
Medical Devices Compliance Program

Erin Skuce, Director
Regulatory Operations and Enforcement Branch

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Medical Devices Compliance Program (MDCP), ROEB – Erin Skuce, Director



Organizational Context



Operations



Risk-based Compliance and Enforcement Approach



Program Priorities

C&E Mandate

- The Medical Devices Compliance Program (MDCP) is part of the Regulatory Operations and Enforcement Branch (ROEB) which is Health Canada's dedicated compliance and enforcement (C&E) branch
- Legal Authority
 - Food and Drugs Act
 - Designated Inspectors
 - S22(1) - Minister may designate individuals as inspectors to exercise powers
 - S23(1) - Outlines the Powers of Inspectors
 - Medical Device Regulations

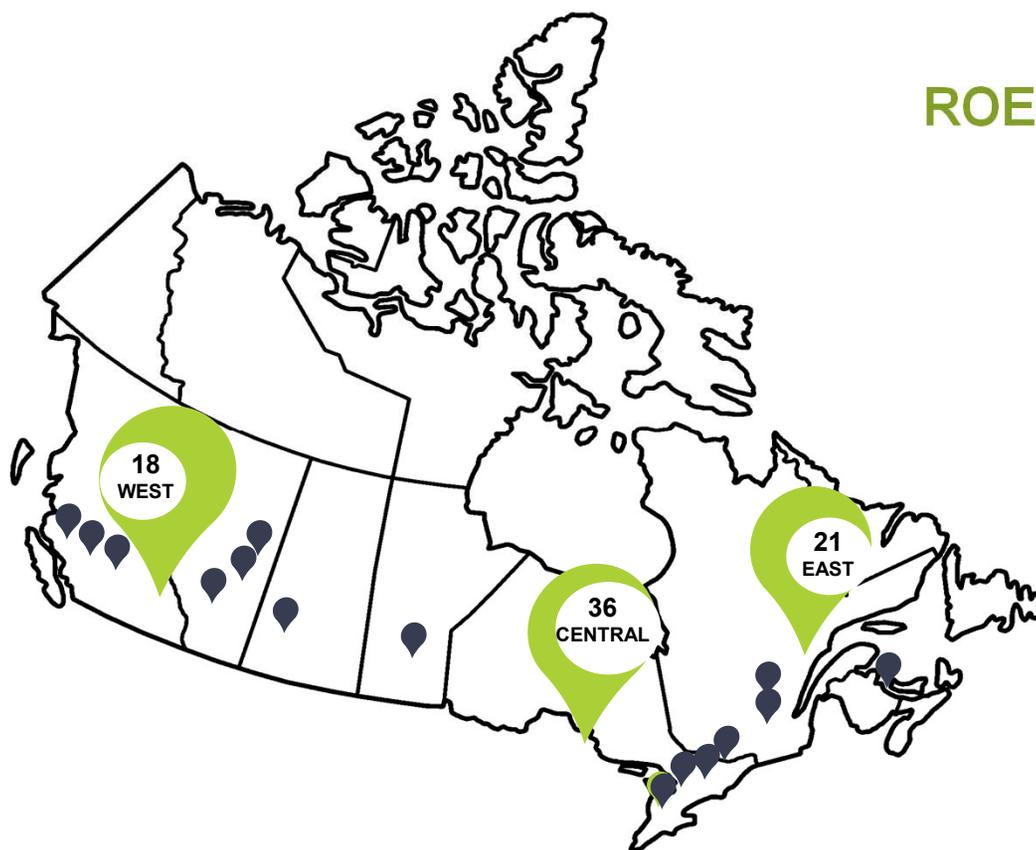
OUR VISION

To be a world-class compliance and enforcement organization with leading-edge practices which produce visible, measurable and positive results to protect Canadians, through an engaged and healthy workforce.

