Health Canada Santé Canada

Canada

Audit of Inspection Activities at Health Canada, 2023-2024 to 2025-2026

Final Report – March 2026
Prepared by the Office of Audit and Evaluation
Health Canada

Health Canada is the federal department responsible for helping the people of Canada maintain and improve their health. Health Canada is committed to improving the lives of all of Canada's people and to making this country's population among the healthiest in the world as measured by longevity, lifestyle and effective use of the public health care system.

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List of acronyms

CTCSD	Cannabis, Tobacco, and Controlled Substances Directorate
C&E	Compliance and Enforcement
EHCPPD	Environmental Health, Consumer Products, and Pesticides Directorate
HC	Health Canada
HPCD	Health Product Compliance Directorate
HPSD	Health Product Shortages Directorate
LD	Laboratories Directorate
MDCCD	Medical Devices and Clinical Compliance Directorate
MYCET	Multi-Year Compliance and Enforcement Transformation Implementation Plan
OAE	Office of Audit and Evaluation
POD	Planning and Operations Directorate
PRSD	Policy and Regulatory Strategies Directorate
QAM	Quality Assurance Management Unit
QMS	Quality Management System
RBIP	Risk-Based Inspection Planning
ROEB	Regulatory Operations and Enforcement Branch

Executive summary

Audit overview

The audit's objective was to determine if there were effective and efficient risk-based planning processes in place to support inspection activities at Health Canada (HC). The audit's scope focused on the risk-based planning frameworks respective to each inspection program for fiscal years 2023-2024 to 2025-2026. The audit also examined specific evidence supporting the implementation of the 2019-2020 Audit of Inspection Activities Management Response and Action Plan (MRAP), as well as current inspection roles and responsibilities.

Overall, we noted that there were good foundational risk-based inspection planning processes in place; however, there is a need to implement an overarching risk-based planning framework that includes strengthened operational procedures to ensure better effectiveness and efficiency.

Good practices

We noted that the Regulatory Operations and Enforcement Branch (ROEB) has well-structured annual operational planning and reporting processes in place at the branch level. For example:

- Since 2022, ROEB's Transformation Initiatives have been consolidated in the Transformation Framework, derived from the Multi-Year Compliance and Enforcement Transformation Implementation Plan (MYCET) 2020 to 2023 projects and Build Back Better (BBB) activities and related processes, with the ongoing aim to ensure that project focuses are continuously re-evaluated, and plan prioritizations are adjusted accordingly through the operational planning process.
- ROEB's consolidated Inspection Program ROEB C&E Dashboard displays a high-level summary of planned and completed inspections and non-compliance results.
- A formalized Quality Management System (QMS) framework was developed to define processes, procedures, and responsibilities, in order to establish quality policies and meet predefined quality objectives.

All inspection programs have identified and implemented various risk management processes to support their Risk-Based Inspection Planning (RBIP). The majority of programs demonstrated use of structured prioritization and scoring risk methodologies that were guided by various operational controls, including quality manuals, standard operating procedures (SOPs), and work instructions (WIs). Despite the complexity of inspection activities, the roles and responsibilities for the inspectors and regulatory support staff

located in both regional and national offices, and other ROEB support functions are clearly defined, such as the QMS audit function, laboratory functions, and roles within the Planning and Operations Directorate (POD), the Policy and Regulatory Strategies Directorate (PRSD), etc. These relationships, and those involving other key stakeholders like partner branches and external subject matter experts, have ensured that RBIP processes were well informed.

Opportunities for improvement

Opportunities exist to formalize an overarching risk framework. We recognize that each program's inspection population, regulatory requirements, licensing regimes, and resulting sampling methodologies will vary. However, an overarching RBIP framework and common tools are critical to identifying who is accountable for RBIP, as well as determining planning timelines, reporting requirements, general risk taxonomies, performance indicators, monitoring strategies, and appropriate alignment with operational guidelines. This framework will facilitate a holistic view across all programs, providing assurance to senior management as they exercise their oversight function.

We noted the need for an ongoing strengthening of individual program operational processes, including refining and documenting risk methodologies and data analytics, to ensure that these processes are consistent and continuous. Additionally, we noted the QMS maturity level across ROEB's programs varied, with some development and refinements still in progress. Also, specific to RBIP, there was fragmented and limited overarching guidance. The overall impact of these limitations may negatively affect the ability to conduct a more consolidated risk analysis and hinder adaptation to emerging environmental and technological risks.

ROEB's senior management is ultimately accountable for the risk-based inspection plan, which is a key activity in managing risks to the safety of the people of Canada. However, in most instances, senior management does not formally approve the inspection planning strategies, opportunities, and resulting risk priorities. Approval of detailed inspection plans is conducted within the relevant directorate. Directorate operational plans, which are approved by senior management, include annual inspection targets, broken down by sector, act, product, etc. as appropriate for each program. The ROEB C&E Dashboard for inspection activities is updated and presented quarterly. There is an opportunity to use the information to inform strategic analysis to support ongoing risk monitoring. There were positive operational controls, whereby non-compliance findings were reviewed to ensure consistent application. Overall we noted there is an opportunity to strengthen the upfront approval of inspection plans by senior management, particularly to ensure they are

focusing on areas of the highest risk, and on ongoing risk monitoring. This will ensure that inspection planning approaches, coverage, resource allocations, and impact determinations are aligned with senior management's risk tolerances and their overall understanding of the broader environmental landscape, and will support their risk-based decision making as issues emerge.

