

MANAGEMENT RESPONSE AND ACTION PLAN
Audit of Inspection Activities at Health Canada

Recommendations	Management Response and Planned Actions	Deliverable	Completion Date*	Accountability/ Responsibility
<p>Recommendation 1</p> <p>The Assistant Deputy Minister, Regulatory Operations and Enforcement Branch (ROEB), should continue efforts to finalize a C&E modernization plan under areas of ROEB mandate, and covering the 11 regulated product categories, that prioritizes initiatives and clearly identifies the deliverables, milestones, timelines, and resource requirements.</p>	Management agrees with the recommendation.			
	<p>Management will continue with its C&E modernization efforts and agrees that a modernization plan covering the 11 regulated product categories will enable ROEB to further articulate its goals, set priorities and coordinate work to modernize inspection programs under its mandate. Much progress has been made since 2016 when ROEB was created as a dedicated C&E branch to strengthen C&E oversight. Since then a national program delivery model has been implemented resulting in greater consistency; a five year Drug GMP Inspection Program transformation including implementing risk-based inspection planning was launched; risk based investments have been made to stabilize some inspection programs; modest investments have been made to allow some modernization of key functions like IT, data & analytics, training and occupational health and safety to begin; and ROEB launched a Strategic Plan to outline a vision for how the branch will continue to modernize the C&E approach. A</p>	<p>1.1 ROEB to establish a Framework to Implement C&E Transformation.</p>	<p>November 2019</p>	<p>DG, Planning and Operations, ROEB</p>
		<p>1.2 ROEB to establish a multi-year plan for C&E modernization that will include deliverables, performance indicators, timelines, and resource requirements.</p>	<p>September 2020</p>	<p>DG, Planning and Operations, ROEB</p>

MANAGEMENT RESPONSE AND ACTION PLAN
Audit of Inspection Activities at Health Canada

Recommendations	Management Response and Planned Actions	Deliverable	Completion Date*	Accountability/ Responsibility
	<p>process is now underway to develop a multi-year, comprehensive, modernization and transformation plan. In areas where ROEB's partner branches lead on C&E, they will be engaged in developing the plan (e.g., Cannabis, Controlled Substances, Consumer Products, Tobacco and Vaping).</p> <p>The ROEB's Strategic Plan has provided the high level direction for C&E modernization and transformation. A framework to implement C&E transformation (FICET) has been developed and will result in the Branch's C&E modernization plan for the 11 categories of regulated products overseen by ROEB's eight C&E programs. The Plan will include priority initiatives with set deliverables, performance indicators, and timelines to address the following six critical success factors needed for C&E modernization to be achieved:</p> <ul style="list-style-type: none"> • Regulatory Framework Development • Quality Management Systems 			

MANAGEMENT RESPONSE AND ACTION PLAN
Audit of Inspection Activities at Health Canada

Recommendations	Management Response and Planned Actions	Deliverable	Completion Date*	Accountability/ Responsibility
	<ul style="list-style-type: none"> • Training and Designations • IT Systems and Tools • Data Analytics Capability • Risk Management Tools 			
<p>Recommendation 2</p> <p>The Assistant Deputy Minister, Regulatory Operations and Enforcement Branch should ensure that the oversight of the C&E modernization plan is effective, and that monitoring and reporting mechanisms are enhanced.</p>	<p>Management agrees with the recommendation.</p>			
	<p>ROEB will use existing governance structures, and monitoring and reporting mechanisms to provide appropriate management oversight of the implementation of a comprehensive C&E modernization plan. In areas where ROEB’s partner branches lead on C&E, they will be engaged in monitoring progress to implement the plan (e.g Cannabis, Controlled Substances, Consumer Products, Tobacco and Vaping).</p> <p>ROEB’s existing Branch Executive Committee (BEC) will be responsible for providing overall governance and oversight for C&E modernization plan.</p> <p>As well, a monitoring framework will be established to monitor progress against the plan for each critical success factor.</p>	<p>2.1 ROEB to update existing governance structures’ TORs to provide oversight for the Plan.</p>	<p>March 2020</p>	<p>DG, Policy and Regulatory Strategies, ROEB</p>
		<p>2.1 ROEB to put in place Key Performance Indicators (KPIs) to measure the work to be done toward addressing each critical success factor.</p>	<p>November 2019</p>	<p>DG, Planning and Operations, ROEB</p>
		<p>2.3 Progress to implement the Plan will be monitored through semi-annual dashboard reporting.</p>	<p>August 2020 November 2020 – first dashboard with progress</p>	<p>DG, Planning and Operations, ROEB</p>

