Third International Workshop on Conformity Assessment

Standards Council of Canada
Conseil canadien des normes

Canadä

The Relationship Between Regulatory Authorities and Accreditation Bodies

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2007-12-10
Rio de Janeiro, Brazil

Presentation Outline

- The Standards Council of Canada

- The Canadian Legislative System

- Conformity Assessment

- Conformity Assessment and Legislation
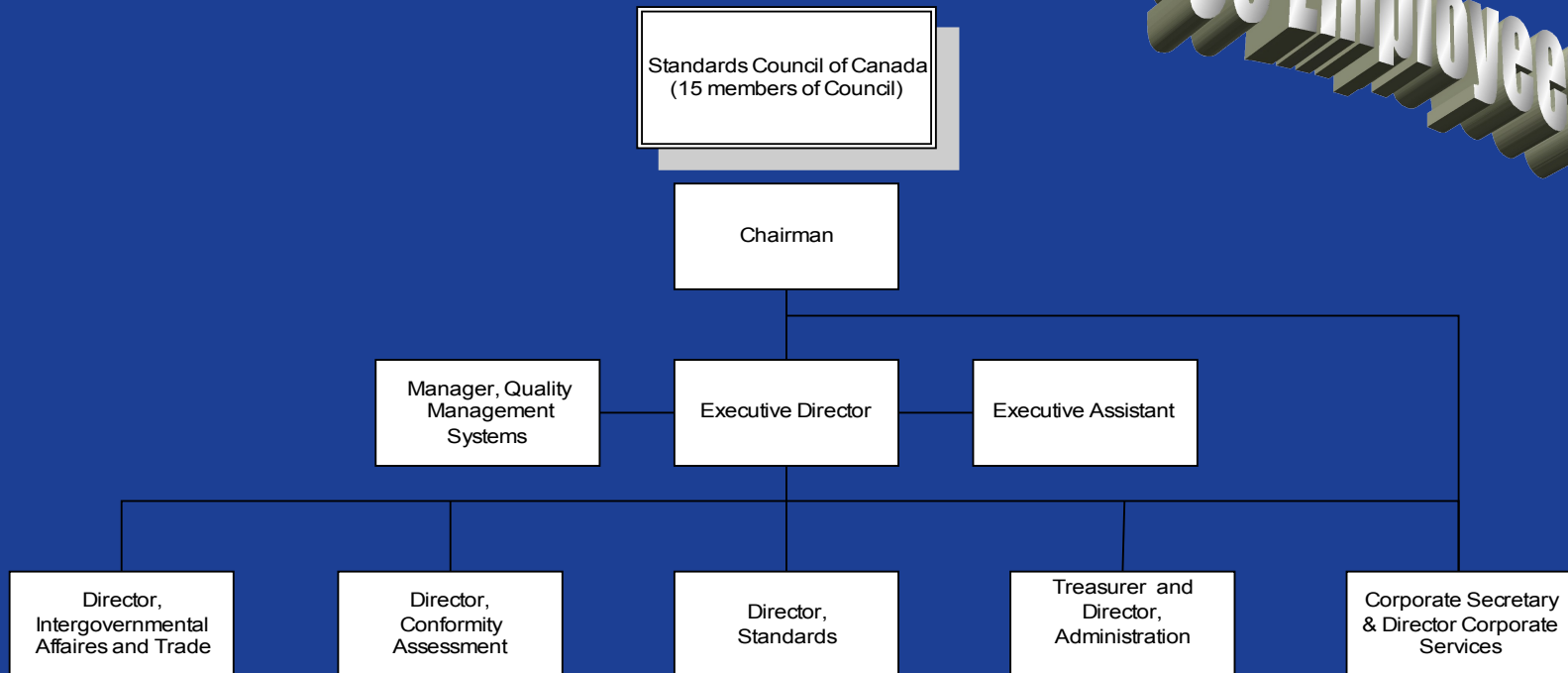
- Questions

Standards Council of Canada

Organization

- Federal Crown Corporation in accordance with the Standards Council of Canada Act

- Founded in 1970

- Reports to the Canadian Parliament via the Federal Minister of Industry

Canada

Organizational Structure

Role and Purpose

- Role:
  - National and international mandate
  - Canadian member to international/regional standardization organizations
  - Encourage the use of Standards