Finally, clarification is needed on the ultimate accountability for RBIP processes, as the involvement of individual partner branches varies across programs. While there appeared to be good collaboration between all directorates and partner branches, the lack of clarity as to who is ultimately accountable for RBIP processes and the ultimate inspection plan, may create duplication or gaps in ongoing RBIP processes.

Introduction

Health Canada's (HC) role as a regulator includes the responsibility to protect the people of Canada from unsafe health and consumer products. In 2016, HC introduced a dedicated Regulatory Operations and Enforcement Branch (ROEB), which was a critical step in strengthening oversight of the Department's acts and regulations, and improving consistency in program delivery. Since its creation in 2016, ROEB has been responsible for the Department's inspection activities, while sharing certain compliance and enforcement (C&E) accountabilities with other branches.

In accordance with its departmental responsibility, ROEB's mission is to be a C&E leader that informs and protects the people of Canada from health risks associated with products, substances, and their environment. ROEB does this by conducting C&E activities, and through complementary scientific programs, that may include inspection activities, such as field inspection, product sampling, compliance verification, and enforcement measures.

Currently, ROEB is the second largest branch in the Department and has over 1500 employees across Canada. It includes eight directorates:

- The Planning and Operations Directorate (POD), the Policy and Regulatory Strategies Directorate (PRSD), the Health Product Shortages Directorate (HPSD), and the Laboratories Directorate (LD), all of whom provide horizontal policy, regulatory, planning, and operational guidance, as well as laboratory services to the remaining four program directorates.
- The Cannabis, Tobacco and Controlled Substances Directorate (CTCSD), the Environmental Health, Consumer Products, the Pesticides Directorate (EHCPPD), the Health Products and Compliance Directorate (HPCD), and the Medical Devices and Clinical Compliance Directorate (MDCCD). All of these directorates are responsible for overseeing direct program activities, including Compliance and Enforcement (C&E). Within these directorates, there are a total of thirteen inspection programs. See Appendix C for more details. These program activities are guided by respective acts and regulations, and protect the safety of the people of Canada. Their scope touches every aspect of Canadian life, from medical supplies and health products to veterinary drugs, to environmental products, to furniture and more.
- Furthermore, there are significant interrelations between the respective HC partner branches, who have a shared responsibility to ensure there are appropriate regulatory frameworks in place.

The 2024 to 2026 Risk-Based Audit Plan (RBAP) identified a need to conduct an Audit of Inspection Activities at HC, with the aim of reviewing the modernization of C&E inspection activities in light of the COVID-19 pandemic, the 2020 to 2023 Multi-Year Compliance and Enforcement Transformation (MYCET), and the 2019-2020 Audit of Inspection Activities, the latter of which assessed the processes and tools in place to support key elements of C&E modernization.

Considering that ROEB modernization efforts are evergreen and that inspection processes continue to evolve, auditing previous tools for implementing modernization efforts may not provide added value.

Through the Office of Audit and Evaluation's (OAE) risk-based planning process, the audit focused on assessing the overarching risk-based planning processes that guide inspection activities and the completion of the Management Response and Action Plan (MRAP) for the 2019-2020 Audit of Inspection Activities.

Criterion 1 – There is effective monitoring of ROEB's C&E transformation projects.

Context

The Planning and Operations Directorate (POD) within ROEB is responsible for the collection and consolidation of planning activities from each ROEB directorate and the required corporate reporting, including its annual operational plan, which includes transformation projects.

The previous Audit of Inspection Activities recommended that ROEB develop and oversee a comprehensive C&E modernization plan. ROEB reported that all MRAP commitments were completed by June 2021. The Audit recommendations were:

- ROEB should continue efforts to finalize a C&E modernization plan under areas of ROEB mandate and covering the eleven regulated product categories that prioritizes initiatives, and clearly identifies the deliverables, milestones, timelines, and resource requirements.
- ROEB should ensure that the oversight of the C&E modernization plan is effective, and that monitoring and reporting mechanisms are enhanced.
- ROEB should ensure that a C&E modernization plan for the inspection function includes specific action plans that address risk-based inspection planning, update

information management and information technology (IM/IT) systems and tools, maintain current operating procedures, and provide appropriate training for inspectors.
- ROEB should consider how Sex and Gender-Based Analysis could be applied to inspection activities.

What we expected to find

We expected to find a documented and overarching C&E modernization framework that clearly outlines each directorate's roles and responsibilities, as well as data collection, analytical, and reporting requirements specific to the prioritization of transformation projects. Furthermore, evidence should demonstrate the implementation of each of these requirements, supported by appropriate oversight of their completion.

Why it matters

An overarching C&E modernization framework, including structured planning and monitoring processes, is critical to ensuring project prioritization, as well as efficient and effective resource use in light of fiscal constraints and ever broadening and evolving health and safety risks.

