

**April 1999**

**Foreword and Main Points  
Other Audit Observations**



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# Report of the Auditor General to the House of Commons for April 1999

## Foreword

I am pleased to present the April volume of my 1999 Report. Bound with this Foreword are the Main Points of 10 separately issued chapters:

1. Correctional Service Canada – Reintegration of Offenders
2. Revenue Canada – Underground Economy Initiative
3. Statistics Canada – Managing the Quality of Statistics
4. Fisheries and Oceans – Managing Atlantic Shellfish in a Sustainable Manner
5. Collaborative Arrangements: Issues for the Federal Government
6. Human Resources Development Canada – Accountability for Shared Social Programs: National Child Benefit and Employability Assistance for People with Disabilities
7. The Atlantic Groundfish Strategy: Contributions and Grants
8. The Atlantic Groundfish Strategy: Follow-up
9. Management of Science and Technology Personnel: Follow-up
10. Indian and Northern Affairs Canada – Funding Arrangements for First Nations: Follow-up

The Main Points are followed by an audit observation on the roles of National Defence and Health Canada in the pre-licensing use of an anti-malarial drug. (Audit observations are specific matters that come to our attention during our financial and compliance audits of the Public Accounts of Canada and that we believe should be brought to Parliament's attention.)

In last December's "Matters of Special Importance – 1998" I noted that in moving from a traditional bureaucratic model to more flexible forms of management, the government needed to keep its focus on serving the public interest, achieving objectives, ensuring accountability and maintaining transparency. Directly or indirectly, the chapters in this volume touch on all of these issues.

In particular, we note that they are basic elements of collaborative arrangements. Given the government's increasing use of these arrangements to deliver services and programs, we have set out a framework for assessing them. We looked at two such arrangements that are still in their early stages, and have suggested some improvements that can be made now to head off potential problems in the future.

We also report on several issues that we have covered in previous reports. In some cases, the government has taken action to improve its performance and has made good progress. In other areas it still has some distance to go. The ability to build on lessons learned from past experience and from other jurisdictions emerges throughout the Report as a key factor in getting the most for the taxpayer's dollar.





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# Correctional Service Canada

## Reintegration of Offenders

### Chapter 1 – Main Points

**1.1** Correctional Service Canada has made a concerted effort to respond to our 1994 and 1996 observations concerning the management of its offender reintegration activities. However, there are some important areas that require further improvement.

**1.2** The Service is now moving in the right direction. It has recently implemented change initiatives in several areas. Among them, it has strengthened the ability of national headquarters to direct and co-ordinate offender reintegration activities Service-wide; implemented a major initiative to streamline its reintegration operations; achieved international recognition for some of its offender rehabilitation programs; and improved its ability to measure the results and performance of its reintegration activities.

**1.3** Progress notwithstanding, improvement is still needed in some key areas:

- more timely acquisition of official documents for initial offender assessment;
- more timely casework preparation to meet the offender's first parole date;
- a clear operational strategy for offender employment programs;
- better-quality offender reintegration reports for the National Parole Board; and
- improved adherence to national standards for frequency of contact with offenders in the community.

#### Background and other observations

**1.4** Correctional Service has as one of its main responsibilities the safe reintegration of offenders into the community. This entails assessing offender risk and needs; preparing the offender for release into the community; reassessing offender suitability for release and making a recommendation to the National Parole Board; and providing supervision and programs for offenders in the community until the end of the sentence.

**1.5** Overall spending on reintegration has risen by \$38 million (13 percent) over the past three fiscal years. Correctional Service Canada spends about \$329 million or 28 percent of its total expenditures for the reintegration of offenders.

**1.6** In 1997–98, there were 13,449 incarcerated offenders in federal institutions and 8,744 offenders in the community, most of whom were supervised by Correctional Service parole officers. Until recently, the proportions of federal offenders in institutions and under community supervision have remained fairly constant. However, in 1997–98, the number of offenders supervised in the community increased by about 500.

**1.7** Under the *Corrections and Conditional Release Act*, there are several different ways that an offender can be released into the community: day parole (six months prior to full parole); full parole (at one third of the sentence) and statutory release (after two thirds of the sentence). Some offenders will be detained until the end of their sentence.

**1.8** A recent change allows offenders serving their first federal sentence who have not been convicted of a violent crime or serious drug offence to be released on day parole at one sixth of their sentence (accelerated parole review).

