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Final Report

Audit of Regional Laboratory Activities

July 2016

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Executive Summary

The focus of the audit was on the Health Canada (HC) regional laboratory (lab) activities for the Drug Analysis Services, the Inspectorate analytical services and the Food Program. The salary and operating expenditures for these activities are approximately \$15 million.

The objective of the audit was to assess the effectiveness of the management control framework for the HC regional laboratory activities as it relates to governance, risk management and internal controls. The audit, covering fiscal years 2014-15 and 2015-16, was conducted in accordance with the Internal Auditing Standards for the Government of Canada and the International Standards for the Professional Practice of Internal Auditing.

During the course of the audit, the senior management structure overseeing the regional labs changed as part of the transition from the Regions and Programs Bureau (RAPB) to the Regulatory Operations and Regions Branch (RORB). This new structure for lab senior management formalized the previous functional reporting relationships and does not impact the conclusions reached in the audit.

Why are regional laboratory activities important?

The three lab clusters provide important services in support of the *Controlled Drugs and Substances Act* and the *Food and Drugs Act*. The Drug Analysis Services labs are Canada's sole provider of analyses of suspected controlled substances seized by all law enforcement agencies across Canada. The Inspectorate labs provide analytical services in support of inspections, investigations and surveillance activities for HC's national compliance and enforcement program. The results of the Food labs research projects contribute to the development of food safety standards, policies and regulations.

What was found?

The audit concluded that the regional labs have an effective management control framework. They are well-governed to support operations, and staff roles and responsibilities are clearly documented and communicated, with up-to-date standard operating procedures.

Management has a good understanding of the external and internal risks that may impact the achievement of objectives. The risks are documented and have suitable mitigation strategies.

Each lab has been accredited by the Standards Council of Canada, in accordance with the requirements of the International Standards Organization (ISO) for Testing and Calibration Laboratories. Moreover, the audit found evidence of chain of custody controls over samples from the time they are received through to testing and reporting on results. The chain of physical custody for samples was tested during the audit and found to be physically secure, tracked electronically using the Laboratory Information

Management System (LIMS) and hardcopies inserted in the files maintained at each location. The labs ensure integrity of testing by following recognized testing techniques that are performed by qualified chemists and biologists. Routine calibration and maintenance of equipment is ongoing and supports the integrity of the testing process.

The labs provide an important service to HC branches and external clients. In order to maintain timely and quality service, management has developed a mechanism to obtain feedback on the services provided. As well, management has developed monthly scorecards to communicate lab performance and assess compliance with service standards.

The audit found three areas that could be further strengthened. Since lab activities depend largely on the use of sophisticated equipment that has a defined useful life, the labs would benefit from permanent dedicated funding for equipment purchases. While all the regional labs have a quality assurance process in place, the Food labs would benefit from strengthening the quality system by identifying detailed quality assurance steps at the beginning of each project. As well, the audit found that to remain viable and relevant, the Food labs require a commitment on the volume and mix of projects and funding from the other branches on an annual basis to offset core expenses. The audit makes three recommendations to strengthen the internal controls related to the regional laboratory activities:

- Conduct an analysis on the feasibility of establishing a minimum sustainable capital budget for regional laboratory equipment;
- Establish the level of laboratory services needed to support the Food program; and
- Apply a quality system for each food project, including detailed quality assurance steps approved at the onset of the project.

Management agrees with the recommendations in this report and has provided an action plan that will further strengthen the management control framework supporting regional lab activities.

A - Introduction

1. Background

The Regions and Programs Bureau (RAPB) at Health Canada (HC) contributes to improving and maintaining the health of Canadians by effectively delivering regulatory, scientific and laboratory-based programs and services. The focus of this audit was on the laboratory-based programs and services that are delivered in eight regional laboratories (lab). In 2015-16, the regional labs employed 174 full-time equivalents (FTE) and had a budget of \$15.4 million. The regional labs are located in three cities across Canada: two in Burnaby, British Columbia; three in Longueuil, Quebec; and three in Scarborough, Ontario. The labs in each region are physically located in the same building, which provides opportunities to share controlled storage, waste disposal and other specialized facility services.

The three lab clusters provide important services in support of the *Controlled Drugs and Substances Act* and the *Food and Drugs Act*. The Drug Analysis Services (DAS) labs are Canada's sole provider of analyses of suspected controlled substances seized by all law enforcement agencies across Canada. The Inspectorate labs provide analytical services in support of inspections, investigations and surveillance activities for HC's national compliance and enforcement program. The results of the Food Program's research projects contribute to the development of food safety standards, policies and regulations.

Drug analysis services laboratories (\$7.7 million, 87 FTEs)

The primary role of the three DAS labs is to analyze, identify and in some instances determine the purity of drugs seized. Upon completion of the analysis, HC provides a Certificate of Analyst that can be used in court, and staff may also be called upon to provide expert testimony. Lab staff also assists law enforcement officers with the dismantling of clandestine labs and delivers training sessions to enforcement officers on the drug analysis services provided, including the protocols that must be followed when a sample is being submitted for analysis.

In 2015-16, the DAS labs across Canada analyzed 116,998 samples for the presence of a controlled substance, assisted in the dismantling of 30 clandestine labs and provided clients with 37 training sessions. As well, analysts provided expert testimony on the analysis and conclusions in 11 court cases.

User fees are not charged to law enforcement organizations for the services provided. The DAS lab activities are federally funded through the National Anti-Drug Strategy, a horizontal initiative involving 12 federal departments and agencies. Drug analysis performance data is submitted annually to support the National Anti-Drug Strategy. HC is also committed to the United Nations Drug Control Treaties. In that regard, DAS staff works with international partners to develop recommendations regarding appropriate and scientifically sound forensic procedures.

Inspectorate laboratories (\$3.3 million, 33 FTEs)

The two Inspectorate labs carry out chemical and microbiological analyses on a variety of health products, including pharmaceuticals, veterinary drugs, medical devices and natural health products. For example, inspectors working on both domestic and imported natural health products have routinely been referring products to the regional labs for content analysis. Test results found that more than half of the samples sent to the labs (64/117) were unsatisfactory and required HC to follow up with manufacturers ([Audit of the Management of the Natural Health Products Program](#), June 2015).

HC inspectors are the main clients for the Inspectorate labs. In 2015-16, the Inspectorate labs analyzed 545 samples.

Food laboratories (\$4.4 million, 54 FTEs)

The three Food labs support researchers across a number of HC branches by performing chemical and biological analysis to generate research data. The research projects are undertaken for the Health Products and Food Branch (HPFB), the Healthy Environments and Consumer Safety Branch (HECSB) and the First Nations and Inuit Health Branch (FNIHB). For example, chemical and microbiological analysis is undertaken on the nutritional components of food to detect residues of potentially health-damaging chemical substances, natural toxic substances and pathogenic bacteria (see [example](#)).