Key findings

Overall, all 2020 audit recommendations have been addressed through MYCET's implementation and its integration into ROEB's ongoing transformation strategy including the development of Sex and Gender Based Analysis Plus Action Plan 2022-2026. While MYCET as a standalone initiative has been phased out, its objectives and governance structures have been embedded into the broader ROEB Transformation Framework, ensuring sustained modernization and periodic performance reporting.

MYCET Projects:

- A consistent and coherent approach to C&E across ROEB.
- Continuous improvement of organizations through employee engagement.
- Appropriate allocation of resources based on risk.
- MYCET projects are all recorded within the Keeping Foundations Strong category.

BBB Activities:

- Leverage ROEB adaptation efforts to re-think how regulatory activities can be delivered in a more resilient and agile manner.
- Identify and address issues that hinder optimal program model.
- Envisioning what ROEB programs could look like in the future.
- BBB activities are categorized under all five pillars of the Transformation Roadmap.

Given the significant level of change required to fully address the MYCET commitments since 2021-2022, a ROEB Transformation

Framework comprised of MYCET projects and Build Back Better (BBB) activities was developed. ROEB indicated that the specific MYCET project deliverables were transitioned into the ongoing transformation strategy; however, some issues were noted in the fragmentation, evolution, and eventual discontinuation of MYCET, including organizational change, which reduced the ability to directly track and measure completion of the original 2020 audit recommendations.

We noted that the 2025-2026 operational planning and reporting cycle was built on these frameworks to address emerging risks, improve data-driven decision making, and sustain operational efficiency. The branch transformation priorities established in 2022 continue to be used in the development of the 2025-2026 Operational Plans. These priorities include:

- Strengthening Data and Analytics
- Positioning ROEB for Emerging Regulatory Priorities
- Maximizing Operational Efficiency
- Keeping Foundations Strong
- Supporting Our Employees

The ROEB Transformation Framework and the above processes ensure that project merits are continuously re-evaluated, and plan prioritizations are adjusted accordingly.

Overall, ROEB has well-structured annual operational planning and reporting processes in place at the branch level.

A ROEB C&E Dashboard is in place to provide a high-level summary of planned and completed inspections and non-compliant results. This Dashboard is a good foundation for reporting; however, it is not clear how the results presented in this report are analyzed to inform future RBIP at the branch and directorate levels. Given varying risk methodologies and operational nuances, program comparisons were more challenging. Furthermore, there was incomplete evidence of a robust analysis and resulting actions.

There is an opportunity to strengthen reporting, as there was limited clear measurement of inspection program results against objectives. Examples of additional information may include:

- standardized risk indicators such as mortality risk, environmental risk, data integrity risk, etc.,
- defined risk tolerance levels or risk impacts,
- variances in plan explanations,
- clear tracking visibility of any identified action or follow-up items,

- noncompliance explanations, as not all errors are equally severe, and
- performance indicators for service standards.

This would facilitate trend analysis, results measurement, and consistent integration of risk outcomes across programs.

In addition, ROEB implemented a formalized Quality Management System (QMS) framework that defines processes, procedures, and responsibilities, in order to establish quality policies and meet predefined quality objectives. Each program's Quality Management System (QMS) requires participation in audits conducted by the ROEB Quality Assurance Management (QAM) Unit. These audits review a sample of inspections to check that compliance and enforcement activities meet requirements described in quality documents and processes are being followed. The main purpose of QAM audits is to confirm that programs are operating according to established processes, but audits themselves are not specifically related to risk-based planning.

We noted that the QMS maturity level across ROEB's programs varies, with some development still in progress. Also, specific to RBIPs, there is fragmented and limited guidance. The overall impact of these limitations may negatively affect the ability to conduct a more consolidated risk analysis and hinder adaptation to emerging environmental and technological risks. While this audit did not directly focus on the overall operational controls and processes for inspection activities, we noted there may be potential opportunities to integrate RBIP considerations into the QMS framework.

Given the importance of this function and the wealth of collected information, trends analysis may strengthen the integrity of RBIP. For example, a QAM audit may identify issues related to non-compliance, which may ultimately lead to potential risk criteria affecting future inspection prioritizations. It was also observed that, although the QAM team reviews audit results with the directorate auditee and solicits their acceptance, there was limited evidence of a detailed follow-up on non-compliance issues to ensure each corrective action was fully implemented. Furthermore, QAM audits are conducted by QAM, but the individual program directorates are responsible for selecting the processes to be audited. During the audit timeline identified by the program, the QAM team revisits the follow-up areas to see whether prior audit findings have been closed, or if similar gaps have reoccurred. Without full independent POD QAM planning, audit follow-up, and results analysis, the value and effectiveness of QAM audits may be limited and not fully leveraged in RBIP processes.

We also noted several planning activities that, while requiring updates, provide a good foundation for operational activities, including RBIP processes:

- The Compliance and Enforcement Policy Framework on Canada.ca was updated on 2018-05-15, as per the web version. We were advised that the framework has not been updated as required since its inception.
- The POL-0149 ROEB Compliance and Enforcement: Decision-making Policy was still in draft format at the time of the audit.