**1.9** Our previous audit work, in 1994 and 1996, identified systemic weaknesses in the Service's management of reintegration activities. Those audits identified concerns in such areas as work standards, quality assurance procedures, performance information, implementing basic changes and learning from successes and failures. This chapter revisits those issues.

**1.10** As promised to the Public Accounts Committee in April 1998, we reviewed changes made by the Service to the custody rating scale and looked at whether the Service had implemented the new offender security reclassification instrument. We found that the changes to the custody rating scale reduced overrides with minimal impact on the number of escapes. The Service has just implemented a new reclassification instrument, as promised.

**1.11** In addition to their institutional security responsibilities, senior correctional officers still do not consistently perform their required offender reintegration duties, a necessary input to offender assessment reports to the National Parole Board. The Service has undertaken an initiative to address this issue.

**1.12** While the Service has developed a continuum of rehabilitation programs from the institution to the community, its ability to deliver these programs to offenders in the community falls short of current needs. Research indicates that many intervention programs that deal with offenders' criminogenic needs are more effective when delivered in the community.

**Correctional Service's responses to our recommendations are included in this chapter. The Service concurs with the recommendations made and its responses indicate its commitment to take the necessary corrective action.**



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# Revenue Canada

## Underground Economy Initiative

### Chapter 2 – Main Points

**2.1** Revenue Canada has reported that the tax impact (taxes resulting from enforcement actions) of its activities to address the underground economy was \$2.5 billion over five years; however, this includes the results of both regular ongoing enforcement programs and the Underground Economy Initiative. The actual tax impact attributable to the detection of unreported income by the 1,000 staff allocated to Initiative audit activities is much less than the \$500 million reported.

**2.2** It is difficult to assess the overall success of the Initiative in combatting the underground economy because the Department does not measure and report on the full range of Initiative activities and how they have changed taxpayer behaviour.

**2.3** Revenue Canada needs to assess the role that social marketing might play in making the public aware of the societal costs of unpaid taxes and in soliciting its support to combat the underground economy. Polls indicate that an alarming number of Canadians would be willing to participate in the underground economy. The Department also needs to strengthen the activities that promote voluntary compliance by businesses.

**2.4** The underground economy is a difficult and complex problem to solve and the size of the tax loss is significant. The problem requires continuous attention and sustained efforts from Revenue Canada and all Canadians.

#### **Background and other observations**

**2.5** The underground economy results in tax evasion and represents an estimated annual loss of federal and provincial tax revenues of \$12 billion. Tax evasion is not a victimless crime. It puts honest businesses at a competitive disadvantage and, in some cases, out of business. It also causes honest taxpayers to bear the tax load of those who cheat. If left unchecked, underground economy activity could lead to a loss of faith in the fairness of Canada's tax system.

**2.6** In 1993, Revenue Canada announced a new initiative to combat the underground economy by allocating 200 staff to its non-filers and non-registrants program and 1,000 staff to the audit of small businesses, where most of the underground economy activity exists. Thirty-five percent of the Department's audit staff for small and medium-sized businesses are now involved in the Underground Economy Initiative audit activities.

**2.7** The Initiative as planned was, in our view, a balanced approach to combatting tax evasion in the underground economy. It included activities to promote voluntary compliance in small businesses such as community visits and consultations with industry associations. As well, it involved other federal departments, provincial and municipal governments and private sector organizations in sharing information to better deal with the underground economy.

**2.8** The Department can improve its targeting of audits for the detection and reassessment of unreported income. As well, legislative opportunities exist to strengthen existing incentives to deter participation in the underground economy.

**Revenue Canada has agreed to take action to address our recommendations.**



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# Statistics Canada

## Managing the Quality of Statistics

### Chapter 3 – Main Points

**3.1** Statistics Canada is committed to producing statistics of high quality. It has put in place a wide range of systems and practices to build quality into its statistical programs and to maintain an environment that encourages a concern for quality throughout the organization. However, the quality of the statistics it produces needs to be better documented and reported both within and outside the Agency. The Agency needs to integrate its many quality-related systems and practices better and adopt a more disciplined approach to documentation.

**3.2** The Agency has employed a number of formal quality assessment mechanisms, but individual programs have not applied them consistently. We concluded that the mechanisms currently used do not, either individually or collectively, provide systematic, transparent information on the adequacy of quality management systems and practices in the Agency's statistical programs or on the quality that they actually achieve.