- Purpose:
  - To support Canadian competitiveness
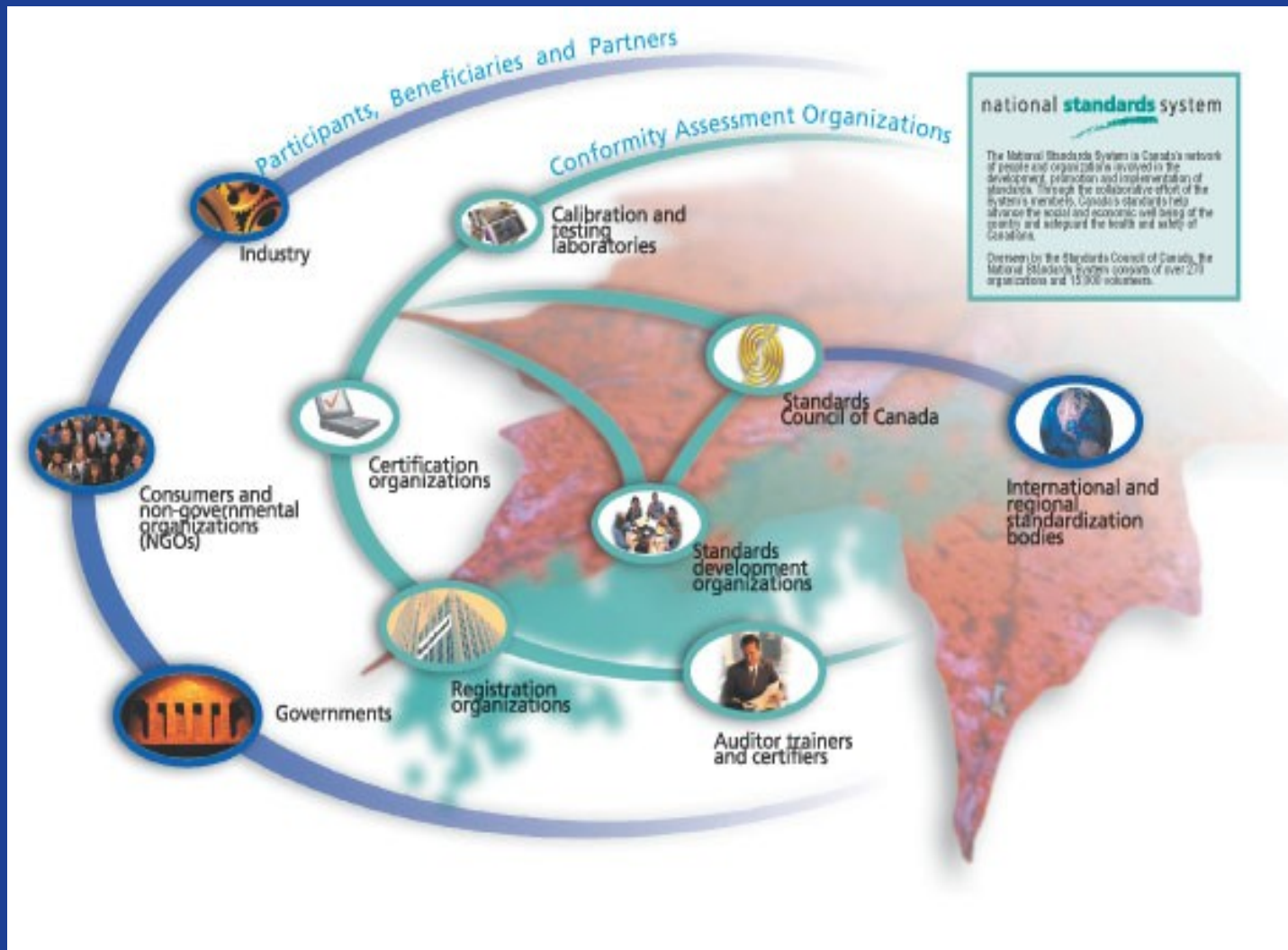 - To promote Canada's social and economic well-being both Nationally and Globally

Canada

People Supporting the System

- Over 15,000 members across Canada
- Approximately 450 standards-development committees

National Standards System (NSS)

The Vision -
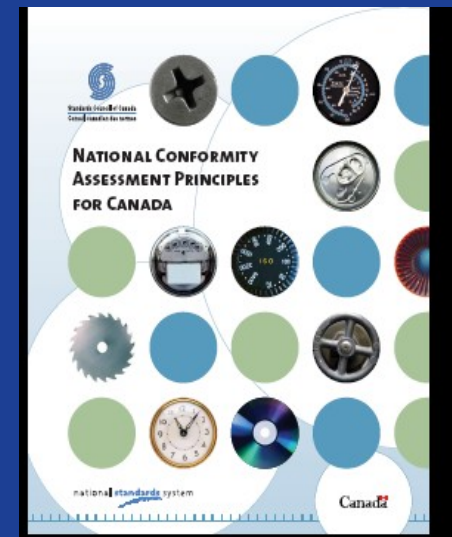## The Canadian Standards Strategy

- Blueprint for Canadian standardization activities

- To advance the social and economic well-being of Canadians

Canadä

The National Conformity Assessment Principles for Canada

- National focus: benefits of standards and conformity assessment

- Working together towards a better quality of life

Accreditation Programs

- Standards development organizations

- Conformity assessment bodies

Canada

Standards Development Organizations

Conformity Assessment Organizations

- Testing and calibration laboratories
- Product certification bodies
- Management system certification bodies
- Inspection bodies
- Personnel certification bodies
- Proficiency testing providers
- OECD – Good laboratory Practices (GLP)