Several initiatives intended to strengthen the efficiency and effectiveness of inspection programs are also under development, including:

- A Risk Management Guide for Compliance and Enforcement (C&E) Decisions at ROEB (draft from April 2024), to support the implementation of POL-0149. While this Guide identifies that "Proportionate and risk-informed C&E activities support effective risk-based resource allocation," it is unclear what the intended standardization of RBIPs will be, as there were limited detailed methodologies for prioritization and planning of C&E operational decisions.
- A project to determine the need for a Health Product Compliance Directorate (HPCD) Risk Framework. The purpose of this project is to assess the various risk management processes at HPCD and, if necessary, develop a risk framework to modernize and streamline the risk-based approach to planning, analysis, and decision making across the Directorate.
- Finally, a Fraud Risk Assessment (FRA) was completed for FY 2024-2025, which we identified as a good assessment tool, particularly given the highly sensitive inspection environment that includes human and recreational drugs and medical supplies. No further analysis was conducted at the program level.

Criterion 1 Conclusion

In conclusion, governance structures, periodic performance reporting, and evolving strategic prioritization are in place, with effective monitoring. Since the 2019-2020 audit, ROEB's MYCET activities encountered some challenges around workload, timely delivery, and process optimization. The 2025–2026 operational planning cycle built on the ROEB Transformation Framework to address emerging risks, improve data-driven decision making, and sustain operational efficiency. Improvements to data analytics for branch RBIP reporting, and continuing the completion and updating the key policy instruments, would help to support robust monitoring efforts.

Recommendation #1 (Medium Priority)

The Assistant Deputy Minister (ADM) of ROEB should consider opportunities to take a more strategic approach to the identification, monitoring, and analysis of inspection risks across the branch by enhancing tools for data analytics, using internal program audits to

support emerging risks trend analysis, and updating and communicating C&E related policies and guidelines regularly.

Criterion 2 – The risk-based planning framework for each inspection activity is comprehensive, operationalized, documented, communicated, and monitored.

Context

In response to the OAE's 2020 Audit of Inspection Activities recommendation to ensure a "risk-based inspection planning" process, ROEB identified the action to improve data analytics capability and risk management tools for all inspection programs.

> ***Risk Tolerance:***
>
> "Is the willingness of an organization to accept or reject a given level of residual risk (exposure). Risk tolerance may differ across the organization but must be clearly understood by the individuals making risk-related decision on a given issue. Clarity on risk tolerance at all levels of the organization is necessary to support risk-informed decision-making and foster risk-informed approaches."
>
> Treasury Board Secretariat *Framework for the Management of Risk*

Inspection planning and operational activities in general are reliant on and guided by numerous inputs from subject matter experts, regulatory and legislative requirements, and various government departments and agencies. The impact of their work touches every Canadian and all aspects of their lives, from medicinal and recreational health products for humans, to veterinary drugs, to environmental products, to furniture.

What we expected to find

We expected to find clear accountabilities and a documented risk-based methodology supported by data collection, analysis, and relevant inspector training. Evidence of the methodology's implementation would include current and complete population data, as well as timely risk assessments informed by the current environment and trends, and periodically reviewed and approved by senior management.

Why it matters

Having an overarching RBIP framework is recognized as a strong foundational control. It is essential for ensuring a coherent and consistent approach, facilitating coordinated risk analysis and oversight across all programs, and supporting better resource alignment. Furthermore, the framework supported by comprehensive procedures and tools, will

ensure that risks do not go undetected or that risk scoring is consistently and continuously applied. Not having a framework may lead to inefficient and ineffective processes and, most importantly, an increased risk to public health, as high-risk products, sites, or license holders may not be inspected within an appropriate timeframe.

Key findings

Risk framework:

As noted under Criterion #1, there are well-structured operational planning processes at the directorate and branch levels. However, the risk-based planning guiding instruments, namely *POL-0149: ROEB C&E Decision-making Policy,* and the *GUI-0155 Risk Management Guide for C&E Decision in ROEB* are not yet being applied as they remain in a draft format.

We noted that no program had a final formal RBIP framework, though several are continuing to draft, modify, and refine their approaches, and individual program frameworks. This includes Cannabis, Border Operations, Natural Health Products Good Manufacturing Practices, and Medical Device Compliance. Although RBIP procedures exist, they are not aggregated into one comprehensive document, nor do they include all aspects expected in a framework. An overarching RBIP framework is an essential control for ensuring an efficient and effective RBIP and includes respective processes like identifying who is accountable for the RBIP processes, planning timelines, reporting requirements, general risk taxonomies, performance indicators, monitoring strategies, and appropriate alignment with operational guidelines.

Risk methodology and operating procedures:

Most programs have established risk-based planning methodologies of varying maturity and complexity, except for programs with primarily reactive inspection requirements. These methodologies all demonstrate efforts to implement structured prioritization and scoring approaches. The audit did not examine the methodologies to ensure alignment with legislative or regulatory requirements. Programs maintain strong document controls, such as quality manuals, SOPs, and work instructions, through their Quality Management Systems (QMS).

However, many programs lack detailed documentation of how risk categories and scores are calculated or the parameters used for their assessment. Opportunities exist to formalize, document, and operationalize RBIP activities and their outcomes to ensure consistency and repeatability.