OUR MISSION

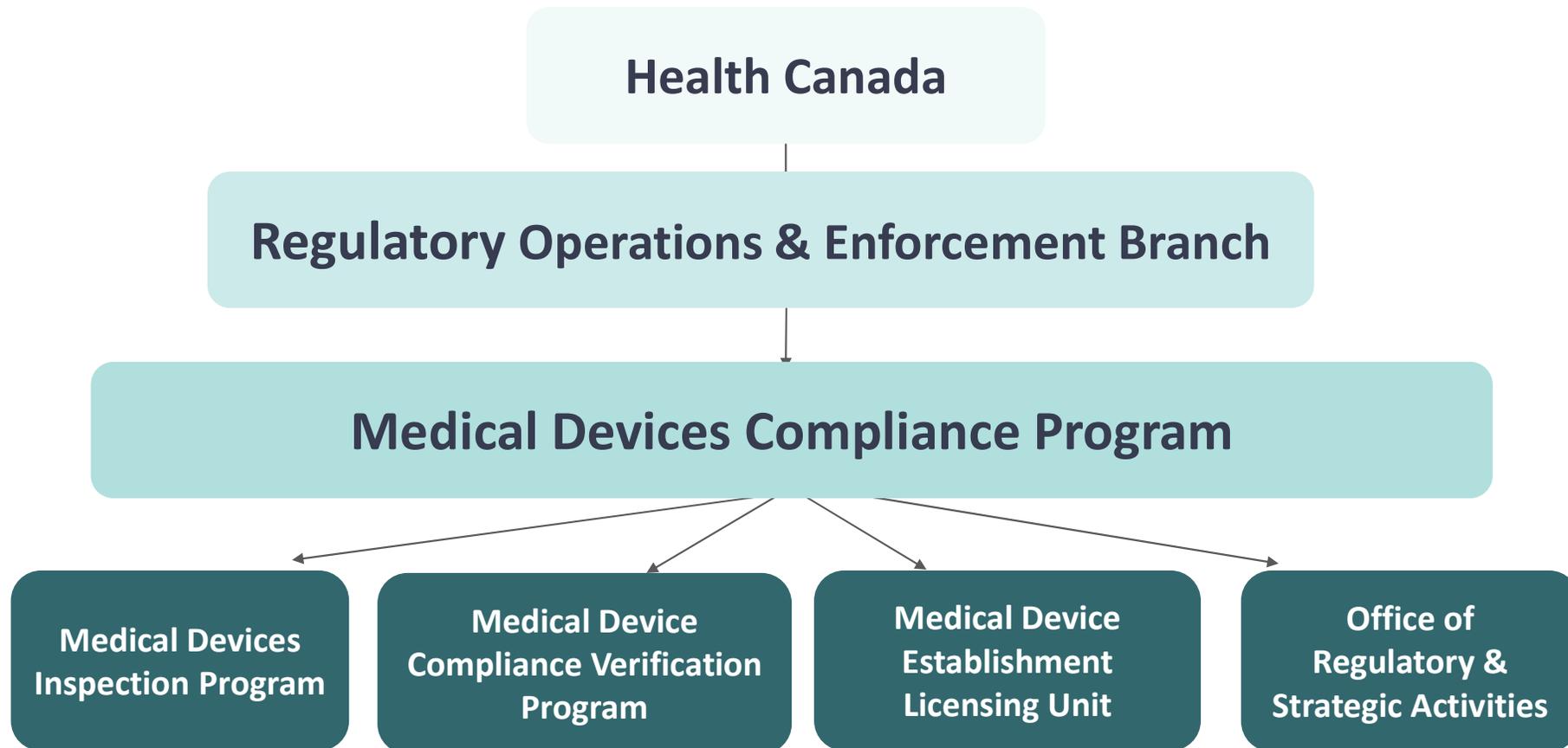
To be a compliance and enforcement leader that informs and protects Canadians from the health risks associated with various health products and regulated biological materials.

C&E National WORKFORCE



ROEB EMPLOYEES ACROSS CANADA

- ROEB is one of the largest federal C&E organizations, with over **1,600** employees in **30** locations across Canada.
- MDCP C&E staff are located across Canada and include:
 - **75 Medical Device Inspectors across Canada**
 - Regulatory C&E risk advisors
 - Licensing and policy officials



Medical Devices Inspection Program

Inspects domestic and foreign manufacturers of Class I medical devices and importers and distributors of Class I–IV medical devices

Priorities

- Increase presence of Health Canada inspectors at foreign MDEL sites.
- Class II to IV manufacturer pilot inspections
- Prioritization of MDEL holders without a compliance history

Medical Device Compliance Verification Program

Conducts compliance verification of potential health hazards and regulatory violations identified via voluntary and mandatory problem reports, complaints, recalls, risk signals and ad-hoc requests

Priorities

- Operationalize regulatory updates to recalls
 - recalls ordered by the Minister
 - industry's reporting and record-keeping obligations for recalls that they initiate
 - Align reporting of low-risk recalls with international regulatory agencies
- Compliance awareness and outreach
- Compliance monitoring project – derma fillers

Medical Device Establishment Licensing Unit

Reviews licence applications, amendments and notifications, and issues licences to companies that import and/or distribute medical devices

Priorities

- Review of new licence applications
- Conduct Annual Licence Review
- Compliance Promotion:
 - Promote awareness of MDEL application and ALR process through updated webinar
- Assertive Enforcement
 - Cancellation and/or suspension of MDELs
- Client services
- Implement internal application processing efficiencies, i.e., automation