Canada's Legislative System
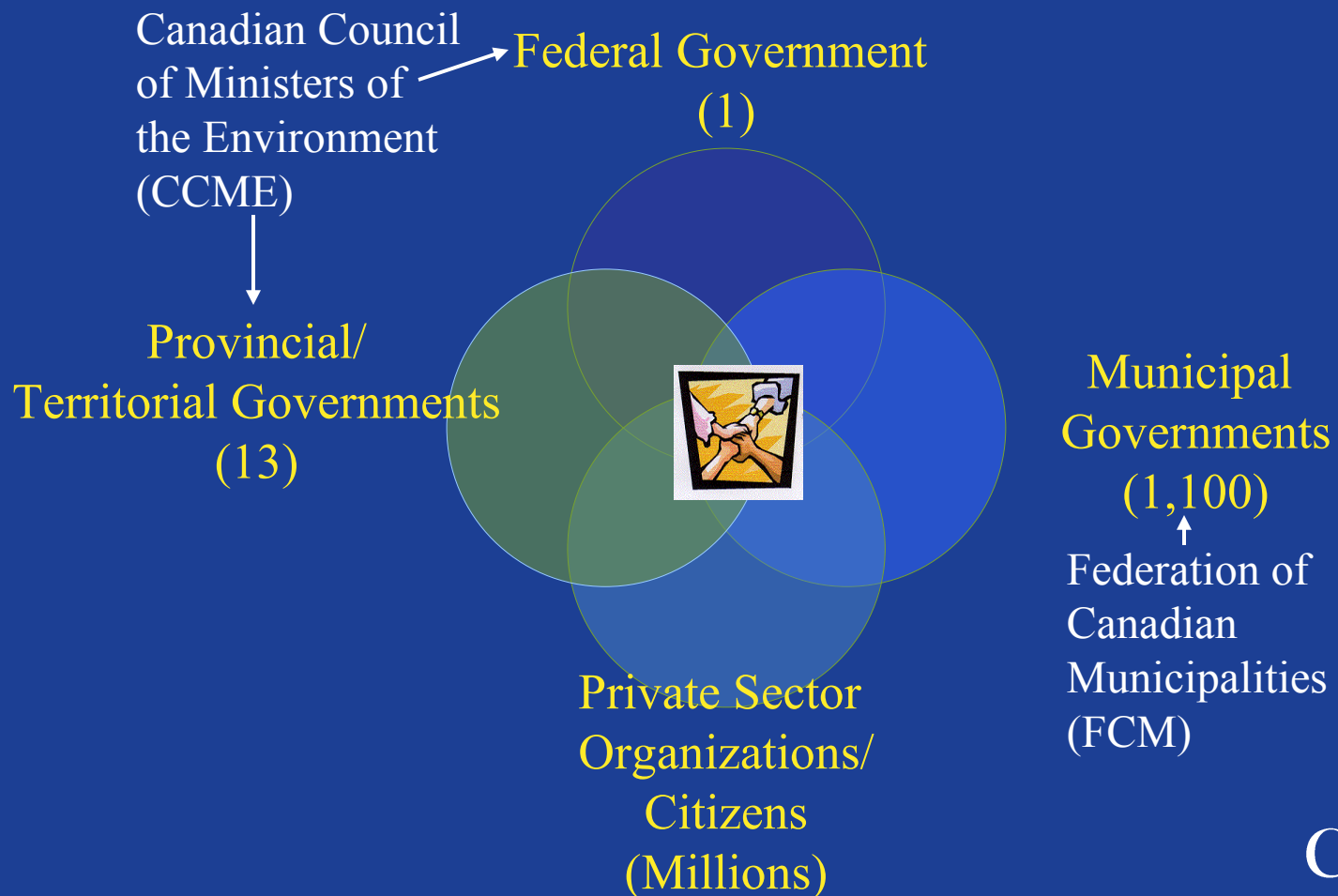
Standards Council of Canada
Conseil canadien des normes

Inter-jurisdictional:
Accountability and Cooperation Framework

Canadian Council of Ministers of the Environment (CCME)

Federal Government (1)

Provincial/ Territorial Governments (13)

Municipal Governments (1,100)

Federation of Canadian Municipalities (FCM)

Private Sector Organizations/ Citizens (Millions)

Canada

Government of Canada: New Key Policy

- *Government of Canada's Cabinet Directive on Streamlining Regulation* which requires Government Departments to make use of national and international standards and conformity assessment procedures when they fulfill intended policy objectives.