It is the program's responsibility to ensure adequate risk management processes, including the determination of a risk methodology that balances the impacts of inspection risks with the costs of mitigating them. Whether using a defined and categorized risk weighting approach, judgmental, or cyclical versus flexible approach, each have their own inherent risks and they must be communicated to all levels of management to support informed decision making. For example, knowing these details provides context when interpreting the ROEB C&E Dashboard results based on highest-risk inspection targets and compliance issues.

We noted that programs generally have a clear understanding of their inspection scope and population. Inspection coverage varied between all programs; as noted above, some were purely risk-based, others were risk-based but ensured cyclical coverage over a period of time.

Understandably, there were challenges for reactive inspection planning activities, as inspection scope depends on emerging issues, new products and trials, or inspection requests. However, once issues arose, we observed a good risk-based triage approach to prioritize inspections. Also, several programs that include substantial volumes of reactive inspections have or were starting to define and track service standard metrics, which we noted was a key control to support the balance between inspection capacity versus inspection planning risks. Furthermore, there was a limited ability to conduct extensive upfront planning for some inspection activities due to the need for many of them to be reactive. There is an opportunity to strengthen the monitoring of these inspections activities using, for example, trend analyses and continual identification of new issues, to ensure they sufficiently identify products and sites requiring an inspection.

Across all programs, there is an opportunity to identify and report on inspection coverage to ensure the long-term RBIP is aligned with senior management's risk tolerances.

We noted that, across all programs, the risk-based planning processes were well-informed. There were good risk-based information-sharing processes and all programs generally had input from various committees, working groups with regional and national teams, ROEB directorates and branch experts, partner branches, other government departments, and external experts. The processes provided opportunities to communicate risks and emerging issues. Furthermore, there is good communication on RBIP between inspectors, supervisors, and managers. Nevertheless, opportunities exist to strengthen communications with senior management to ensure that the inspection plan is aligned with their risk tolerances or overall branch risks.

Most programs rely on multiple shared legacy databases and spreadsheets to capture and assess risk data, leading to inefficiency and the potential for data inaccuracy. These fragmented systems limit the ability to conduct ongoing data integrity monitoring and risk trend analysis.

We also noted that, across programs, inspection results are considered in varying degrees within risk scoring, ranging from automatic follow-ups to compliance-weighted scoring.

Finally, most inspection planning strategies, opportunities, and risk priorities were not formally approved by senior management. Senior management is ultimately accountable for inspection plans, which are a key control in the safety of the people of Canada. Operational plans which are approved include high-level aspects of inspection activities. It is therefore important that the Inspection Plan approach, coverage, resource allocations, and impact determinations are aligned with senior management's overall understanding of the broader environmental landscape. Furthermore, some programs lack terms of reference or records of decision for their individual planning committees.

- *Inspection reporting and other operational controls:*

As noted in Criteria #1, all RBIP statuses were generally reported on the ROEB C&E Dashboard. However, within each program directorate, other than this Dashboard, we did not find any evidence of other formal reporting and ongoing analysis of the inspection activities.

Several programs demonstrated additional positive reporting controls, such as:

- The Health Product Compliance Directorate's Drugs Program implemented a review of non-compliance findings to ensure consistent application;
- The Pesticides Program implemented an evergreen form to allow collection of information on emerging issues, and industry trends reports; and
- The Consumer Product Safety Program completed Enforcement Summary Reports.

Several programs demonstrated additional positive operational controls, such as:

- The Health Product Compliance Directorate - Good Pharmacovigilance Practices Program had detailed work instructions were implemented;
- The Cannabis Program conducted annual proactive risk assessments with complex scoring by using multiple criteria to inform inspection planning;
- The Tobacco and Vaping Program had proactive inspection planning based on compliance history, product type, and market presence; and,

- The Pesticides Program had multiple spreadsheets on risk criteria and inputs, past results, environmental scans, and planning calendars.

However, given the volume of inspections, and different program nuances, there is an opportunity to strengthen the reporting on inspection results within each directorate, ensuring robust information, documented trend analyses, and applicable follow-up actions, as this information may highlight important amendments to the Inspection Plan.

Training:

There are strong processes for national certification requirements and their tracking through HC's corporate myLearning platform. We noted that there is a mature training framework for generic inspector training including the ongoing refinement of training policies, but there is no overall consolidated view of standard inspector skill sets to allow for cross-sharing of resources. A few programs have developed and are tracking specialized inspection skills applicable to them; however, they are mostly still in the development stage. Although not statistically representative of each individual program, the inspectors' survey demonstrated that 79% of inspectors felt they were well supported in their training needs.

A Building Inspector Capacity (BIC) project was recently initiated (2025-2026). The goal is to maximize the use of HC's inspector workforce by developing a robust HR strategy aligned with priorities, ROEB's mandate, the financial context, and by cross-training inspectors where possible. This initiative appears to be a good starting point to support the allocation of inspection resources and ultimately manage risks to public health by ensuring that high-risk products, sites, or license holders are inspected in an appropriate timeframe. Once this project currently underway is completed, it is anticipated to provide the consolidated view of standard inspector skill sets and cross-sharing of resources, where deemed appropriate.