Chemical analyses are carried out in all three Food lab locations, while microbiological analyses are carried out only at the Longueuil location. In 2015-16, the Food labs worked on 14 food-specific research projects and 16 other analytical services projects. The number of samples analyzed in the course of each project varies in size, from fewer than 10 to over 2,000 samples. The annual budget for the Food labs includes salary funds, but the majority of the ongoing operating and maintenance costs are provided by other branches, based on the projects undertaken.

Soy in wheat flour

The Food Directorate initiated a two-year information and data gathering process to conduct a risk assessment on the issue of cross-contamination from using the same equipment for harvesting, transporting, storing and processing both soy and wheat.

The Food Directorate asked the Food labs to analyze 300 wheat flour samples for trace levels of soy.

Based in part on the data generated by the Food labs, HC issued a public allergy information notice on the cross-contamination issue. It determined that exposure is not likely to represent a health risk for individuals allergic to soy.

Organizational restructuring

Effective April 2016, the senior management structure overseeing the regional labs changed as part of the transition from the Regions and Programs Bureau (RAPB) to the Regulatory Operations and Regions Branch (RORB). The formal reporting for the labs was reorganized based on program clusters. The newly created position of Director, Drug Analysis Services (DAS) Laboratories, is responsible for the three DAS labs across the country. Likewise, the newly created position of Director, Health Products and Food Laboratories, is responsible for the two Inspectorate and three Food labs. These two directors report to the Director General, Laboratories.

This new structure for senior lab management formalized the previous functional reporting relationships and consolidated all the Inspectorate functions (inspectors, program and labs) under RORB.

2. Audit objective

The objective of the audit was to assess the effectiveness of the management control framework for the HC regional lab activities as it relates to governance, risk management and internal controls.

3. Audit scope

The audit covered the national coordination of activities in the delivery of HC's regional lab activities. Examination of lab activities included the 2014-15 and 2015-16 fiscal years. Regional site visits were carried out in Quebec, British Columbia and Ontario.

The scope of the audit did not include the financial aspects related to cost recovery for pharmaceuticals, veterinary drugs and medical device lab activities, as they were recently audited (see the [Audit of Cost Recovery of Health Products](#), June 2015).

4. Audit approach

The audit approach included a review of documentation such as committee terms of reference, records of decisions, standard operating procedures, risk registries and performance measures; testing of the compliance of lab activities to procedures; and interviews with key staff at headquarters and in the regions.

The audit criteria, outlined in [Appendix A](#), were mainly derived from the Office of the Comptroller General Internal Audit Sector's Audit Criteria Related to the Management Accountability Framework: A Tool for Internal Auditors (March 2011). The audit was conducted in accordance with the Government of Canada's *Policy on Internal Audit* and examined sufficient, relevant, reliable and useful evidence and obtained sufficient information and explanations to provide a reasonable level of assurance in support of the audit conclusion.

5. Statement of conformance

In the professional judgment of the Chief Audit Executive, sufficient and appropriate procedures were performed and evidence gathered to support the accuracy of the audit conclusion. The audit findings and conclusion are based on a comparison of the conditions that existed as of the date of the audit, against established criteria that were agreed upon with management. Further, the evidence was gathered in accordance with the Internal Auditing Standards for the Government of Canada and the International Standards for the Professional Practice of Internal Auditing. The audit conforms to the Internal Auditing Standards for the Government of Canada, as supported by the results of the quality assurance and improvement program.

B - Findings, recommendations and management responses

1. Governance

1.1 Governance

Audit criterion: The regional laboratories have an effective governance structure in place to support decision-making.

Appropriately governing and managing programs is important in order to achieve public service effectiveness and efficiency. The audit examined the governance structure that existed at the time of the audit, which included seven key committees. The committee structure is used to support the coordination and planning among the regions. In the case of the Inspectorate and Food laboratories (lab), the committees also provided a forum for ongoing inter-branch governance between the Regions and Programs Bureau (RAPB) and the Health Products and Food Branch (HPFB). For each committee, the audit found up-to-date terms of reference, including a list of approved committee members. Committee membership was found to be at the right authority level to allow for effective governance. An analysis of the records of decisions for the two fiscal years found that each committee is meeting as required and discussions and decisions are consistent with their mandates.

The **Branch Executive Committee (BEC)** is the most senior management committee for regional operations. As per the terms of reference, the committee is responsible for providing direction and oversight in the allocation, re-allocation and expenditure of resources, as well as for ensuring that the legislative, corporate, government-wide and other mandatory obligations and requirements are fulfilled. Membership includes the Senior Director General, regional directors general, executive directors, directors, the Senior Financial Officer, the Human Resources Advisor, the External Communications Executive and the Senior Advisor to the Director General.

The **Branch Executive Committee Sub-Committee on Laboratories** provides for the exchange of information to facilitate the collaboration and the coordination among the regions for activities and issues related to the labs. The sub-committee provides information, analyses and recommendations to BEC. Meetings are held monthly, as required by the terms of reference. Membership includes the Executive Director, DAS National and Laboratory Coordination, a second BEC member, regional directors, laboratory staff from British Columbia, Quebec and Ontario and the Senior Manager of Policy and Strategic Planning (DAS National and Laboratory Coordination).

Drug analysis services laboratories

The **DAS Management Committee** coordinates the operation of the three DAS labs, which includes reviewing processes, collaborating on common practices and transferring samples to meet service standards. The committee meets every two weeks, as per the terms of reference; membership is drawn from the DAS National and Laboratory Coordination (Executive Director,

National Quality Manager and Senior Manager of Policy and Strategic Planning) and the three DAS lab managers (British Columbia, Quebec and Ontario).

Inspectorate laboratories

The **Inspectorate Laboratory Strategic Management Table** is the decision-making body for the Inspectorate Laboratory Program on areas where both RAPB and HPFB have joint responsibility. The management table provides strategic direction on management priorities for the Inspectorate Laboratory Program. The meetings are held monthly, as required by the terms of reference; membership is drawn from the DAS National and Laboratory Coordination (Executive Director and Senior Manager of Policy and Strategic Planning), the Inspectorate (Executive Director, Risk Management and Laboratory Program Manager) and the regional directors, Laboratory Services (Quebec and Ontario).