#### **Background and other observations**

**3.3** Statistics Canada is responsible for collecting, compiling, analyzing and publishing statistical information on the economic, social and general conditions of Canada and Canadians. The statistics that the Agency produces support the development, implementation and evaluation of policies, programs and decision making in all sectors. They help us make informed decisions about such matters as where to live, what careers to pursue and how to vote. The Agency is widely respected among its peers, and has an international reputation for independence, innovation and quality that is second to none.

**3.4** Rapid social, economic and other changes have heightened the demand for reliable, objective statistical information on a wide variety of issues. As the demand for and use of statistics grow, their quality becomes increasingly important. Statistics Canada has identified six characteristics that its systems and practices for managing quality need to address: relevance, accuracy, timeliness, accessibility, interpretability and coherence.

**3.5** The Agency carried out self-assessments of four major surveys for our audit. Each assessment reached a positive conclusion about the overall adequacy of quality management. The work was well planned and executed. We concluded that in three of the four surveys, the self-assessments provide reasonable assurance that quality management systems and practices are adequate. In the remaining case, however, we concluded that the weaknesses identified and the recommendations made are more important than the self-assessment suggests, and deserve the attention of senior management.

**3.6** While its policy on informing users of data quality and methodology is clear and well structured, the Agency's implementation of the policy is inconsistent. Consequently, users are not always appropriately informed of the strengths and limitations of statistics. We also noted that while the quality of statistics figures prominently in its commitments to Parliament for results, the Agency's most recent Performance Report, tabled in October 1998, provides only limited information on the quality of the statistics that it produced.

**Statistics Canada's responses to our recommendations are included in this chapter. The Agency either agrees to take action or notes that initiatives are under way in the case of six of the eight recommendations we make. In the remaining two cases, the Agency agrees with the intent of our recommendations and indicates that it will consider the issues further.**



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## Fisheries and Oceans

### Managing Atlantic Shellfish in a Sustainable Manner

#### Chapter 4 – Main Points

**4.1** In October 1997, we reported on problems associated with the Department's management of the Atlantic groundfish fisheries. In the current audit, we found that many of these problems also exist in the Department's management of the Atlantic shellfish fisheries. For example, we noted increases in harvesting capacity and the encouragement of increased fisher participation through open access licensing in the shellfish fisheries. In addition, we found weaknesses in the information used in making resource decisions, and gaps in monitoring, control and surveillance. The full impact of these problems is not obvious, as most shellfish fisheries are currently recording high landed values. However, in our view these are significant concerns that must be addressed to ensure that the shellfish fisheries are managed in a sustainable manner.

**4.2** The Department's decisions have a profound impact on those engaged in the fishing industry and the communities that rely on the income generated from the industry. The absence of a fisheries policy that fully reflects sustainability concepts means that decisions are made on an ad hoc and inconsistent basis rather than as part of an overall framework for achieving a sustainable fishery. An open and transparent process in which clearly articulated and consistently applied principles guide decision making would provide all stakeholders with assurance that their interests are considered and that the resource is protected over the long term.

**4.3** We observed resource use decisions that are not consistent with the Department's currently stated objectives for fisheries management. As we reported in October 1997, there is a need to have the government clarify fisheries objectives in legislation. The Department needs to move forward with the development of a sustainable fisheries framework that incorporates the interdependent factors — biological, economic and social — that affect the fishery.

#### Background and other observations

**4.4** In the 1990s, Atlantic Canada saw a virtual collapse of its commercial groundfish fishery (cod, haddock, pollock, halibut and various flatfish). In the same period, however, there was a general rise in the value of shellfish landings (lobster, scallop, snow crab and shrimp). In 1997, the landed value of all shellfish in Atlantic Canada was \$920 million, which represented 81 percent of the landed value of all fish landed in the region.

**4.5** The Department has stated in its key parliamentary accountability documents that its objective is conservation, or protecting the productive capacity of the natural resource that supports the fishery. It has also reported that it has an economic objective, but the expected results for this objective are not stated. The Department has indicated that it is not responsible or accountable for social outcomes. We found that most resource use decisions in the shellfish fisheries are heavily influenced by social and economic factors.

**4.6** The Department's "Fishery of the Future" strategy reflects objectives that include ensuring economically viable and self-reliant fisheries, over time. However, these objectives are not fully reflected in the Department's reporting to Parliament. We found resource use decisions in the shellfish fisheries that are inconsistent with the concept of an economically viable industry.