Criterion 2 Conclusion

In conclusion, all programs have identified and implemented risk management processes supporting their inspection planning activities. Opportunities exist to formalize an overarching risk-based planning framework and continue strengthening operational processes, including refining and documenting risk methodologies, reviewing data integrity, leveraging data analytics, improving ongoing RBIP reporting across the Portfolio, and providing specific inspector training.

Recommendation #2 (Medium Priority)

- The Assistant Deputy Minister (ADM) of ROEB should consider the feasibility of implementing an enterprise-wide risk-based planning framework that outlines clear roles and accountabilities and provides guidance on inspection planning.

Recommendation #3 (Medium Priority)

- The Assistant Deputy Minister (ADM) of ROEB should consider mechanisms to strengthen available information on training, competencies, and capacity of inspectors, in order to support risk-based inspection planning.

Criterion 3 – There are clear, documented, and communicated inspection roles and responsibilities.

Context

Programs are complex, with significant variations in each of their inspection populations, regulatory requirements, licensing regimes, and key stakeholders. There are approximately six hundred inspectors in ROEB across fourteen inspection programs. These programs within ROEB directorates collaborate with numerous partners and stakeholders.

What we expected to find

We expected to find formal inspection and management oversight roles and responsibilities that guide all operational activities in planning, delivering, and monitoring inspections.

Inspection Planning Partners:

- Health Canada branches and the Public Health Agency of Canada
- Other departments and agencies
- Law enforcement agencies
- Public health organizations
- Provinces and territories
- Indigenous communities
- Other international regulatory authorities

Stakeholders:

- Regulated industries
- Pharmacies and hospitals
- Associations
- Public and communities
- Health care providers

Why it matters

Clear, documented, and communicated roles, responsibilities, and accountabilities are fundamental control to ensure operating efficiency and effectiveness. Furthermore, as the BIC project evolves, having these elements be well defined and clearly understood, allowing for comparability, will support future sharing of inspector capacity.

Key findings

Within ROEB, and specific to RBIP, the following are key activities:

- The Policy and Regulatory Strategies Directorate (PRSD) is responsible for the overarching C&E policies that are guided by and aligned with regulatory and legislative directions.
- POD is responsible for the preparation of the branch's Corporate Risk Profile, the ongoing consolidation of C&E Inspection reporting via a ROEB C&E Dashboard, the Build Back Better (BBB) Project initiative, and the QAM unit that develops and enforces the QMS. They are also responsible for program development and training.
- Each program directorate manages inspector activities related to a given product line, including engagement with their partner branch, which varies by program.
- In conjunction with ROEB POD, and in consultation with their respective partner branch as needed, each program directorate prepares the individual RBIP documents, and develops and maintains their individual QMS.
- Partner branches' roles and responsibilities with respect to inspection planning vary between programs, with some having:
    - the lead responsibility,
    - joint responsibility, for example through the provision of inspection lists, and reviewing and providing direction on required inspections, or
    - collaborative and expert input during the planning cycle.

We noted that inspectors, QMS auditors, and lab analysts generally have clear and documented roles and responsibilities relating to operational activities. The inspector's survey results, show that 64% of inspectors indicated that they were satisfied with clarity of roles and responsibilities specific to their overall activities. While these roles and responsibilities had commonalities, there are some variations between regional and head offices, and programs, including their communications. Given these variations and that approximately one-third of inspectors who responded to the survey did not indicate satisfaction with clarity of roles and responsibilities, opportunities exist to continue to streamline and communicate inspector roles and responsibilities.

Overall accountability for RBIP processes and the ultimate plan are unclear, with several programs identifying either ROEB's POD or the partner branch as the lead or co-lead in risk-based inspection plan development. While there appeared to be good collaboration among all directorates and partner branches, the lack of clarity as to who is ultimately accountable for planning processes and plan may create duplication or gaps in ongoing processes.

Criterion 3 Conclusion

Overall, the clarity of controls for roles and responsibilities are clear and documented. Opportunities exist to clarify the ultimate accountability of RBIP processes.

Recommendations – See Criteria #2 Recommendation # 2

Criterion 4 – An assessment of best practices and processes in place to share these best practices across ROEB inspection activities.

The findings associated with Criterion #4 (Best Practices) have been included in the findings for Criteria 1 to 3 throughout the report.

Finding Highlights

Several best practice procedures or activities were identified. As several of these processes are periodic or currently being refined, we noted that their continued implementation and development will contribute to a more effective and efficient RBIP process. These best practices include:

- A formalized Quality Management System (QMS) framework that defines processes, procedures, and responsibilities, in order to establish quality policies and to meet predefined quality objectives.
- A Risk Management Guide for Compliance and Enforcement (C&E) Decisions at ROEB (draft from April 2024). While this Guide identifies that “Proportionate and risk-informed C&E activities support effective risk-based resource allocation”, it is unclear what the intended standardization of RBIP will be, as there were limited detailed methodologies for prioritization and planning of C&E operational decisions.
- A Health Product Compliance Directorate (HPCD) Risk Framework project. The purpose of this project is to assess the various risk management processes in HPCD and, if necessary, develop a risk framework in order to modernize and streamline the risk-based approach to planning, analysis, and decision making across the Directorate.
- A mature training framework for generic inspector training that contributes to both ongoing employee talent management and the assurance of quality inspections.
- A Fraud Risk Assessment (FRA) was completed for FY 2024-2025, and we identified it as a good assessment tool, particularly given the highly sensitive

inspection environment, including human and recreational drugs and medical supplies.