The **Laboratory Program Management Committee** is the advisory committee to the Inspectorate Laboratory Strategic Management Table, providing advice and recommendations on emerging and strategic priorities. It is also a decision-making body for operational priorities and issues, to ensure consistent delivery of the Inspectorate Laboratory Program. Meetings are held biweekly, as required by the terms of reference; membership includes the laboratory managers, supervisors and specialists from the two Inspectorate labs and the HPFB Inspectorate Laboratory Program Manager, the Coordinator and the Quality Manager.

Food laboratories

The **Food Directorate/Regions and Programs Bureau Committee** is an inter-branch committee of the Food Directorate and RAPB. It addresses operations affecting both parties, including service delivery programs, planning, reporting and standards development. Discussions include regional food liaison activities, in addition to lab services. Meetings are held quarterly, as required by the terms of reference. Membership is drawn from the Food Directorate (Director General and Management Committee), all regions (regional directors, Laboratory Services and regional directors, Program and Policy Services) and the Executive Director, DAS National and Laboratory Coordination.

The **Food Laboratories Managers Committee** addresses operational issues and provides a forum for exchanging information and addressing operational issues. The committee reports to the BEC Sub-Committee on Laboratories. Meetings are held quarterly, as required by the terms of reference. Membership includes the Executive Director, DAS National and Laboratory Coordination, the Food laboratory managers and the Microbiology Laboratory supervisor.

In conclusion, the governance committees provide a venue for discussion, decision-making and the use of potential synergies through information sharing among similar labs across the country.

1.2 Roles and responsibilities

Audit criterion: Roles and responsibilities are documented and communicated.

The documentation and communication of roles and responsibilities within the labs are important, given the technical nature of the work. It is essential that management and personnel understand the roles and responsibilities and only undertake those tasks for which they are qualified.

The audit found a similar structure of roles and responsibilities in each of the labs across all the regions at both the management and operational levels. At the management level, the labs within each region were led by the Regional Director, Laboratories, who reported to the Regional Director General. Additionally, the Executive Director, DAS National and Laboratory Coordination, had functional authority over the operations and budgets for all regional labs.

Laboratory roles and responsibilities

At the operational level, each lab has a laboratory manager supported by specialists and analysts. The roles and responsibilities of each position in relation to various activities are documented in the Standard Operating Procedures and the Quality Manual.

The **laboratory managers** manage a lab unit that provides scientific and analytical services. They monitor adherence to national and regional quality standards and participate on national committees with other laboratory managers and client representatives. As well, each laboratory manager is responsible for allocating and managing financial and human resources, and reporting on performance against work plans and service standards. The manager's role in terms of releasing the test results varies by lab cluster. In the Inspectorate and Food labs, the laboratory manager approves the release of results to clients while in DAS labs, the specialist carries out this task.

The **quality assurance specialist** ensures that the quality system is implemented and followed. In that capacity, the quality assurance specialist:

- Develops and coordinates quality assurance activities;
- Provides guidance on quality issues;
- Develops and updates quality procedures;
- Assesses the ongoing performance of all elements of the quality system by planning and managing lab audits;
- Develops and implements a program of continuous improvement, based on client feedback and input from staff and managers, and undertakes corrective actions;
- Ensures that document and data systems support the quality manual; and
- Can recommend halting operations if a problem is identified.

Specialists are senior analysts who lead projects, provide training and technical support to staff and perform analyses involving highly sophisticated methodology and equipment. They assess the data, results and reports from the analysts, to ensure suitability for the client and conformity to quality standards. Specialists also participate in the development, assessment and application of the quality assurance program and in the development of new analytical methods.

Analysts participate in the development of analytical methods, undertake testing, generate analytical data and prepare working papers and technical reports. They participate in the development of and apply the quality assurance program, including performing lab audits. Analysts ensure the quality of their own work by:

- Maintaining accurate records;
- Monitoring the performance of equipment; and
- Providing recommendations on the unit's quality assurance program.

Analysts who are trained and assigned responsibilities for the maintenance of equipment are designated as “custodians” in the equipment maintenance databases.

In conclusion, based on file testing, interviews and an examination of the standard operating procedures and quality manual, the audit found that the regional labs have documented and communicated roles and responsibilities to ensure consistency and quality in the processes and procedures performed.

2. Risk management

2.1 Risk management

Audit criterion: Risks related to the management and delivery of laboratory activities are identified, assessed and managed.

A robust risk management process allows an entity to manage more effectively the impact of a risk event or to reduce the likelihood of the event taking place. Risk management information also helps support effective decision-making. In November 2014, an environmental scan was conducted of the regional lab clusters to review current and anticipated factors that may impact the labs. The environmental scan, which was updated in 2015-16, includes a summary of lab issues and details on how these issues are expected to impact the labs in either a positive or negative manner. The information collected in the environmental scan was used to develop a branch risk register.

The audit examined the 2014-15 and 2015-16 risk registers, in which [three key risks](#) were identified and assessed. The registries provide a description of the risks and how they are linked to the departmental mandate, various risk mitigation strategies and implementation timelines. The operational plan also identified the risks and mitigation strategies. While the management team has clearly identified risks and related mitigating strategies, they can further strengthen this good practice by identifying performance indicators to provide assurance that the

Key lab operating risks

1. Ability to achieve results compromised by outdated tools, business processes and service delivery models.
2. Ability to perform laboratory activities and respond to market innovation/adaptation compromised by a lack of sustainable source of funding for equipment and infrastructure, as well as by a lack of resources to fully implement capital investment plan purchases.
3. Ability to maintain program integrity and service delivery requirements while responding to increasing expectations and rapidly changing regional, national and global contexts.

selected risk mitigation strategies are having the desired effect on the individual risks. The management team currently produces monthly operating performance information which, along with other information and analysis, could be useful to monitor the impact of the mitigation strategies on the individual risks.

In conclusion, the regional lab risks have been identified, assessed and managed at the branch level.

3. Internal controls

3.1 Resource management

Audit criterion: Human and financial resources are effectively managed to coordinate nationally the delivery of laboratory activities.

It is important for management to have information and processes to support decision-making on resource allocations to each lab's activities. The audit examined how the regional labs allocated resources in fiscal years 2014-15 and 2015-16 and examined the impact of the resource allocation process on the ability of the labs to carry out their responsibilities.

National coordination

The audit found that across the regional labs, decisions on resource allocations for salaries and operating expenses are coordinated nationally through the office of the Executive Director, DAS National and Laboratory Coordination. The delivery of laboratory activities and workloads are coordinated nationally by lab programs. For example, the DAS managers confer weekly to compare the number of samples awaiting analysis with the available capacity. Based on this comparison, samples can be redistributed among the three labs to meet the service standards for timely processing. The Food lab managers coordinate the initial allocation of projects, based on specialization, expertise and available capacity, while the Inspectorate lab managers work with headquarters to track the allocation of samples for testing.

