. Easier Access to Funding

*Administrators understand that the standard must be met. It makes it easier for everyone when certain changes must be made, especially when the changes require funding.*

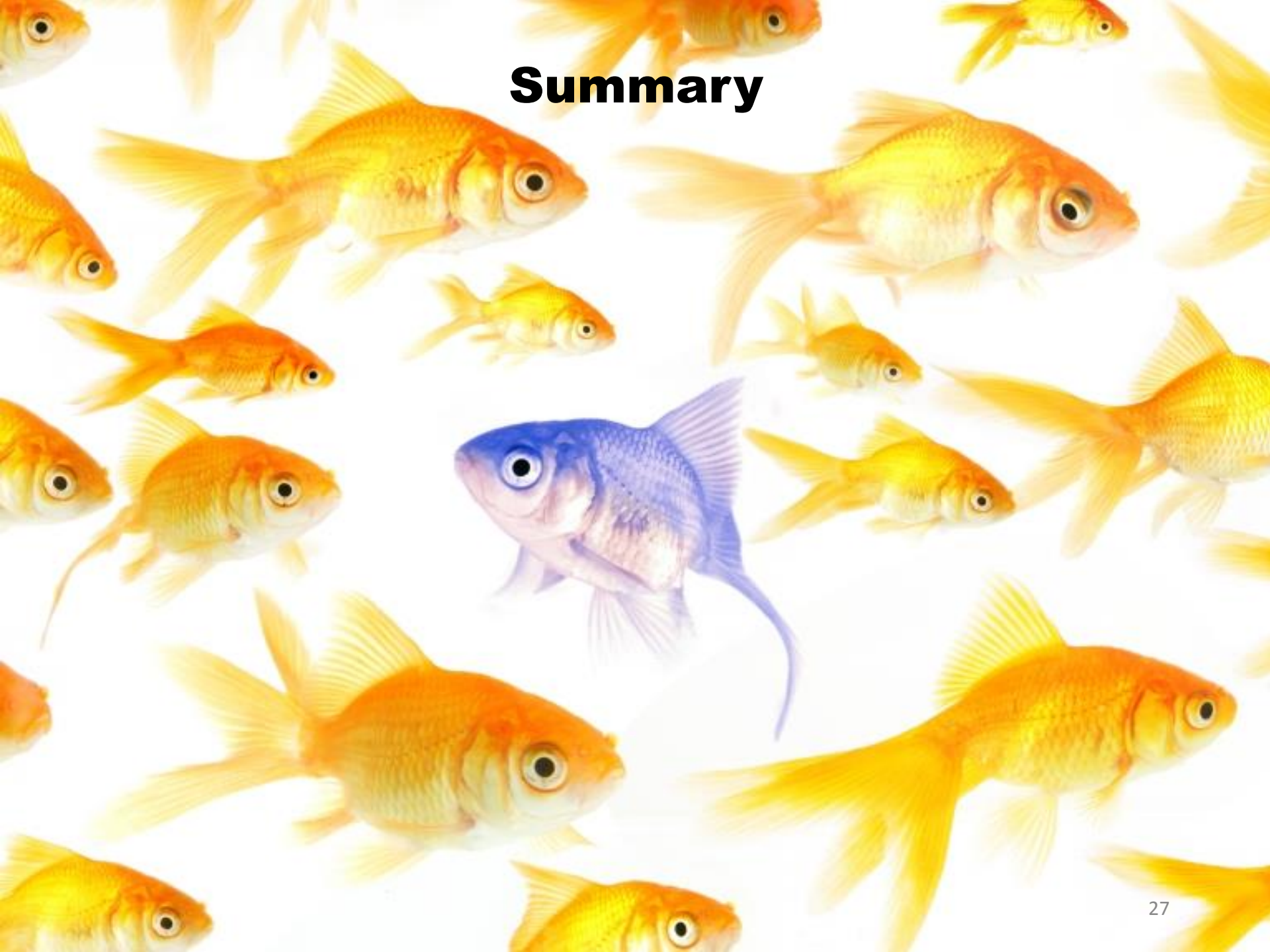
*— Dr. Douglas Gornall, Toronto East General*

# Client Satisfaction with ISO15189

**94%**  
**Enhanced**  
**Level of Service**



# Summary



# Contact Information



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