**4.7** Co-management, designed to increase industry's role, responsibility and accountability in fisheries management, is an important aspect of the Department's Fishery of the Future strategy. Participants assuming greater responsibility for their industry is an important element of sustainability. However, very little power sharing has actually occurred. In our opinion, there are weaknesses in the Department's current approach to co-management.

**4.8** The Department has recognized that there are weaknesses in the fisheries management framework in the existing *Fisheries Act*. However, amendments to deal with these weaknesses have not yet been re-introduced in the House of Commons.

**Fisheries and Oceans' responses to our recommendations are included in this chapter. The Department either agrees to take action or notes that initiatives are under way to address three of our four recommendations. The Department has not indicated an intention to take action at this time on our recommendation that addresses co-management.**



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# Collaborative Arrangements

## Issues for the Federal Government

### Chapter 5 – Main Points

**5.1** Collaborative arrangements are an alternative way — a potentially more innovative, cost-effective and efficient way — to deliver programs and services that traditionally have been provided by federal government departments and Crown corporations. In collaborative arrangements, the federal government, other levels of government and organizations in the private and voluntary sectors agree to share power and authority in decisions on program and service delivery.

**5.2** With the growing use of these arrangements, more taxpayer dollars are being spent and the risks need correspondingly more attention. The risks include arrangements set up poorly among the partners, limiting their chances for success; partners not meeting commitments; insufficient attention to protecting the public interest; insufficient transparency; and inadequate accountability.

**5.3** We believe that serving the public interest, effective accountability and greater transparency are basic elements of a framework for these arrangements, and we suggest questions that parliamentarians might wish to raise when assessing them.

#### Background and other observations

**5.4** In the desire for greater efficiency, it is very important that the federal government and its partners not lose sight of the public purpose behind the collaborative arrangement, and of the need to provide transparent, fair and equitable service to the public.

**5.5** Effective accountability is more complex in a collaborative arrangement. The federal government is accountable to Parliament for the use of federal funds and authorities, to its partners for keeping its commitments, and, with its partners, to the public for the results the arrangement produces. In our view, this shared accountability means that more parties are accountable and it in no way lessens the federal government's accountability for its own responsibilities in the arrangement.

**5.6** Delivering programs and services to the public through collaborative arrangements often requires more transparency than traditional delivery by a government department. Because partnerships are involved, it may be more difficult for citizens to know who is responsible. Consequently, the federal government needs to be as open as possible with information about agreements, decisions and results of the arrangements.

**5.7** The Treasury Board Secretariat has informed us that it intends to continue to provide advice and to develop guidance on collaborative arrangements for federal departments and agencies that will address many of the issues identified in this study.



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# Human Resources Development Canada — Accountability for Shared Social Programs

## National Child Benefit and Employability Assistance for People with Disabilities

### Chapter 6 – Main Points

#### National Child Benefit

**6.1** The National Child Benefit (NCB) represents a new form of collaborative arrangement between provinces (except Quebec) and territories and the federal government. A key challenge for all involved is to assure taxpayers that moneys are spent for the purposes intended, with due regard to economy and efficiency and with appropriate means to measure and report on effectiveness. Because there are many governments involved, it is also necessary to respect the jurisdictional competence of the different parties. As the NCB is implemented it is critical that, at a minimum, there be no less accountability because it is shared than if only one jurisdiction were involved.

#### Background and other observations

**6.2** The goal of the National Child Benefit is to reduce the depth of poverty among families with children and to increase parental attachment to the work force. The NCB involves no new law, contract, or contribution agreement, but rather an increased federal child tax benefit (the NCB supplement) for low-income families — about \$850 million in 1998, rising to \$1.7 billion by 2000. In turn, jurisdictions providing social assistance benefits to families may reduce their payments by the amount of the increased tax benefit. They have agreed to reinvest these savings in programs that have mutually agreed-upon objectives and that benefit poor families with children.

**6.3** One of the clear achievements of the negotiations leading to the NCB was the partners' agreement on the overall goals of both the federal and the provincial elements of the program. They also have committed to a new kind of joint accountability to the public. What is distinctive about this commitment is that no level of government is more responsible for reporting on the results than another. Each is accountable for the overall program.

**6.4** It will be a significant challenge in the first few years, before evaluation results are available, to demonstrate precisely how the National Child Benefit has contributed to reduced depth of poverty and increased employment among its recipients. In assessing progress, the NCB accountability report will also need to be clear about any trade-offs among goals and to discuss the implications. Otherwise, readers may expect that all goals can be achieved at the same time.