Overall Audit Conclusion

Overall, we noted that there were good foundational risk-based inspection planning (RBIP) processes in place; however, there is a need to implement an overarching risk-based planning framework that is linked with strengthened operational processes, which will help to improve the overall effectiveness and efficiency of RBIP.

Management Response and Action Plan

Recommendations	Management Response and Planned Management Action	Deliverables	Expected Completion Date	Responsibility
1. The Assistant Deputy Minister (ADM) of ROEB should consider opportunities to take a more strategic approach to the identification, monitoring and analysis of inspection risks across the branch by enhancing tools for data analytics, using internal program audits to support emerging risks trend analysis, and updating and communicating C&E related policies and guidelines regularly.	Management agrees with the recommendation. ROEB will undertake the review of existing C&E risk-based inspection planning, monitoring, and reporting mechanisms and will explore opportunities to strengthen the monitoring and analysis of inspection risks across the branch. This will include reviewing existing branch inspection risk monitoring tools and processes along with internal audits. ROEB will clarify roles and responsibilities to finalize and maintain branch C&E related policies and guidelines. ROEB will also look to explore expanding the AI capabilities of existing tools, such as Cyclops, to other programs, and assess opportunities to apply AI in other	1.1 Develop recommendations to improve ROEB's internal quality audit program by strengthening audit planning, audit closure, corrective action follow-up, and monitoring processes, including proposed roles and responsibilities to support consistent implementation across ROEB.	Q3 FY2026-27	Director General (DG), Planning and Operations Directorate (POD), Regulatory Operations and Enforcement Branch (ROEB)
		1.2 As part of ongoing, iterative enhancements to the ROEB C&E Dashboard, recommendations for changes to strengthen risk identification within the branch are developed.	Q2 FY2027-28	DG, POD, ROEB OSI: Directorate DGs, ROEB
		1.3 Recommendations for the expanded use of AI tools within ROEB to strengthen inspection risk identification are developed.	Q4 FY2026-27	DG, POD, ROEB OSI: Directorate DGs, ROEB; DG, Digital Transformation Branch (DTB)

	areas (e.g., through the Single Window Initiative) to inform risk-based inspection planning.	1.4 The approach to maintain branch-wide C&E policies and guidelines will be confirmed and a communicated.	Q4 FY2026-27	DG, Policy and Regulatory Strategies Directorate (PRSD), ROEB
		1.5 POL-0149 ROEB Compliance and Enforcement – Decision-making Policy and Risk Management Guide for Compliance and Enforcement (C&E) Decisions at ROEB is approved.	Q4 FY2026-27	DG, PRSD, ROEB
2. The Assistant Deputy Minister (ADM) of ROEB should consider the feasibility of implementing an enterprise-wide risk-based planning framework that outlines clear roles and accountabilities and provides guidance on inspection planning.	Management agrees with the recommendation. ROEB would benefit from assessing the feasibility of a common risk framework that supports programs in improving risk-based inspection planning. To support this approach, ROEB, in consultation with program partner branches, will undertake a review of current RBIP processes with the aim of developing and implementing a horizontal risk-based inspection planning framework that outlines clear roles and responsibilities.	2.1 The ADMs of ROEB, CSCB, and HECSB will meet to discuss roles and responsibilities for C&E in respect of programs, including responsibilities in the development of risk-based inspection plans.	Q2 FY2026-27	ADM, ROEB OSI: ADMs. Controlled Substances and Cannabis Branch (CSCB), Healthy Environments and Consumer Safety Branch (HECSB)
		2.2 Recommendations to strengthen RBIP are developed, based on reviewing processes used by programs to identify and analyze risk during inspection planning.	Q4 FY2026-27	DG, POD, ROEB OSI: DG PRSD, ROEB; Inspection Program DGs, ROEB; DG, Consumer and Hazardous Products Safety Directorate (CHPSD), HECSB; DG, Compliance

				Directorate, CSCB; DG, Controlled Substances and Overdose Response Directorate (CSORD), CSCB; DG, Tobacco Control Directorate (TCD), CSCB
		2.3 Feasibility of a risk-based planning framework is assessed, including elements such as clear accountabilities, communication expectations, minimum standards for how often RBIP is done, approval of inspection plans and results analysis.	Q4 FY2026-27	DG, POD, ROEB OSI: DG, PRSD, ROEB; Inspection Program DGs, ROEB; DG, CHPSD, HECSB; DG, Compliance Directorate, CSCB; DG, CSORD, CSCB; DG, TCD, CSCB
3. The Assistant Deputy Minister (ADM) of ROEB should consider mechanisms to strengthen available information on training, competencies, and capacity of inspectors, in order to support risk-based inspection planning.	Management agrees with the recommendation. ROEB would benefit from more information on the training, competencies, and capacity of inspectors, in order to support improved risk-based inspection planning. To that end, ROEB will develop a branch-wide designation poli	3.1 New Designation Policy implemented and communicated to ROEB employees.	Q2 FY2026-27	DG, POD, ROEB OSI: DG, PRSD, ROEB
		3.2 Inspector competency inventory tracking mechanism and process for timely updates with clear roles and responsibilities is developed.	Q4 FY2026-27	DG, POD, ROEB OSI: Directorate DGs, ROEB
		3.3 Recommended actions to integrate inspector	Q4 FY2026-27	DG, POD, ROEB