Once resources and workloads have been allocated, lab managers use the analysis of the management variance reporting to track financial expenditures in relation to the budget. A monthly scorecard covering all the labs is used to report and review progress towards meeting targets for key activities (see [Section 3.6](#)).

In conclusion, management has systems in place for the national coordination of the delivery of lab activities based on available human and financial resources.

Equipment budget

Lab activities depend on the use of sophisticated equipment that has a defined useful life. Management recognizes this need and has identified in its risk register that the ability to perform lab activities and respond to market innovation and adaptation without a sustainable source of funding for equipment and infrastructure needs to be risk-managed.

The regional labs have two processes to acquire equipment. The first is based on funds made available to the labs from surpluses identified annually within RAPB. Lab management reviews the equipment proposals received from each of the eight regional labs. The equipment proposals are prioritized based on a collective rating and ranking approach, with the highest ranked items within the available surplus being approved for purchase.

The second source of equipment funding is obtained from the HC annual surplus funds. Decisions on branch business cases for equipment purchases are made by the DG Science Laboratory Equipment Committee.

The audit found a process for prioritizing equipment purchases and notes that management reports equipment needs as being met; however, there is a risk that annual surpluses may not be available in the future to fund equipment purchases, resulting in the labs not having the required and up-to-date equipment to deliver the services.

Recommendation 1

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.

Management response

Management agrees with this recommendation.

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.

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.

Working with the DG Science Laboratory Equipment Committee, 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 supplement RORB's ADM-approved internal laboratory capital funding.

Long-term planning

When the three regional Food labs were transferred from the Food Directorate to RAPB in 2009-10, the transfer included salary funding for 54 FTEs and approximately \$100,000 for operating costs directly related to lab staff. The additional operating and maintenance costs for the lab facilities were to be covered by project funding transfers from the Food Directorate, in line with the projects that would be assigned to the regional Food labs. Management reports that over the last few years, the funding associated with the Food projects assigned by the Food Directorate to the regional Food labs has decreased from \$1.1 million in 2009-10 to \$210,000 in 2015-16.

To offset this decrease in the number of projects, the regional Food labs have promoted their expertise across HC and have obtained projects and associated funding transfers from the Healthy Environments and Consumer Safety Branch and the First Nations and Inuit Health Branch.

The combined funding from within RAPB and from project-specific transfers from other branches has been sufficient to cover project costs and general operating and maintenance costs (total of \$1.1 million in 2015-16). However, level of project funding is not guaranteed from year to year and sustaining core operating costs (approximately \$450,000) could become problematic without a full slate of projects.

In order to remain viable and relevant in the long term, the regional Food labs require greater clarity on the service needs of the Food Program as their primary client. With this information, the Food labs have a starting point to ensure that sufficient funding and capacity (employees, equipment and systems) are available to meet these needs.

Recommendation 2

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.

Management response

Management agrees with this recommendation.

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.

RORB will engage HPFB to establish the level of laboratory services needed to continue to support the Food Program's analytical needs.

3.2 Testing process

Audit criterion: The laboratories have implemented and follow procedures to ensure the chain of custody and the integrity of samples.

Chain of custody is a control mechanism that traces samples from the time they are received at the labs, through to when they are processed and returned to the client or destroyed. This mechanism is important to ensure the reliability of reported results. To verify the integrity of sample testing, the audit examined the use of reference samples, calibration and the maintenance of the equipment, as well as the quality assurance procedures outlined in the standard operating procedures. The audit also examined the physical security of the lab facilities as part of ensuring the integrity of the samples.

Drug analysis services laboratories

Chain of custody and integrity over the samples (exhibits) is crucial for the DAS labs, given that the results of their exhibit testing for the presence of controlled substances may become evidence in legal proceedings. The chain of custody of exhibit handling and the integrity of the analyses carried out by the DAS labs may therefore be scrutinized in court. The audit tested a random sample of 60 DAS files from the Scarborough and Burnaby labs.

Equipment calibration – Before the analysis of an exhibit is carried out, the equipment used for testing is calibrated. Calibration is important to ensure that the equipment is operating as expected in order to provide consistent and accurate readings. The calibration is done by injecting a known substance (referred to as reference standards or standard mix) into the equipment and checking to see if it is providing the expected results.

Blanks are used in each batch analyzed throughout the day, to ensure that the equipment is clean. The 60 DAS files reviewed all showed evidence that the assigned custodian(s) calibrated the equipment daily and used blanks at the time of testing.

Reference standards – Every exhibit goes through an extraction process where the laboratory analyst prepares the substance for testing. Once the exhibit is in a form that can be tested, its characteristics are assessed and compared against the known characteristics of controlled substances stored in a drug reference data library. To positively identify a controlled substance, the analyst must confirm a strong correlation between the characteristics of the exhibit and the characteristics in the drug reference data library. In some cases, more refined testing may be required to support the analyst's conclusion. The use of a drug reference standard was identified in all 60 DAS exhibits tested.

Chain of custody – Each of the 60 exhibits had chain of custody information entered into the Laboratory Information Management System (LIMS). This information included:

- The date the exhibit was received at exhibit control;
- The date it was entered into LIMS and the name of the exhibit control clerk who did so;
- The date it was transferred from exhibit control to an analyst, including name of analyst;

- The date it was sent back to exhibit control and the name of the exhibit control clerk who received it; and
- The date the exhibit was sent back to the client and the Canada Post tracking number or the date the exhibit was released for pick up by the client.

When an exhibit has been assigned to a specific analyst and it is not being processed in the lab, it is in exhibit control, where it is locked in a vault. In order to enter the exhibit control area, one must sign in and there must be an exhibit control clerk available at the desk. The audit compared chain of custody information from LIMS to the information contained in the permanent hardcopy files and no exceptions were noted.

When the exhibit envelope with the remaining amount of the substance is returned to the client by courier (Canada Post), the date and tracking number are recorded in LIMS. Of the 60 samples examined, the return of 43 samples could be confirmed either through the tracking number on the Canada Post website, signed confirmation of receipt by the client or the client picking up the exhibits. For the remaining 17 exhibits, the Canada Post tracking number was found in LIMS but could not be confirmed through the Canada Post website because the transactions were more than a year old.

Quality assurance – The conclusion of the DAS testing is reported using a standardized Certificate of Analyst (COA) for the controlled substance under the *Controlled Drugs and Substances Act* (CDSA) and an Analyst Report (AR) for the substances not controlled under CDSA. The COA and AR are legally binding documents that can be used as evidence in court. These reports contain the following information:

- Name of the client;
- Date the exhibit was received at the lab;
- Date the analyst took possession of the exhibit;
- Name of the analyst;
- Conclusion of the analysis done by the analyst; and
- Date the report was printed and signed by the analyst.