Office of Regulatory and Strategic Activities

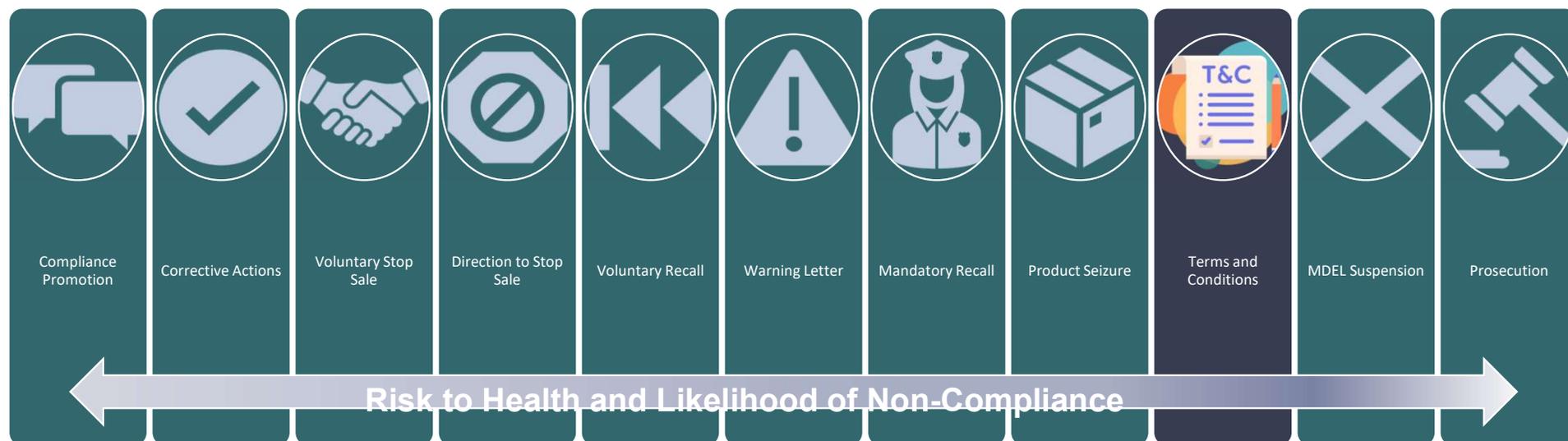
Provides horizontal operational policy & regulatory support including engagement, compliance promotion & project management

Priorities

- Support Phase 2 of MDEL Regulatory Modernization which includes risk-based licensing, supplier information and documentation requirements
- Project and transformation initiatives e.g., strengthening device classification process, CMPs
- Stakeholder engagement coordination including international outreach

MDCP's Risk-Based Compliance and Enforcement Approach

- Based on Health Canada's Compliance and Enforcement Policy for Health Products ([POL-0001](#))
- Involves the identification, evaluation and classification, and management of risk



Keeping Stakeholders Informed:

- MDCP shares key notifications and bulletins to active MDEL and MDL holders via mass emails
- The [Medical Devices Compliance Program Bulletin](#) has been available on-line since 2020.
 - This bulletin provides information on our regulatory activities, process changes and hot issues.
- MDEL holders can also find more information on:
 - **How medical devices are regulated in Canada** [eLearning course](#)
 - **The MDEL Annual Licence Review (ALR)** through the annual [ALR Webinar material available on GC collab](#)



How we prioritize our work



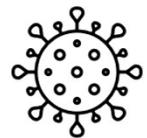
- Department legislation & plan
- Minister’s mandate letter, e.g., supporting innovation, Red tape reduction, Comprehensive expenditure review, enabling supply chains, eliminating interprovincial trade barriers, international collaboration



- Industry
- Provinces & Territories
- Patients/consumers
- Healthcare providers



- SaMD/Artificial Intelligence
- Globalized supply chains (e.g. eCommerce)
- Lessons learned e.g. COVID



- IT & data integration
- Risk-based operations
- C&E alignment
 - drugs, NHPs

MDCP Key Priorities

Transformation

- Streamline triaging processes
- Continue to build internal expertise to support accurate classification
- Prioritize the use of risk-based C&E tools for C&E planning e.g., Site Risk Profiles
- Support the Department's forward regulatory agenda

Partnership and Visibility

- Enhance domestic and international partnerships with key trusted regulators
- Continue to strengthen collaboration and information exchange with industry to maximize voluntary compliance
- Conduct compliance promotion and compliance monitoring projects

Modernization

- Leverage automation for C&E activities, reporting and administration
- Undertake Business Process Optimization processes to be more effective and efficient

People and Workplace Culture

- Continue to support the MDCCD workplace Wellness Charter
- Encourage a culture of continuous improvement and continuous learning

Questions



erin.skuce@hc-sc.gc.ca