- **Cabinet Directive on Streamlining Regulation – http://www.regulation.gc.ca**

Standards References in Federal Regulations

- Approximately 3,100 Federal regulations in Canada:

  - Approximately 300 standards that are developed by SCC accredited Standards Development Organizations are referenced

  - In addition, approximately 1,400 other industry and government standards are referenced which are developed by other organizations (e.g. industry associations, other countries standards development organizations to name a few)

Canada

Example of Standards in Federal Regulations

- Minister responsible: *Minister of the Environment*

- Act: *Canadian Environmental Protection Act, 1999*

- Regulation: *Gasoline Regulations (C-15.31 – SOR/90-247)*

- Standard: *CAN/CGSB-3.- No. 19.5-2004: Methods of Testing Petroleum and Associate Products Determination of Lead and Automotive Gasoline (Atomic Absorption)*

- Standards developer: *Canada's General Standards Board (CGSB-PWGSC)*

- Legislative link: *http://alert.scc.ca/std_e/std19116.html*

Canada

Benefits of standards for use in legislation

- Reduction in barriers to trade

- Elimination of unnecessary regulatory burdens (incorporation of international best practices in domestic regulatory systems)

- Reduces time and costs for changes

- Enhanced consideration for the views of interested parties in standardization work

- Foster respect for intergovernmental and international agreements in regulatory practices

- Increased confidence of foreign investors and trade partners in the national industries

Conformity Assessment

Conformity Assessment Programs
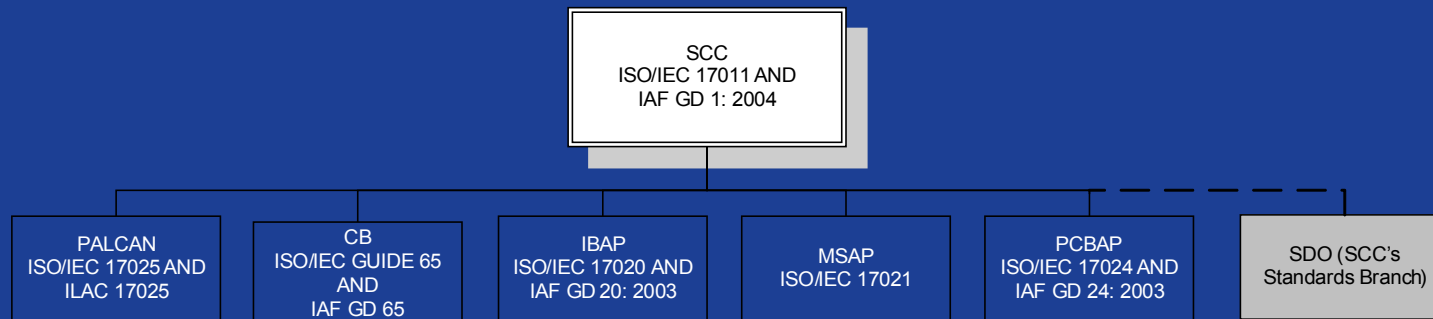
1,000,000's of Annual Tests, Certifications, Verifications

Canada

Market Drivers For Certification

- Industry policy

- Government policy

- Customers

- Non-Governmental Organization's

- International policy
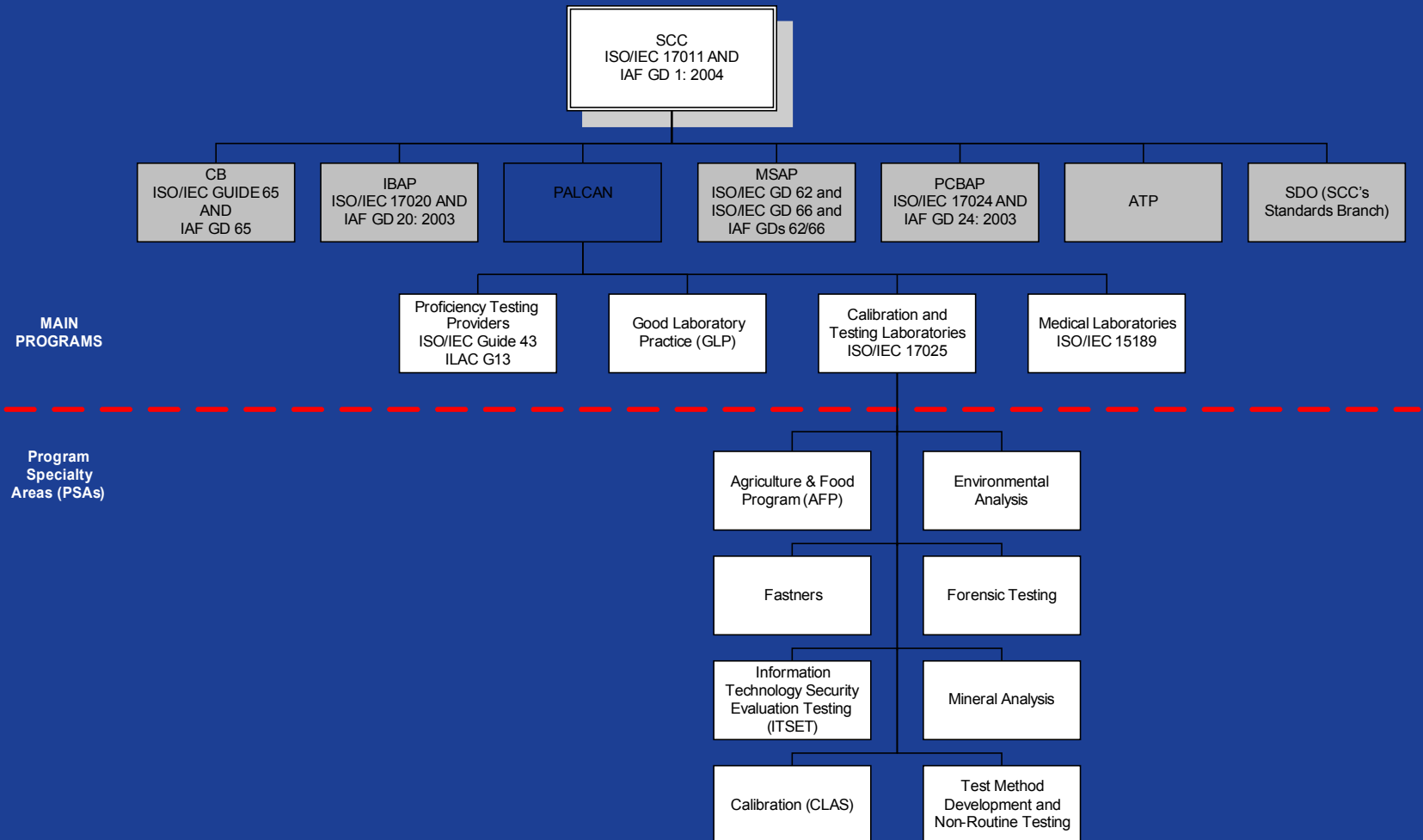
- Procurement Policies

