

# Integration of Accreditation, Inspection and Licensing in Laboratory Regulatory Programs

Assuring Water Safety –  
a case for regulatory cooperation

**National Standards System Conference  
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# Setting the Stage

- May 2000 – the tragic events of Walkerton
- August 2000 – Ontario Regulation 459/00 – *Drinking Water Protection Regulation - Larger Waterworks*
- December 2001 – Ontario Regulation 505/01 -*Drinking Water Protection Regulation - Smaller Waterworks Serving Designated Facilities*
- January 2002 – *The Report of the Walkerton Inquiry* (RWI) Part One released
- May 2002 – *The Report of the Walkerton Inquiry* Part Two released

# RWI Part Two

- Recommendations to ensure the safety of drinking water across the province
- 93 recommendations provided
- Ontario government commits to implementing all of the recommendations
- 50 recommendations to be addressed through the *Safe Drinking Water Act, 2002* (SDWA) and the related regulations

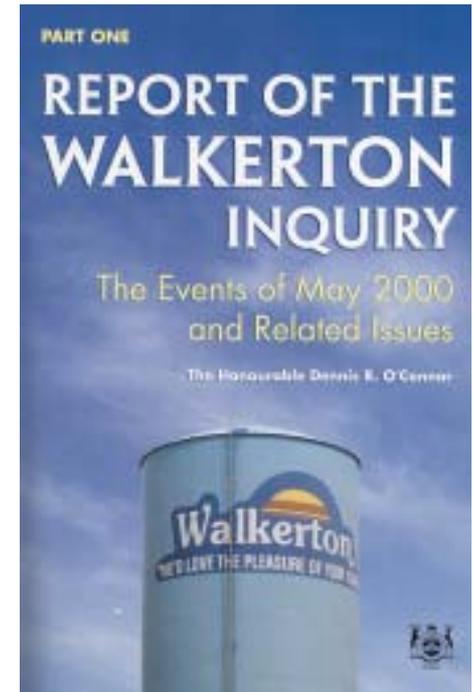
# Safe Drinking Water Act, 2002

“The purposes of this Act are as follows:

1. To recognize that the people of Ontario are entitled to expect their drinking water to be safe.
2. To provide for the protection of human health and the prevention of drinking-water health hazards through the control and regulation of drinking water systems and drinking-water testing.”

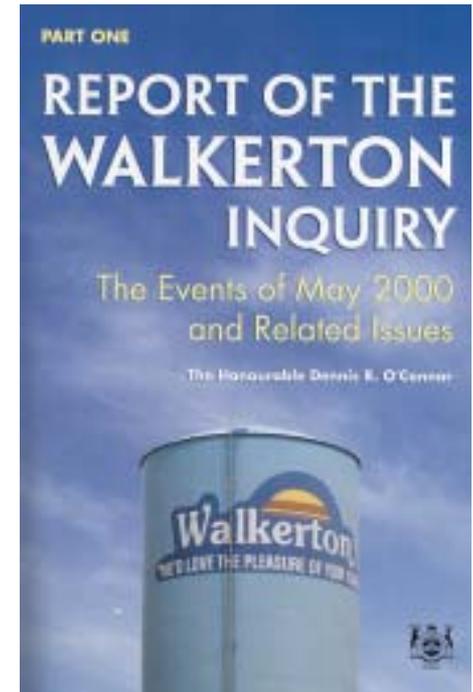
# RWI Recommendation 39

- “Ontario Regulation 459/00 should be modified to require standard protocols for the collection, transport, custody labelling, testing, and reporting of drinking water samples and for testing all scheduled contaminants, that meet or better the protocols in Standard Methods.”



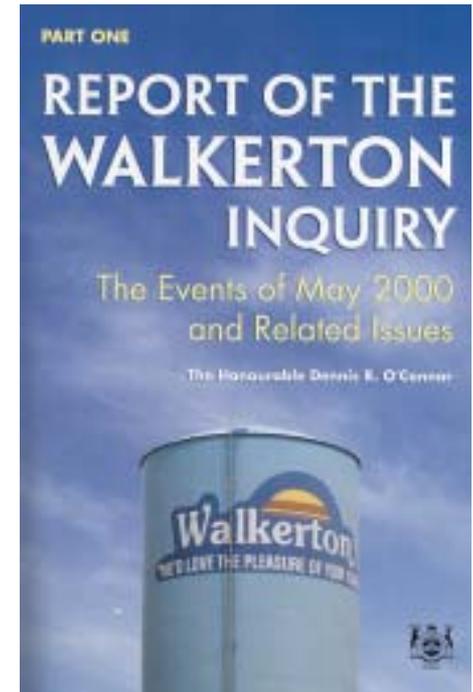
# RWI Recommendation 41

- “The provincial government should phase in the mandatory accreditation of laboratories for all testing parameters, and all drinking water testing should be performed only by accredited facilities.”



