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**Management Response and Action Plan**  
**Audit of Regional Laboratory Activities**

**July 2016**

**Canada**

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Recommendations	Management Response and Planned Management Action	Deliverables	Expected Completion Date	Responsibility
<p><b>Recommendation 1</b></p> <p><i>It is recommended that the Assistant Deputy Minister, Regulatory Operations and Regions Branch, conduct an analysis on the feasibility of establishing a minimum sustainable capital budget for regional laboratory equipment.</i></p>	<p>Management agrees with this recommendation.</p> <p>Management recognizes that up-to-date equipment is important to provide essential quality and timely laboratory services in a constantly changing operating environment. The Regulatory Operations and Regions Branch (RORB) will work in partnership with the Chief Financial Officers Branch (CFOB) to examine the budgets and to seek recommendations on resource allocations to support establishing a sustainable capital investment budget.</p>			
	<p>As a part of the planning process for regional laboratory activities, RORB Laboratory Management has established a multi-year Capital Investment Plan and will engage CFOB to identify potential sustainable funding sources for laboratory equipment purchases. The laboratory equipment renewal and potential funding sources will be tabled at the Branch Executive Committee meeting for information.</p>	<p>1.1 Based on an analysis of historical internal funding, pressure lists and other financial triggers, RORB and CFOB to establish a funding amount for internal laboratory capital in RORB.</p>	<p>March 2017</p>	<p>Director General, Regional Laboratories, RORB, in partnership with CFOB</p>
	<p>Working with the DG Science Laboratory Equipment Committee (LEC), RORB will table its multi-year Capital Investment Plan for inclusion in the Departmental Laboratory Equipment Strategy, for consideration as a part of the annual department-wide equipment purchase process to</p>	<p>1.2 RORB to establish a three-year Laboratory Equipment Capital Investment Plan for regional laboratory equipment approved by RORB ADM.</p>		

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	supplement RORB's ADM-approved internal laboratory capital funding.	1.3 RORB's Laboratory Capital Equipment Plan will be prioritized and included in the Health Canada Laboratory Capital Equipment Three-Year Plan prepared by the Laboratory Equipment Committee, a sub-committee of DG-Science.		
<p><b>Recommendation 2</b></p> <p><i>It is recommended that the Assistant Deputy Minister, Regulatory Operations and Regions Branch, work with the Assistant Deputy Minister, Health Products and Food Branch, to establish the level of laboratory services needed from the regional laboratories to support the Food Program.</i></p>	<p>Management agrees with this recommendation.</p> <p>The management team in the new Regulatory Operations and Regions Branch (RORB) is in the process of analyzing its various programs and activities within the expanded mandate and will partner with the Health Products and Food Branch (HPFB) to establish consistent laboratory service requirements and to support future Food Program activities.</p>			

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	RORB will engage HPFB to establish the level of laboratory services needed to continue to support the Food Program's analytical needs.	2.1 Establishing the recurrent minimal level of laboratory services and resources required to support the Food Program.	December 2016	Director General, Laboratories, RORB, and DG, Food Directorate, HPFB
<p><b>Recommendation 3</b></p> <p><i>It is recommended that the Assistant Deputy Minister, Regulatory Operations and Regions Branch, ensure that a quality system be applied for each food project, including detailed quality assurance steps approved at the beginning of the project.</i></p>	Management agrees with the recommendation.			
	The RORB Food labs develop analytical methods and data of the appropriate quality for the purpose of decision-making and risk assessment by its clients. Building on the existing quality system processes, management will document an enhanced process supported by new and improved quality documents.			
	The Food laboratories design, implement and complete projects aligned with customer's requirements and within its Quality System. All methods developed, as well as supporting activities, are validated to appropriate quality standards.	3.1 Implement the list of quality assurance steps document as part of the Quality System.	October 2016	Director General, Laboratories, and Director, HPF Laboratories, RORB
Develop and establish a list of quality assurance steps for each project, including accountabilities and responsibilities, which will be approved at the beginning of a project.	3.2 Implement transition plan for existing projects	July 2016		
	Develop a transition plan for projects already underway, to ensure that quality assurance requirements are met.			