Prior to releasing the COA or AR to the client, a quality assurance process is conducted that includes a technical and administrative review. The technical review, which is done on a minimum of 25 percent of the exhibits in a batch, is usually completed by a Level 3 specialist. The technical review ensures that equipment printouts match the results recorded on the worksheets, that the information on the COA is accurate, and that the proper method and conclusions were carried out in the testing. If a technical review of any exhibit in the batch shows any error in the testing or an inaccurate recording of results on the worksheets, the analysis of the entire batch may then be repeated or all the exhibits may undergo a technical review.

The administrative review is conducted on all the exhibits to ensure that all of the necessary documentation is present, that pages are numbered correctly and that all signatures are present. Once the exhibit has gone through the quality assurance process, the exhibit control personnel will send the original exhibit envelope with any unused substance back to the client, with a signed copy of the COA. DAS keeps the signed original COA.

In conclusion, all 60 DAS files had evidence of equipment calibration, use of reference standards and blanks, a full report on the chain of custody and a sound quality assurance process.

Inspectorate laboratories

The integrity and chain of custody for Inspectorate lab samples are important because the results of analyses can lead to actions that have legal or commercial implications. The challenge that the Inspectorate labs face is that staff can be required to analyze the chemical composition of a wide range of products to determine the presence of steroids, controlled substances, prescription drugs or other substances. To ensure a conclusive determination of the contents of the sample, the Inspectorate labs always reach their conclusion using at least two different analytical methods.

The audit reviewed 10 files from the Scarborough Inspectorate lab. The samples selected varied in nature from natural health products to over-the-counter and prescription drugs.

Use of reference standards and blanks – Reference standards contain known quantities of the pure substances for which a batch is being tested; they are used in calibrating the testing equipment and analyzing the results. Blanks are used as part of the calibration process to detect contaminants in a batch that could contribute to imprecision and bias in the sample results. The audit found that the Scarborough lab had detailed standard operating procedures to follow for the various testing methods and that reference standards and blanks were used in equipment calibration, the quality assurance process and the analysis of the test results. The use of reference standards and blanks was found in each of the 10 samples tested.

Chain of custody – The Inspectorate samples are complex to test and unlike DAS testing, they may have more than one analyst carrying out the analysis, based on the range of testing methods needed. Transfers between the sample custodian and the analyst(s) are documented in the working paper file. The audit found that the chain of custody for each of the 10 samples tested was documented on the Record of Sample Receipt and Return Form and in LIMS.

Quality assurance – The audit testing confirmed that each completed file includes a Verification of Analytical Data and Records Form that was completed prior to final approval of the information and results by the laboratory manager. This verification includes a review of both the administrative information contained in the file and a review and confirmation that the approved methodology was used to complete the testing and that the data supports the analyst's conclusions. The names of the analyst who completed the analysis and the analyst who completed the verification are included in both LIMS and on the Verification of Analytical Data and Records Form that is retained in each file.

The process in the Inspectorate labs requires the laboratory manager to provide the final approval on all sample results. The secure reports function in LIMS is used to assist managers with this process. This feature allows the manager to verify that all the required quality assurance steps included in LIMS have been finalized. The manager also reviews documentation contained in the paper file prior to giving final approval on the results of the sample testing.

In conclusion, all 10 Inspectorate files sampled had evidence of equipment calibration, use of reference standards and blanks and a full report on the chain of custody, and followed the quality assurance process.

Food laboratories

Food lab analyses are conducted on a project basis rather than an individual sample basis. Thus, integrity and chain of custody were reviewed at the project level. Of the 10 HPFB Food Directorate projects completed in the Burnaby and Scarborough Food labs during the scope of the audit, four were selected for testing purposes.

Chain of custody – For the Food labs, chain of custody involves tracking and identifying individual samples from acquisition to the final reporting of test results. The audit found that the Food labs assigned a unique number to each sample as it was received and used this number to track the results through each step of the project, including the final report.

Method validation and use of controls – Testing at the Food labs is organized into projects, with the end result being a data set that the HC client can use for research or risk assessments purposes. There is no formal process for clients to define the testing they require, but the labs communicate with clients at the beginning and during individual projects and use information gathered during similar projects undertaken for the client in the past. Clients are often involved in reviewing the methodology and preliminary testing results, but their involvement is not formally documented.

The testing method used for each project is developed, validated and recorded in standard operating procedures (SOP) that are typically approved by the laboratory manager before testing begins. For one of the projects selected, the laboratory manager did not approve the methodology in the SOP formally until after the project was completed and the report was issued. However, the laboratory manager was involved in discussions with the laboratory specialist as the methodology was being developed and refined.

The testing methodology typically includes controls to ensure the integrity of the entire process. For instance, prior to the extraction and testing process, the analysts add a known amount of a substance (surrogate and internal standard) to each sample that acts similarly but can be identified separately from the substance being tested. By monitoring the levels and characteristics of the known substance through the extraction and testing process, insight is gained into the extent to which the substance being tested is being accurately captured and measured. Blanks, calibration samples, reference standards, quality control samples and duplicate samples in batches are used to confirm that the equipment used in testing is calibrated and performing properly over the run of all the batches in a project. These control samples can require 10% to 30% of the resources used in testing, such as supplies, staff time and equipment run time.

Quality assurance – Unlike the standardized quality assurance process that is followed in the DAS and Inspectorate labs, the Food labs do not have standardized quality assurance steps. Due to the variety of testing methodologies used in the Food labs, a one-size-fits-all review approach is not appropriate. However, the audit expected to find documented quality assurance steps specific to each project.

In the four projects reviewed, the audit noted that the plan for quality assurance steps were not identified and approved prior to the start of the testing phase of the project. In the execution of the quality assurance review during the project, the audit noted a lack of segregation of duties in three of the projects; project leaders were reviewing their own work rather than having a second staff member complete this review. In two of the projects, there was no documentary evidence of the details of the quality assurance steps completed and in a third project the quality assurance steps were only approved after the report was issued.

In conclusion, the audit found that the four Food projects included evidence of chain of custody, equipment calibration and use of controls within batches, such as reference standards, blanks and quality assurance measures. However, the quality assurance phase of each project could be strengthened by ensuring that detailed quality assurance steps are documented and approved at the beginning of the testing phase of each project.

Recommendation 3

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.

Management response

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.

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.

Develop a transition plan for projects already underway, to ensure that quality assurance requirements are met.