Program for Accreditation of Laboratories – Canada (PALCAN)

PALCAN

SCC
ISO/IEC 17011 AND
IAF GD 1: 2004

CB
ISO/IEC GUIDE 65
AND
IAF GD 65

IBAP
ISO/IEC 17020 AND
IAF GD 20: 2003

PALCAN

MSAP
ISO/IEC GD 62 and
ISO/IEC GD 66 and
IAF GDs 62/66

PCBAP
ISO/IEC 17024 AND
IAF GD 24: 2003

ATP

SDO (SCC's
Standards Branch)

MAIN PROGRAMS

Proficiency Testing
Providers
ISO/IEC Guide 43
ILAC G13

Good Laboratory
Practice (GLP)

Calibration and
Testing Laboratories
ISO/IEC 17025

Medical Laboratories
ISO/IEC 15189

Program Specialty Areas (PSAs)

Agriculture & Food
Program (AFP)

Environmental
Analysis

Fastners

Forensic Testing

Information
Technology Security
Evaluation Testing
(ITSET)

Mineral Analysis

Calibration (CLAS)

Test Method
Development and
Non-Routine Testing

Example: Clean Water

Clean Water

- Environmental Incident – Driver of Change

- Government response
    - "*. . . All drinking water-testing should be performed only be **accredited** facilities . . .* ".

    - Ontario *Safe Drinking Water Act* (2002)
        - Use licensed and accredited laboratories

    - *Ontario Ministry of the Environment* Memorandum of Understanding (**MOU**) with the *Standards Council of Canada . . .* focus on laboratory testing

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Clean Water System in Ontario

Ontario Ministry of Environment → Protocol of Accepted Drinking-Water Testing Methods