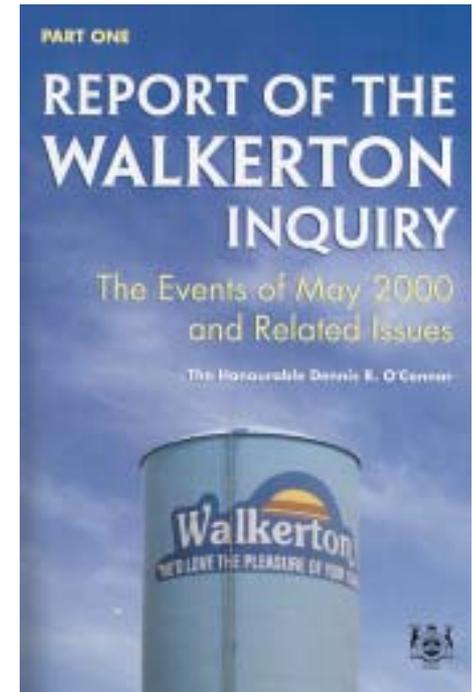
# RWI Recommendation 42

- “The Ministry of the Environment should license and periodically inspect, as required, environmental laboratories that offer drinking water testing; as with treatment operations, continuing accreditation should be a condition of licence.”



# RWI Recommendation 43

- “The results of laboratory accreditation audits should be provided to the Ministry of the Environment and should be publicly available.”



# Guidance on Accreditation

- “...accreditation...is not by itself sufficient “
- “The purpose of accreditation is to provide a means of assessing the competence of a laboratory in a given field of testing.”
- “It is not to review and verify the individual laboratories knowledge of and compliance with regulatory standards.”
- “The Province therefore cannot rely on accreditation alone as a means of overseeing water testing laboratories.”

# Guidance on Licensing

- “The Ministry of the Environment’s (MOE) Laboratory Services Branch, using provincial standards, should license and if necessary inspect laboratories to ensure that they comply with provincial standards under Ontario Regulation 459/00, the Drinking Water Standards and other applicable regulatory instruments.”

# Guidance on Inspection

- “The most important issues for a laboratory are ensuring that proper procedures are followed in tracking water samples, conducting tests, and reporting results to the water providers and provincial authorities.”
- “Inspections should be done only as often as required and should include unannounced inspections.”

# Guidance on Inspection

- “The MOE’s Investigation and Enforcement Branch should also be available to address any breaches of provincial standards.”
- “As recommended in Chapter 13, enforcement should be strict in this area.”

# The Challenge

- To develop and implement a Laboratory Licensing and Inspection program for Ontario drinking-water testing laboratories
- To ensure consistency with the *Report of the Walkerton Inquiry* recommendations
- To incorporate accreditation while avoiding duplication of efforts, but eliminating all gaps
- To identify and address all necessary communications and operational linkages
- To achieve maximum buy-in and compliance from all stakeholders.

# The Accreditation Options

1. Establish an Ontario provincial conformity assessment agency
2. Carry out an open tender for accreditation services from external providers.
3. Seek senior-level approval to negotiate an agreement to work within a modification of the existing environmental accreditation strategy.