Equipment maintenance

The lab equipment is critical to generating reliable and accurate testing results from all the labs. Therefore, equipment maintenance is important. The audit found that all the labs have an SOP or maintenance schedule for each piece of equipment. As well, each piece of equipment is assigned

to a main custodian and back-up custodian(s) who are responsible for carrying out the maintenance of the equipment.

For the eight pieces of equipment tested within the DAS laboratory, all were maintained as per their respective SOP. The date, type of maintenance and name of the custodian were recorded in a binder kept beside the equipment.

Equipment testing within the Inspectorate lab included the review of six pieces of equipment. The review found that the maintenance of four pieces of equipment was up-to-date, as per their respective SOP. The remaining two were not fully maintained because they were not currently in use. The Inspectorate labs risk managed maintenance by delaying upkeep and related costs for equipment not currently in use. These pieces of equipment were clearly labelled as being out-of-service.

Thirteen pieces of equipment were tested in the Food labs. The review found that the maintenance of seven pieces was up-to-date, as per their respective SOP. The remaining six were not fully maintained because they were not required for a current project. The laboratory managers were risk managing the maintenance by delaying maintenance and related costs until the equipment was required for a project. These pieces of equipment were clearly labelled as being out-of-service.

The audit found that there was a maintenance plan for all pieces of equipment tested. The maintenance schedule was being followed for all equipment in active use.

Physical security

The physical security of the labs is an integral component of ensuring the integrity of the samples being analyzed, especially for the controlled substances received at DAS laboratories. Site visits were made to the Longueuil, Scarborough and Burnaby facilities. The audit found that all of the lab buildings have secured main entrance doors. Authorized staff is required to use swipe cards to enter and exit the building. Swipe cards also controlled access to the individual lab areas and DAS exhibit control.

The audit tested the accuracy of the access to the individual labs for a sample of 90 staff members and found no instances where lab staff had access to the facilities where they should not have been permitted or after they had left the organization. Of the 90 staff reviewed in the audit, 59 worked in DAS labs where this control is most important. Within the DAS and Inspectorate labs, each analyst has a secure locker to store samples in his or her possession. Within the Food labs, there are common areas for the analysts to securely store samples, including locked freezers. Based on the testing completed in the audit, no issues were identified with controls over physical security for the labs.

In conclusion, the audit found that the labs have developed and implemented internal controls to ensure accurate testing and support for reported results. These controls included chain of custody, testing protocols, equipment maintenance and the physical security of the labs. However, the

documentation of the quality assurance plan for each project completed by the Food labs should be improved.

3.3 Standards

Audit criterion: Regional laboratories have met and maintained the Standard Council of Canada's ISO standards.

Testing results from the regional labs are used in health research, product monitoring and criminal cases. To support the integrity of these results, it is important that lab activities comply with recognized standards for lab operations.

The ISO standard used by organizations that produce testing and calibration results is ISO 17025 General Requirements for the Competence of Testing and Calibration Laboratories. Labs that are accredited to this international standard have demonstrated that they are technically competent and able to produce precise and accurate test data. ISO 17025 is used by labs to develop their management system for quality, administrative and technical operations. Clients, regulatory authorities and accreditation bodies may also use the standard to confirm or recognize the competence of labs. As well as meeting the general requirements for ISO 17025, labs are accredited for standards related to their specific areas of testing, as shown in Table 1.

Table 1: Summary of Standards Accreditation

Laboratory Standards	Accreditation			
	ON/BC Food	QC Food	ON/BC/QC DAS	QC/ON Inspectorate
CAN-P-4E (ISO/IEC 17025): General Requirements for the Competence of Testing and Calibration Laboratories	✓	✓	✓	✓
CAN-P-1595:2011: Requirements for Accreditation of Laboratories Engaged in Test Method Development and Non-Routine Testing	✓	✓	N/A	N/A
CAN-P-1587: Requirements for the Accreditation of Agricultural Inputs, Food, Animal Health and Plant Protection Testing Laboratories	✓	✓	N/A	N/A
CAN-P-1585: Requirements for the Accreditation of Environmental Testing Laboratories	N/A	✓	N/A	N/A
CAN-P-1578: Guidelines for the Accreditation of Forensic Testing Laboratories	N/A	N/A	✓	N/A

To maintain the accreditation, each lab undergoes an audit once every two years, led by the Standards Council of Canada (SCC). For any issues identified in these audits, a plan to address the issue must be provided and approved by the SCC within 30 days and the resolution must be in place within 90 days. The present audit confirmed the accreditation of each of the eight labs on the SCC website.

In addition to the biennial audits by the SCC, the labs conduct annual peer review internal audits on the quality systems in each of the eight labs. These peer reviews are led by the lab's program quality manager, who is assisted by staff from another regional lab. The internal audits assess compliance with the ISO standards and the policies and procedures set out for each lab. These audits may identify instances where procedures are not in place to satisfy the standards or where activity within the audit scope did not comply with the procedures or the standards. Any issues identified in these peer reviewed internal audits must also have an action plan approved within 30 days and the resolution in place within 90 days.

In conclusion, the eight labs have met and maintained the requirements for ISO accreditation under the SCC standards.

3.4 Information management

Audit criterion: The information management system captures the required information confidentially and securely, as prescribed in the policies and procedures for the laboratories' activities.

It is important for the labs to have secure information management systems that support business activities by providing information to make operational and strategic decisions. Information related to DAS and Inspectorate lab activities are recorded in the Laboratory Information Management System (LIMS) and in hardcopy files. The Food labs have hardcopy files for each of the projects, along with individual databases for managing and sharing documents.

Drug analysis services laboratories

When exhibits are received by the DAS labs, only the name of the police officer or police unit is provided to identify the exhibit. To ensure confidentiality, the police do not provide information on the accused.

The DAS hardcopy files contain information that supports the conclusions of the testing. The hardcopy files also include the original signed Certificate of Analyst (COA) or Analyst Report (AR), the signed worksheets summarizing the testing details and evidence of quality assurance and supporting material such as equipment print-outs. All completed DAS working paper files are stored in a controlled-access room. All records are retained by the lab for a minimum of 15 years, after which they are destroyed.

DAS uses a LIMS database to manage the main information related to an exhibit and the results of the testing. This includes the exhibit identification information, key dates related to lab processing,

the names of staff who had a role in the analysis of the exhibit and the results and conclusion of testing.

The DAS LIMS has usernames and passwords to restrict access to the system and uses role profiles to ensure that users have an appropriate level of access to enter data or approve reports. The testing found that all users across Canada were current employees within DAS. Further testing of 25% of employees found that their access level within the DAS LIMS (role profile) was consistent with their position.