Accreditation Body
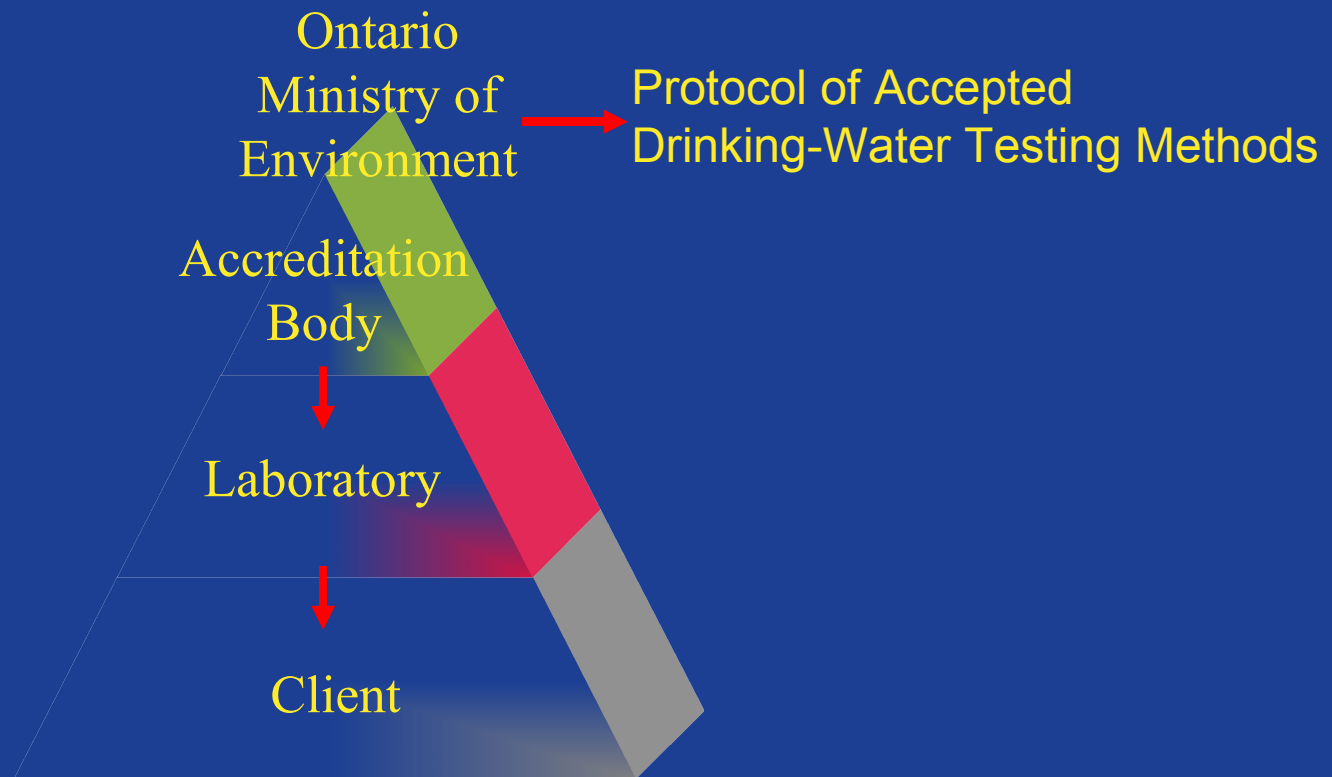
Laboratory

Client

Clean Water: Why Accreditation?

- Laboratory benefits
    - Enhance expertise and efficiencies
- Client benefits
    - Confidence in testing results
- Regulatory benefits
    - Better information to protect public health and environment
- Public benefits
    - Building trust in the system overall
- Business benefits
    - New environmental technology and innovation for improving water treatment operations
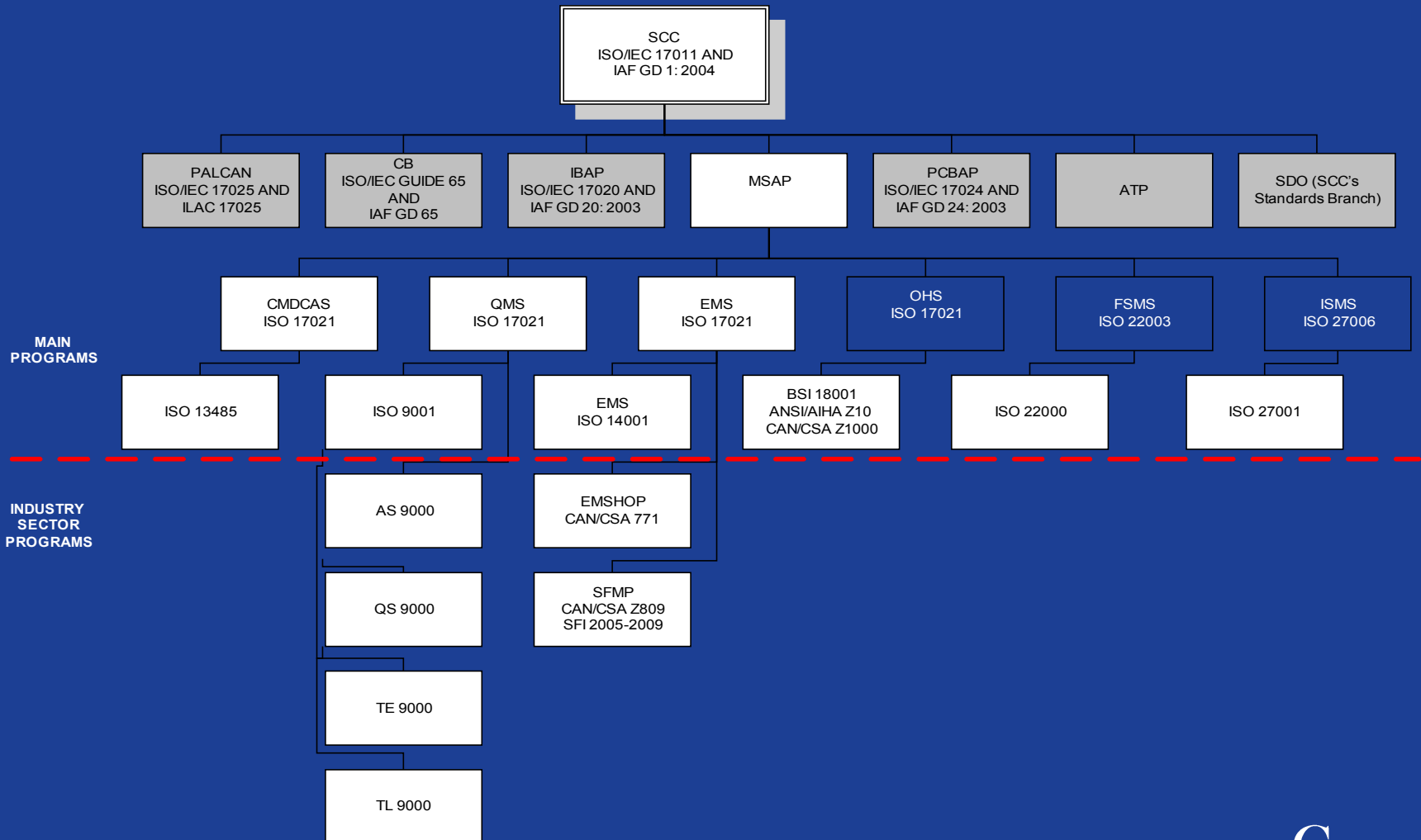   - Exportability of environmental technologies