# The Balanced Consideration

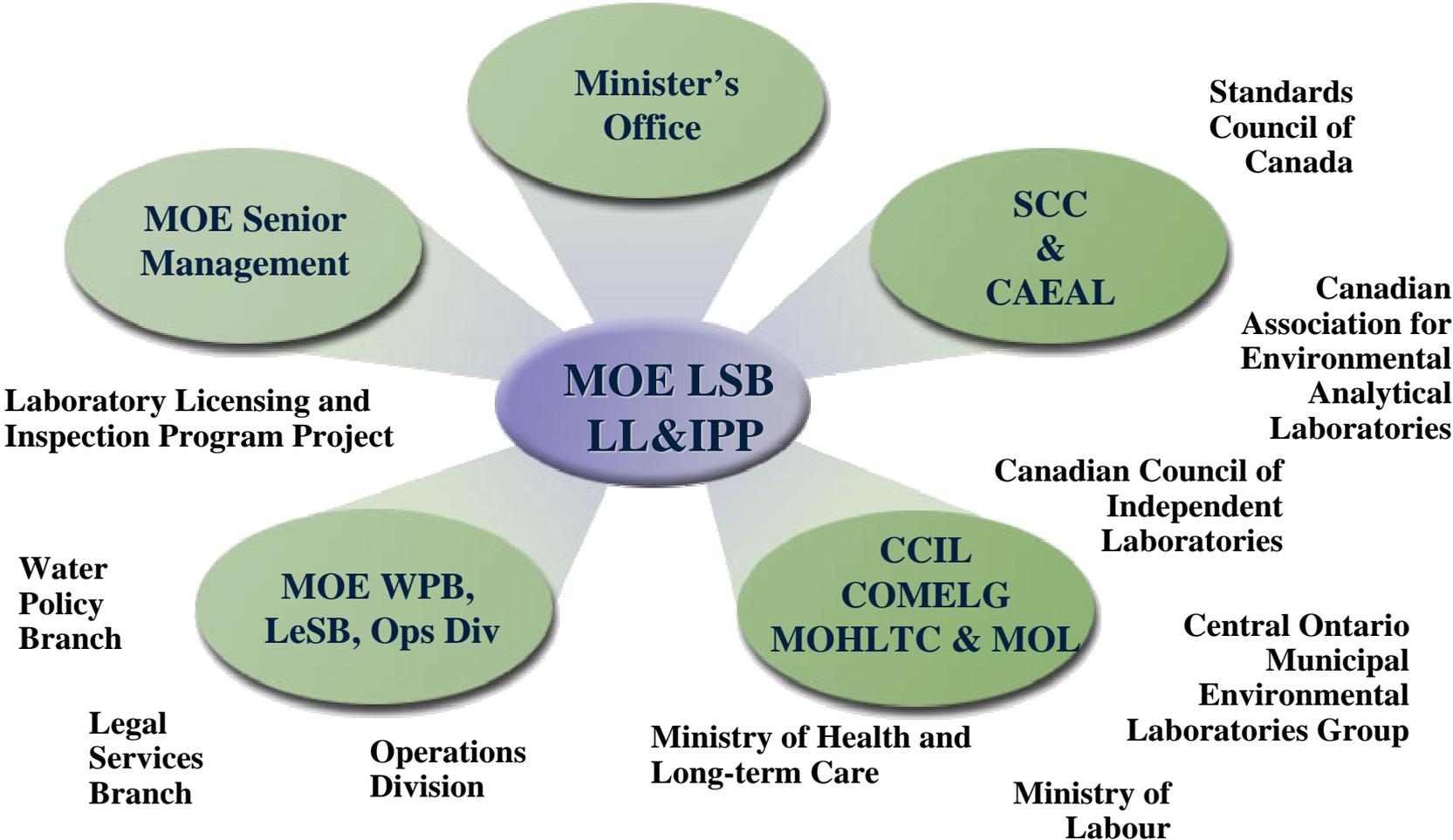
- Benefits

- Third-party scientific objectivity
- Sound international recognition/reputation
- Alternate service delivery mechanism
- Smooth and timely transition for laboratories and waterworks

- Difficulties

- Determining the functional divide
- Managing public access vs. private confidentiality
- Dispute resolution
- Anticipating and managing change

# The Developmental Linkages



# Critical Milestones - Policy

- Development of the *Safe Drinking Water Act*
- Development of the enabling regulations
  - *Drinking-Water Testing Services Regulation*
  - **Compliance and Enforcement Regulation (laboratories)**
- Alignment with related regulations
  - *Drinking-Water Systems Regulation*
  - *Drinking-Water Standards Regulation*
  - **Compliance and Enforcement Regulation (waterworks)**
- Designation of the accrediting body for laboratories
  - **Determination of the process**
  - **Development of the regulation or agreement**
- Resource planning and acquisition
- Establishment of fees

# Critical Milestones - Program

- Establishing the Laboratory Licensing & Inspection Program Project team
- Design all required business processes
- Hiring new staff and procuring accommodations
- Establish and deliver training for inspectors
- Develop the inspection protocol, checklists
- Creating required forms, communications, information systems
- Operationalize linkages

# Details are in the Paperwork

- *Safe Drinking Water Act*
  - *Drinking-Water Systems Regulation*
  - *Drinking-Water Standards Regulation*
  - *Drinking-Water Testing Services Regulation*
  - { **Compliance and Enforcement Regulation** }
- Laboratory Accrediting Body Designation Agreement
- Scope of Accreditation Documents
- Laboratory Direction for the Release of Audit Reports
- Audit Reports; Proficiency Evaluation Data
- Protocol of Accepted Drinking-Water Testing Methods
- Sampling guide & Chain of custody form
- Licence, Eligible Laboratory Notice, Direction, Order