**6.5** There are potential gaps in the quality of financial and other information. The credibility of the accountability reports depends on the comparability, accuracy and verifiability of information from all parties — not only those who negotiated the arrangement (provinces, territories and the federal government) but also those who are responsible for designing and implementing only specific sub-programs (Ontario municipalities and First Nations). This is also a challenge for audit offices that serve the partners in this arrangement.

**6.6** We think the key ingredients in reporting the NCB's results to the public are transparency and adequacy of the information. This means:

- appropriate care is taken to ensure that the information is credible and, at least for financial information, subject to audit;
- data are adequate to determine if the program's overall goals are being achieved; and
- data are sufficiently comparable that outcomes of different provincial approaches can be compared.

It must also be clear whose responsibility it is to do all this, and who will provide assurance that it has been done. Moreover, those charged with the responsibility must have the capacity to undertake the task.

**The Department has said that this chapter will be of considerable assistance in its work to build an accountability regime for the NCB. Some issues are already being addressed. The remaining issues identified in this study will be raised by the federal government in its capacity as co-chair of the federal-provincial-territorial group working on the NCB.**

## **Employability Assistance for People with Disabilities**

**6.7** Employability Assistance for People with Disabilities (EAPD) is the other program to emerge from federal-provincial discussions in 1997–98 on the social union. The aim of this 50–50 cost-shared arrangement is to help people with disabilities overcome the barriers they face in the labour force. EAPD supports provincial and territorial programs and services ranging from programs that assist in the first steps toward developing skills to those that support a person at work so the person can keep working. Our interest in the program at this early juncture is that steps be taken to ensure that the information each partner will provide on its own expenditures and programs is credible, and permits comparisons of different approaches and assessments of the overall program's effectiveness.

### **Background and other observations**

**6.8** Each province has signed an agreement with the federal government. Taken together, the agreements illustrate several of the elements of a collaborative arrangement discussed in Chapter 5 of this Report. For instance, the governments agree to follow a co-ordinated, participative planning process and to evaluate program results.

**6.9** Human Resources Development Canada (HRDC) and provincial partners have set about to solve implementation issues in a collaborative fashion. For example, the provinces have committed to annual accountability to HRDC. However, so far there is no specific commitment to the format, substance, or timing of any overall annual report, nor are there specific goals or targets over any time frame. We recommend that HRDC prepare a brief overall annual report for EAPD, comparing activities, expenditures, program outputs and performance of the partners.

**6.10** The partners still have important work to do. When so many jurisdictions are involved, those with oversight and audit responsibilities face the challenge of helping to ensure that the quality of financial and performance reporting is maintained and enhanced.

**The Department has said that the case study will be useful in its work with provinces. It agrees in principle with the recommendation to produce an overall annual report on EAPD expenditures and performance. It pointed out that it will be important to note that EAPD is only one part of overall programming for people with disabilities.**



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# The Atlantic Groundfish Strategy

## Contributions and Grants

### Chapter 7 – Main Points

**7.1** We have little assurance that all contributions under The Atlantic Groundfish Strategy (TAGS) were used for their intended purposes. These were part of TAGS active labour adjustment measures managed by Human Resources Development Canada (HRDC).

**7.2** Most of the deficiencies noted in the audit relate to a lack of diligence in assessing project proposals and signing contribution agreements, as well as lack of monitoring by the Department.

**7.3** Many of the files contained no project proposals; in others, proposals were not sufficiently developed to allow proper assessment. Some agreements lacked complete information, included ineligible costs, or did not correspond to the measure under which the project was funded. There was little evidence of on-site monitoring visits to examine expense records.

#### **Background and other observations**

**7.4** The Atlantic Groundfish Strategy, in effect from 16 May 1994 to 29 August 1998, comprised measures to assist those affected by the groundfish moratorium. About \$150 million of the \$1.9 billion allocated to TAGS was spent on active labour adjustment measures such as training, mobility assistance, wage subsidies and employment bonuses.

**7.5** Those expenditures were not covered in our audit of The Atlantic Groundfish Strategy, reported in Chapter 16 of our October 1997 Report. Following the publication of that Report, the House of Commons Standing Committee on Fisheries and Oceans requested that we audit the expenditures.

**7.6** Our Office and the Internal Audit Bureau (IAB) of Human Resources Development Canada agreed that IAB would audit the grants and contributions made under TAGS. We closely monitored and reviewed that audit so we could rely on the findings for this chapter.