In addition, the DAS LIMS uses audit tables (detailed audit trails) that record any changes made to the database. The audit tables identify the name of the person who entered or changed the information, along with the date and the old and new value.

The DAS LIMS also has controls in place to prevent changes to a signed COA after it has been approved for release to client. Once the quality assurance process has been completed and exhibit control enters the return date into LIMS, the report on test results is locked down into authorized mode.

DAS also uses LIMS to create work flow batches for processing similar substances and priority levels. Extracts from LIMS are used to develop a scorecard reporting on the volumes of processing and adherence to the 60-day service standard.

Inspectorate laboratories

The Inspectorate hardcopy files contain the information that supports the conclusion of the testing. The hardcopy files include the approved methodology for testing, a copy of the Report of Analysis and supporting documents and proof of quality assurance reviews. These working paper files are kept under the control of the manager of each laboratory for at least 25 years and are stored in locked cabinets.

To ensure confidentiality, the Inspectorate labs have a procedure stating that users other than lab staff are required to sign a confidentiality agreement before being able to access Inspectorate files. This procedure was followed at the Scarborough facility before the auditors were provided access to the files.

The Inspectorate also uses a version of the LIMS database to enter the main information related to a sample and the results of the testing. Inspectors have access to the Inspectorate LIMS to enter the initial information on samples when they request testing. LIMS captures the following information:

- Sample identification information;
- The name of the inspector who requested testing;
- Key dates in lab processing;
- The names of staff who had a role in the analysis of the sample; and
- Testing results.

Similar to DAS, the Inspectorate LIMS has usernames and passwords to restrict access to the system and uses role profiles to ensure that users have an appropriate level of access to enter data or approve reports. The testing found that all users were current employees of the Inspectorate program or Inspectorate lab. Further testing compared a sample of employee positions with their access levels within the Inspectorate LIMS (role profile) and no exceptions were found.

The Inspectorate LIMS also contains audit trails that record any changes made to the database. The audit trail identifies the name of the person who entered or changed the information, along with the date and the old and new value. As well, the system has a secure report function that captures the status of various workflows as they are completed and approved. Once the test data and the final report of analysis have been reviewed and approved, a re-activation is required at the supervisory level to be able to modify data. The reactivation of a test causes an e-mail notification to be sent to the staff who performed or reviewed the original test.

Extracts from LIMS are used for reporting on volumes of processing and adherence to service standards.

Food laboratories

Unlike DAS and Inspectorate labs, the Food labs do not deal with investigations of specific samples that may lead to legal or commercial implications. The Food labs support clients' research projects by providing chemical and microbiological analysis services to build research data sets. Consequently, they manage their clients' unique data requirements for each project by using a systematic approach to capturing and storing information, rather than an information management system such as LIMS, which controls the workflow sample by sample.

Similar to DAS, samples received by the Food labs do not include personal or confidential information. Project files may include electronic spreadsheets, pictures of packaging, lab notebooks and hardcopy documents to support work completed, quality assurance reviews and the final report to the client. Secure databases and networks are used to store each project's electronic files. Access to add or change information in these documents is restricted to authorized lab staff. As set out in the SOP on information retention, hardcopy files are retained for 25 years.

In conclusion, the information management systems in the regional labs capture the required information confidentially and securely, as prescribed in the policies and procedures.

3.5 Client consultation

Audit criterion: Regional laboratories have an effective methodology to measure client satisfaction with the services provided.

Regular client feedback for a service provider such as the regional labs is an important tool to confirm client satisfaction and identify opportunities for improvement. Furthermore, information collected through client consultations can serve as a real-time warning system, giving management the opportunity to revise or adjust processes before more serious issues can arise.

To identify the client consultation methodology, the audit conducted interviews and reviewed procedures documented in the relevant SOPs. Evidence of the application of the methodology was found through samples of completed surveys and examples of national summaries.

Drug analysis services laboratories

The clients of the DAS labs include law enforcements officers (municipal, provincial and federal), the Canadian Border Services Agency and court prosecutors (if a case has to go to court).

To determine if they are meeting client needs, the DAS labs communicate at least annually with clients to get feedback. The feedback on lab analysis services is requested each year from a sample of clients, either through a formal survey or in face-to-face meetings. Surveys on clandestine lab dismantlement aid, training sessions and analyst testimony in court are sent to all the clients who received these services during the year. The results of this feedback are reviewed annually by the individual DAS lab and at the national level. The laboratory manager and the quality specialist in each lab ensure that any identified issues or concerns from the feedback are resolved as soon as possible. SOPs set out the overall requirements for client consultations and the actions to be taken when a client raises a concern regarding the services received from DAS.

Inspectorate laboratories

The quality manual for the Inspectorate labs documents the formal process used to gather, analyze, resolve and report on client feedback or complaints.

In the course of the work being carried out, the laboratory managers and their clients regularly discuss aspects or concerns with testing, such as expectations and timing. The labs send specific client feedback surveys for all special projects completed (for example, testing of teething rings for HECSB). General client feedback surveys on the lab services were sent to HC managers in the various inspection units (regions and headquarters) several years ago and again in March 2016.

Food laboratories

The Food labs regularly communicate with their clients to ensure that the testing work is being conducted in a manner that will meet the client's needs and that useful and timely information is being provided for each project. As the labs develop the testing methodology for a particular project, they may communicate with their client to ensure that any issues or concerns are resolved before the testing begins.

As set out in the SOP for client consultation, the Food labs seek formal feedback from clients by providing a survey at the conclusion of each project. The laboratory manager, the laboratory specialist and the quality assurance specialist review the feedback from clients to resolve any concerns and ultimately to improve the quality of work and to better meet client needs.

In conclusion, the regional labs regularly consult with their clients to measure client satisfaction with the services provided. Furthermore, the labs have formal processes in place to accept and resolve complaints.

3.6 Performance measurement

Audit criterion: Regional laboratories have performance measures designed to monitor outputs.

Performance measurement information is an integral part of any organization's internal controls. The information supports management's decision-making processes and can identify potential issues that may require mitigation measures prior to the emergence of more complex problems. The regional labs use performance information to measure the extent to which targets for activities have been achieved and to provide a variance analysis on actual performance compared with targets. It is essential that the appropriate performance measurement information include ongoing monitoring in terms of planned results, and that this information be used to support management's decision-making process.

Regional laboratory management contributes data to a national monthly scorecard used to communicate performance information to management and other interested parties. The information contained in the scorecard highlights the key metric that the labs use to manage their business. The scorecard works in conjunction with monthly financial data to provide timely information on progress in meeting their objectives.