# The Desired Outcome

- High scientific credibility
  - Competence (accreditation)
  - Fit for purpose (licensing)
- Demonstrated performance
  - Confirmed proficiency (proficiency evaluation and inter-laboratory studies)
  - Confirmed regulatory compliance (inspection)
- Guidance and flexibility
  - Promote and foster continuous improvement
  - Allow for method development and research

# Accreditation Features

- Accreditation ensures that a laboratory is competent to carry out specific environmental analytical tests
  - Delivered through a partnership between the Canadian Association for Environmental Analytical Laboratories (CAEAL) and the Standards Council of Canada (SCC)
  - Internationally recognized joint system based on ISO/IEC17025
  - Includes on-site assessment once every two years and can also include verification audits
  - Includes mandatory proficiency testing samples for more than 80% of the drinking water contaminants listed in regulation
  - Failure of proficiency testing studies can result in suspension of accreditation

# License Classes

- Licenses are categorized based on the type of drinking-water testing performed in five classes:
  - *Microbiological (E. coli)*
  - *Organic chemical (pesticides)*
  - *Inorganic chemical (metals)*
  - *Radioanalytical (tritium)*
  - *Physical/other (hardness)*
  - A laboratory can apply for a license for one or all of these classes of tests, based on their accreditation standing
  - The certificate of license shows which classes are held by the laboratory and the certificate must be displayed in a location where a laboratory customer would be expected to see it

# Licensing Prerequisites

- Laboratories are licensed by MOE when they show proof that they meet regulatory obligations
  - Accredited to perform specific tests included in their license application (exceptions for method development, research, in-plant testing)
  - Comply with requirements for notification of adverse water quality
  - Comply with requirements for reporting of all analytical results
  - Provide guidance to water system owners/operators for sample handling, storage transport and labeling as required
  - Comply with the requirements for acceptable analytical testing
  - Comply with the requirements for sub-contracting analytical tests
  - Provide adequate facility, resources and training to conduct drinking-water testing

# Inspection System Overview

- The LSB Inspection Team conducts several categories of inspections:
  - Planned
    - Pre-licensing inspection
    - Post-licensing inspections (minimum twice per year)
      - Announced
      - Unannounced
      - Focused inspection
  - Responsive
    - Suspicion of non-compliance at licensed laboratory
    - Allegation of service delivery requiring a licence at an unlicensed business

# Scientific Challenges

- Fair comparisons of reference methods and lab methods.
- Comparison of Method Detection Limits, Regulatory Detection Limits, & Standards – “fit for purpose” assessments.
- Addition of new methods to the “Protocol of Accepted Drinking Water Testing Methods”
- On-line microbiological testing on the horizon.

# Current Status

- **Licensing and inspection key activities**
  - August 2003: Deadline for laboratories to submit an application for a license and be assured of a decision by October 2003
  - August - October 2003: Application review, inspection, inspection report with recommendation and conditions, and approval by Review Panel
  - October 2003: MOE licenses 51 private, municipal and public sector laboratories; other applications follow
  - February – March 2004: Unannounced inspections
  - February 2004: Review of SCC/CAEAL/ MOE agreement
  - May 2004: First meeting of Director's Advisory Committee

# Current Status

	Applied	Granted	Denied	In Progress
Applications	60	59	0	1
Microbiology	46	45		1
Inorganic Chemistry	31	30		1
Physical/Other	27	26		1
Organic Chemistry	23	22		1
Radioanalytical	3	3		0
Total Unique Parameters Licenced		1054		
Total Class Level Licences		129		
Total of Active Parameter Level Licences		4201		

- Group Leader
- Licensing Coordinator
- Proficiency Evaluation Scientist
- Six inspectors
- Reporting Clerk
- 2 System Officers

November, 2004

# Reasons for Program Success

- Pre-existing successful accreditation program built on cooperation and impact from multiple key stakeholders – CAEAL, SCC, CCIL, MOE, EC
- High level of expertise and efficiency in the delivery of site assessment by the private interest body CAEAL
- High level of public recognition and confidence in the public interest body overseer SCC
- Ready support from all stakeholders to move quickly and constructively

# Challenges Ahead

- Required and desired transitions under ISO 17011
- Different provincial strategies for regulating drinking-water testing
- Extension of drinking-water accreditation and licensing delivery to other regulatory needs e.g. brownfields (records of site condition), nutrient management, other public requests (IPAT Report)