Canada

Management Systems Accreditation Program

MSAP

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                              │         SCC         │
                              │  ISO/IEC 17011 AND  │
                              │   IAF GD 1: 2004    │
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| PALCAN ISO/IEC 17025 AND ILAC 17025 | CB ISO/IEC GUIDE 65 AND IAF GD 65 | IBAP ISO/IEC 17020 AND IAF GD 20: 2003 | MSAP | PCBAP ISO/IEC 17024 AND IAF GD 24: 2003 | ATP | SDO (SCC's Standards Branch) |

MAIN PROGRAMS

| CMDCAS ISO 17021 | QMS ISO 17021 | EMS ISO 17021 | OHS ISO 17021 | FSMS ISO 22003 | ISMS ISO 27006 |

| ISO 13485 | ISO 9001 | EMS ISO 14001 | BSI 18001 ANSI/AIHA Z10 CAN/CSA Z1000 | ISO 22000 | ISO 27001 |

- -

INDUSTRY SECTOR PROGRAMS

| AS 9000 | EMSHOP CAN/CSA 771 |

| QS 9000 | SFMP CAN/CSA Z809 SFI 2005-2009 |

| TE 9000 |

| TL 9000 |

Example: Sustainable Forest Management

Canada's forest landscape fragments
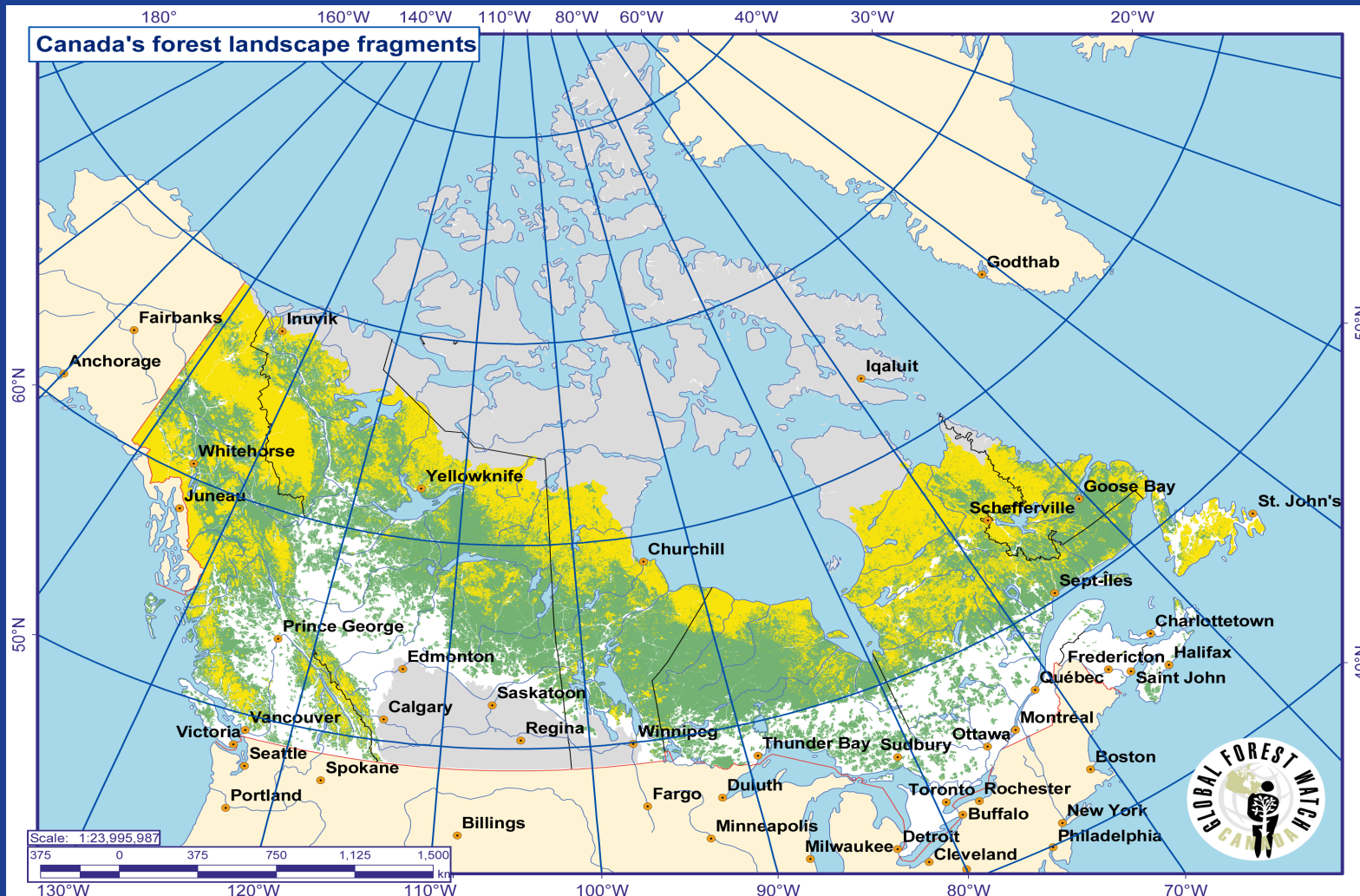
Canada's Sustainable Forest Management Accreditation Program