MANAGEMENT RESPONSE AND ACTION PLAN
Audit of Inspection Activities at Health Canada

Recommendations	Management Response and Planned Actions	Deliverable	Completion Date*	Accountability/ Responsibility
	Reporting on progress will be done through a branch-level dashboard.			
Recommendation 3 The Assistant Deputy Minister, Regulatory Operations and Enforcement Branch, should ensure that a C&E modernization plan for the inspection function includes specific action plans that address risk-based inspection planning, update IM/IT systems and tools, maintain current operating procedures, and provide appropriate training for inspectors.	Management agrees with the recommendation.			
	As part of its C&E modernization plan, ROEB will include specific action plans that address risk-based inspection planning, IM/IT systems and tools, operating procedures, and training for inspectors.	3.1 Key performance indicators that specify the expected level of achievement for each critical success factor to be approved.	November 2019	DG, Planning and Operations, ROEB
	Specific action plans to address the critical success factors for each of its eight C&E programs will be developed.	3.2 Baseline analysis that specifies how each of ROEB's eight C&E programs does or does not meet each critical success factor.	April 2020	DG, Planning and Operations, ROEB
	3.3 Action plans for the achievement of each critical success factor for each of ROEB's eight C&E programs. The action plans will outline the work to be done to address the six critical success factors, which align with the four areas highlighted in Recommendation 3 as follows: <ul style="list-style-type: none"> • Data analytics capability and risk management tools 	June 2021	DG, Planning and Operations, ROEB (accountable) ROEB DGs (responsible)	

MANAGEMENT RESPONSE AND ACTION PLAN
Audit of Inspection Activities at Health Canada

Recommendations	Management Response and Planned Actions	Deliverable	Completion Date*	Accountability/ Responsibility
		(“improve risk-based inspection planning”) <ul style="list-style-type: none"> • IT Systems and Tools (“update IM/IT systems and tools”) • Quality Management Systems (“maintain currency of operating procedures”) • Training for Designation (“provide appropriate training for inspectors”.) 		
Recommendation 4: The Assistant Deputy Minister, Regulatory Operations and Enforcement Branch, should consider how Sex and Gender-Based Analysis could be applied to inspection activities.	Management agrees with the recommendation.			
	ROEB currently provides awareness of SGBA+ to its employees. The Branch will assess SGBA+ applicability to inspection activities. The Branch is planning to provide employee training in SGBA+ concepts as part of a time-limited project, beginning in fall 2019.	4.1 ROEB to provide an analysis of whether SGBA+ related risk factors exist in the context of inspection activities, and assesses the need to develop mitigation and monitoring strategies.	June 2021	DG, Policy and Regulatory Strategies, ROEB
	ROEB will identify whether SGBA+ related risk factors exist in the context of inspections and assess the need to develop mitigation and monitoring strategies.	4.2 ROEB will perform a full review and update of the Tactical Communication and Interview Skills course intended for inspectors to reflect an SGBA+ lens. 4.3 Integration of an SGBA+ lens into Foundations of Inspections	June 2021 June 2021	DG, Policy and Regulatory Strategies, ROEB

MANAGEMENT RESPONSE AND ACTION PLAN
Audit of Inspection Activities at Health Canada

Recommendations	Management Response and Planned Actions	Deliverable	Completion Date*	Accountability/ Responsibility
	<p>ROEB will continue to update and modernize learning programs to reflect the SGBA+ lens in both format and content.</p> <p>ROEB will provide SGBA+ training to its staff, including key staff who inform training content, or who develop and deliver training.</p>	<p>and Regulations during next review cycle.</p> <p>4.4 ROEB to provide SGBA+ training to staff, specifically to facilitators, developers, and working group members who are involved in inspector training.</p>	June 2021	

***Rationale(s) for timeframe(s) requiring longer than one year for completion of a deliverable**

Deliverable #	Rationale
3.3	Completion date June 2021. This deliverable is part of the implementation of ROEB's Framework to Implement C&E transformation (FICET).