	cy to support increased maintenance and monitoring of inspector data. In addition, by leveraging the ongoing Building Inspector Capacity (BIC) project, ROEB will identify improvements that enhance inspector capacity and designation monitoring.	competencies into risk-based inspection planning are developed.		OSI: Directorate DGs, ROEB
		3.4 Identify required enhancements to the inspector designation database and develop proposed options for a branch-wide designations dashboard to improve data accuracy, monitoring, and reporting for designated inspectors and their authorized activities.	Q3 FY2026-27	DG, POD, ROEB

Appendix A

Audit objective

The objective of this audit was to determine if there were effective and efficient risk-based planning processes to support inspection activities at Health Canada (HC).

Audit scope

The scope of the audit focused on the risk-based planning framework respective to each inspection activity for fiscal years 2023-2024 to 2025-2026. The audit also examined specific evidence supporting the implementation of the 2019-2020 Audit of Inspection Activities Management Response and Action Plan (MRAP), as well as current inspection roles and responsibilities.

Audit approach

The audit methodology included but was not limited to:

- Interviews with each Regulatory Operations and Enforcement Branch (ROEB) directorate's management and functional staff;
- Interviews with partner branches;
- Examination and analysis of documentation and reporting tools; and,
- Inspectors survey.

Note: The findings associated with Criterion 4 (Good Practices) have been included in the findings for Criteria 1-3 throughout the report.

Statement of Conformance

The Office of Audit and Evaluation conducted this audit engagement in conformance with the IIA's Global Internal Audit Standards and is supported by the results of the OAE's Quality Assurance and Improvement Program.

Audit criteria

Audit criterion #1: There is effective monitoring of ROEB's C&E transformation projects.

Audit criterion #2: The risk-based planning framework for each inspection activity is comprehensive, operationalized, documented, communicated, and monitored.

Audit criterion #3: There are clear, documented, and communicated inspection roles and responsibilities.

Audit criterion #4: An assessment of best practices and processes in place to share these best practices across ROEB inspection activities.

Appendix B – Recommendation ratings

Recommendations are ranked to assist management in prioritizing their response to audit findings. These ratings are intended to assist with resource allocation to address identified weaknesses and help improve internal controls and operating efficiency. Please note that ratings are for guidance purposes only. Management must evaluate ratings provided by OAE based on their own experience and risk tolerance.

Recommendations are ranked according to the following definitions:

- **High priority**: Item should be given immediate attention due to the existence of either a significant control weakness, such as a control not existing, or not being adequately designed, or not operating effectively, or there is a significant operational improvement opportunity.

- **Medium priority**: This is a control weakness or operational improvement that should be addressed in the near term.

- **Low priority**: This is a non-critical recommendation that could be addressed to either strengthen internal controls or enhance efficiency, normally with minimal cost and effort. Individual ratings should not be considered in isolation and their effect on other objectives should be considered.

Appendix C – Inspection Programs

We examined the Risk-based Inspection Planning (RBIP) processes for the following programs:

- Cannabis, Tobacco and Controlled Substances Directorate (CTCSD) – Cannabis Program
- Cannabis, Tobacco and Controlled Substances Directorate (CTCSD) – Tobacco and Vaping Compliance and Enforcement Program
- Cannabis, Tobacco and Controlled Substances Directorate (CTCSD) – Controlled Substances Program
- Environmental Health, Consumer Products and Pesticides Directorate (EHCPPD) – Pesticides Compliance Program
- Environmental Health, Consumer Products and Pesticides Directorate (EHCPPD) Consumer Product Safety Program
- Health Product Compliance Directorate (HPCD) – Good Manufacturing Practices Program (Natural Health Products)
- Health Product Compliance Directorate (HPCD) – Good Manufacturing Practices Program (Drugs)
- Health Product Compliance Directorate (HPCD) – Health Product Compliance Verification Program (Drugs, Natural Health Products, Biocides)
- Health Product Compliance Directorate (HPCD) - Good Pharmacovigilance Practices Program (Drugs)
- Medical Devices and Clinical Compliance Directorate (MDCCD) - Medical Device Compliance Program
- Medical Devices and Clinical Compliance Directorate (MDCCD) - Border Operations Program
- Medical Devices and Clinical Compliance Directorate (MDCCD) - Health Product Border Compliance Program
- Medical Devices and Clinical Compliance Directorate (MDCCD) – Clinical Trial Compliance Program
- Medical Devices and Clinical Compliance Directorate (MDCCD) – Biological Product Compliance Program