- National Sustainable Forest Management standard – (CAN/CSA Z809) (e.g. based on Canadian Council of Forest Ministers' (CCFM) framework of Criteria and Indicators – related to biological diversity, ecosystem condition, productivity, soil and water, aboriginal interests etc.)

- Agreement with Ontario Natural Resources

- Sustainable Forest Management Accreditation Program (1999)

- Canada is the global market leader – EMS/SFM certification

- Market access - signatory to the *Programme for the Endorsement of Forest Certification Schemes (PEFC)* Mutual Recognition Agreement (i.e. INMETRO is a member of this scheme as well)

Canada

Example: Canadian Medical Devices Conformity Assessment System (CMDCAS)

Canadian Medical Devices Assessment System

- CDMCAS – regulatory/conformity assessment program

- Health Canada and Standards Council of Canada – 2003

- Only Medical Device Program in the World Recognized by Regulator

- SCC only accreditation body delivering services on behalf of Health Canada/Government of Canada

Canada

Certification Bodies Accreditation Program (CBAP)

Program Scope

Product certification bodies certify a diverse range of products and services such as electrical equipment, plywood, hockey helmets, fuel burning appliances etc.

Expanding the CB Program

New Program - Chain of Custody of Forest Based Products
- Accreditations to PEFC Annex 4 International Standard for Chain of Custody for Forest Based Products
- Allows traceability of wood and wood materials from certified sustainable forests up the chain to processors, manufacturers, distributors and retailers of wood products.

Organic Food
- Health and safety concerns about foods
- Claims made by growers and retailers
- Regulated sector that relies on certification

Regulated Areas - Product Certification

Electrical Safety

- CACES – Regulatory Authority Body for Electrical Safety in Canada
- Any CB delivering certifications must be accredited by SCC

Gas Products (natural and propane)

- Inter-provincial Gas Advisory Council (IGAC)
- Any CB delivering certifications must be accredited by SCC
- Fuel burning appliances (e.g. furnaces, stoves)

Plumbing

Regulatory Authorities Plumbing Products in Canada

- Provincial/Territorial Subcommittee on Plumbing Codes (PTSPC)
- Canadian Advisory Council on Plumbing (CACP)

Canada

Regulated Areas – Product Certification (cont)

Building Products

- Provincial/Territorial Subcommittee on Building Codes (PTSBC)
- Building Code of Canada

Drinking Water

- Federal/Provincial/Territorial Committee on Drinking Water
- Product certification related to: drinking water treatment system.

Energy Efficiency

- Natural Resource Canada (NRCan) – Regulatory Authority and Product Marking (electrical and gas appliances)

Canada

Inspection Bodies Accreditation Program (IBAP)

Program Scope

Inspection of:

- Electrical Equipment
- Medical Gas Piping Systems
- Sprinkler Systems
- Electro-medical Equipment (dev.)

Expanding the IB Program

- New areas such as Installation of Polyurethane Foam Insulation and Fire Alarm and Electrical systems inspections.

Personnel Certification Body Accreditation Program (PCBAP)

Program Scope

- Voluntary personnel certification organizations (e.g. Insulation Specialist, Auditors, Health and Safety Professionals, Scuba Divers, Financial Planners etc.) and Organizations with delegated authority (e.g. Medical Doctors, Dentists, Nurses, Engineers, Accountants etc.)

Conformity Assessment and Legislation

Governmental Arrangements

- Health Canada – *Canadian Medical Device Conformity Assessment System (CMDCAS)*
- Ontario Ministry of the Environment – *Drinking Water License Agreement*
- Pest Management Regulatory Agency – *Monitoring of facilities involved in testing of pest control products*
- Ontario Ministry of Natural Resources – *Sustainable Forest Management*
- Canadian Food Inspection Agency (CFIA) – *Technical Assessors*
- National Research Council (NRC) – *Calibration/Testing Laboratories*
- Department of Foreign Affairs and International Trade (DFAIT) – *World Trade Organization/North American Free Trade Agreement Inquiry Point*
- *Pari-Mutuel Agency – Facilities involved in detection of the uncontrolled drugs and medications in race horses*

Canada

If you have any questions, please contact:

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