The DAS scorecard records a number of performance metrics, including:

- The number and percentage of samples analyzed within performance standards (60 days or negotiated delivery date);
- The number of samples in the DAS vaults waiting to be tested;
- Client satisfaction information;
- The number of samples transferred among the three DAS labs to improve timeliness of testing; and
- Quarterly DAS lab highlights.

This level of information is valuable since it demonstrates how management works proactively to match workflows to resources in order to meet the performance standards and maintain client satisfaction.

The Inspectorate labs also use a scorecard to monitor monthly performance metrics to aid in management decision-making. The Inspectorate labs are different from the DAS labs in that they deal with significantly fewer samples; however, these samples are usually more complicated to analyze. Due to this key difference, the Inspectorate labs use hours to track their production on the scorecard, as opposed to the number of samples analyzed. The Inspectorate scorecard includes planned hours available per activity (e.g., human drugs, natural health products, veterinary drugs) compared with the actual hours used to process samples. The performance information also includes the number of samples completed and the average number of hours required by location to complete each sample. This level of detail helps management to decide if issues are arising at either Inspectorate lab location and if corrective action is required.

The Food lab activities are project-based. The Food labs establish quarterly milestones for each project and document how each project is progressing throughout the year. Notations are provided to explain variance from the plan for each project. The Food labs portion of the scorecard uses the red-yellow-green colour scheme to highlight possible issues with progress on a particular project.

In conclusion, the regional labs have measures that track performance and allow laboratory management to monitor their activities and outputs.

C - Conclusion

The audit concluded that the Health Canada regional laboratories (lab) have an effective management control framework.

The labs have a governance structure in place to support their operations and have documented and communicated the roles and responsibilities for all lab personnel. Management has identified the key risks that may impact the achievement of their work objectives and have developed mitigation strategies to address them.

The audit found that lab buildings and information management systems were secured through the use of access controls. Lab activities support the integrity of testing, ensure chain of custody and are subject to a quality assurance process. However, the Food labs could benefit from strengthening their quality system by identifying detailed quality assurance steps at the onset of each project.

While the labs have a strategy to evergreen the equipment holdings and have been able to purchase the equipment required in the last few years, they do not have a dedicated budget for these purchases. The funding model for the Food labs, although adequate during the scope of the audit, could lead to situations in the future where these labs do not have adequate operational budgets to cover all core expenses related to the ongoing operation of the labs.

The labs have a methodology in place to obtain feedback from clients to help them to continuously improve their services. As well, they have implemented service standards for the work they do, which are captured and monitored nationally using monthly scorecards.

The April 2016 restructuring of the senior management for the regional labs was part of the transition from the Regions and Program Bureau to the Regulatory Operations and Regions Branch. The change formalized the previous functional reporting relationships and does not impact the conclusions reached in the audit.

The areas for improvement that have been noted in this audit report will collectively strengthen the effectiveness of the management controls for the regional laboratories.

Appendix A – Lines of enquiry and criteria

Audit of Regional Laboratory Activities		
Criteria Title		Audit Criteria
Line of Enquiry 1: Governance		
1.1	Governance ¹	The regional laboratories have an effective governance structure in place to support decision-making.
1.2	Roles and responsibilities ¹	Roles and responsibilities are documented and communicated.
Line of Enquiry 2: Risk Management		
2.1	Risk management ¹	Risks related to the management and delivery of laboratory activities are identified, assessed and managed.
Line of Enquiry 3: Internal Controls		
3.1	Resource management ¹	Human and financial resources are effectively managed to coordinate nationally the delivery of laboratory activities.
3.2	Testing process ¹	The laboratories have implemented and follow procedures to ensure the chain of custody and the integrity of samples.
3.3	Standards ²	Regional laboratories have met and maintained the Standard Council of Canada's ISO standards.
3.4	Information management ^{1,3}	The information management system captures the required information confidentially and securely, as prescribed in the policies and procedures for the laboratories' activities.
3.5	Client consultation ¹	Regional laboratories have an effective methodology to measure client satisfaction with the services provided.
3.6	Performance measurement ¹	Regional laboratories have performance measures designed to monitor outputs.

¹ Office of the Comptroller General – Audit Criteria related to the Management Accountability Framework

² ISO 17025

³ Treasury Board *Policy on Government Security* (2012)

Appendix B – Scorecard

Audit of Regional Laboratory Activities					
Criteria	Rating			Conclusion	Rec #
	DAS	Inspectorate	Food		
Governance					
1.1 Governance				The regional laboratories have established an effective governance structure to oversee activities.	
1.2 Roles and responsibilities				Roles and responsibilities are documented and communicated.	
Risk Management					
2.1 Risk management				Risks related to the management and delivery of laboratory activities are identified, assessed and managed.	
Internal Controls					
3.1 Resource management					
- National coordination				Processes exist to coordinate nationally the delivery of laboratory activities, including the purchase of equipment.	
- Equipment budget				There is no established budget for ongoing equipment purchases.	1
- Long-term planning				The regional Food labs require greater clarity on the service needs of the Food Program as their primary client.	2
3.2 Testing process				The laboratories document and follow procedures to ensure chain of custody, integrity of samples and consistency in testing. However, the Food laboratories do not have clear documentation and approval of the quality verification process to be followed for each project.	3
3.3 Standards				All regional laboratories are accredited for their relevant Standard Council of Canada's ISO standards.	
3.4 Information management				The Laboratory Information Management System captures sample information and testing results in a confidential and secure manner.	
3.5 Client consultation				The regional laboratories have an effective methodology to measure client satisfaction with the services provided.	
3.6 Performance measurement				Performance (timeliness of processing, volumes) is measured and reported.	

Satisfactory	Needs Minor Improvement	Needs Moderate Improvement	Needs Improvement	Unsatisfactory	Unknown; Cannot Be Measured

Appendix C – List of acronyms

AR	-	Analyst Report
BEC	-	Branch Executive Committee
CA	-	Certificate of Analyst
CDSA	-	<i>Controlled Drugs and Substances Act</i>
DAS	-	Drug Analysis Services
DG	-	Director general
FNIHB	-	First Nations and Inuit Health Branch
FTE	-	Full-time equivalent
HC	-	Health Canada
HECSB	-	Healthy Environments and Consumer Safety Branch
HPFB	-	Health Products and Food Branch
ISO	-	International Standards Organization
Lab(s)	-	Laboratory (laboratories)
LIMS	-	Laboratory Information Management System
RAPB	-	Regions and Programs Bureau
RORB	-	Regulatory Operations and Regions Branch
SCC	-	Standards Council of Canada
SOP	-	Standard operating procedures