**7.7** TAGS had increased the caseload of officers by some 40,000 participants over a short period of time. This created pressure to identify, approve and contract for an unprecedented number of projects.

**7.8** Several contributions went to projects that were not clearly related to TAGS. More than half of the agreements were signed after projects had begun. Expenditures were reimbursed without supporting documentation for the claims. For more than half of the projects reviewed, there was no evidence that the files had been closed, although most of those projects had been completed more than two years earlier.

**Overall, Human Resources Development Canada agrees with the findings of the audit and recognizes that a number of important points and concerns are raised in the chapter. Actions undertaken to address the issues include the development of new policies and procedures, training for managers and staff and, in new initiatives, securing resources to ensure sufficient monitoring.**



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# The Atlantic Groundfish Strategy

## Follow-up

### Chapter 8 – Main Points

**8.1** We believe the government's efforts to implement the recommendations in our October 1997 Report Chapter 16 on The Atlantic Groundfish Strategy (TAGS) have been satisfactory.

**8.2** New fishery restructuring and adjustment measures are being implemented. In contrast to our observations of 1997, the eligibility criteria for the new measures are clear, logical and applicable. The accountability framework established for the measures corrects the shortcomings we had identified in TAGS: it clearly defines the responsibilities of the organizations involved, sets out an overall strategic plan and provides for a formal co-ordination mechanism.

#### **Background and other observations**

**8.3** The objective of TAGS (1994–98) was to restructure the fishery industry in Atlantic Canada to make it economically viable and environmentally sustainable.

**8.4** Close to \$1.9 billion was allocated to TAGS. Most of the funding was used to provide income support to the some 40,000 fishers and plant workers affected by the groundfish moratorium.

**8.5** In October 1997, we urged the government to carefully examine the impact of the decisions made under TAGS in order to benefit from the valuable lessons that could be learned.

**8.6** This follow-up examined progress to date in addressing our 1997 recommendations. Some of our observations in this chapter relate to TAGS and others to the Atlantic fishery restructuring and adjustment measures announced in June 1998.

**8.7** Human Resources Development Canada completed an evaluation of the labour adjustment component of TAGS. It also reviewed the duration of eligibility of TAGS participants. The departments involved in implementing the new measures now have considerable information on the profile of the targeted populations, in sharp contrast to the situation that prevailed when TAGS was developed.

**8.8** We believe the orderly way in which the departments are implementing the new fishery restructuring and adjustment measures represents satisfactory progress.



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# Management of Science and Technology Personnel

## Follow-up

### Chapter 9 – Main Points

**9.1** We are satisfied with the efforts made by the science and technology community to follow up on our audit recommendations of 1994 and the concerns we raised in our 1996 follow-up report. In our view, the community is showing leadership and perseverance in dealing with the human resource management issues we raised.

**9.2** As a result of all the work done since 1994, the science and technology community is now in a position to act. But the community is faced with considerable challenges. It must give priority to resolving the oncoming changes in its demographic profile that could weaken or compromise the government's science and technology capacity. It must tackle the dual challenges of attracting and recruiting promising young scientists and technologists while retaining high-calibre employees to mentor and develop the new recruits. The community is thus seeking new measures, tools and resources for external recruitment, as it estimates that over the next five years it may have to recruit between 2,500 and 3,300 employees to build a renewed and rejuvenated science and technology work force.

#### Background and other observations

**9.3** At 31 March 1998, the federal government had close to 20,000 scientific and technical employees working in science-based departments, agencies, Crown corporations and research establishments in the fields of natural sciences and engineering (hereinafter referred to as the "science and technology community").

**9.4** The science and technology community makes an important contribution to the government's 1996 science and technology strategy, which focusses on sustainable job creation and economic growth, improved quality of life and the advancement of knowledge.

**9.5** Expenditure and work force reduction in the public service has changed the profile of the science and technology community and worsened the long-identified problems of rejuvenation and recruitment. The change in the age profile is a major challenge to the future of the community. Not only have most senior and experienced scientists and technologists left the government since 1994, but the youngest and most promising as well.

**9.6** Following our 1994 audit of federal science and technology activities, the community mobilized to develop a management framework and a results-oriented plan for human resources management in science and technology. It addressed such issues as the need for a more strategic approach to the management of scientific personnel; for more systematic renewal of scientific personnel; and for more effort to maintain the skills and knowledge base in research establishments. Working groups were created to study important human resource issues. Among their recommendations to the Science and Technology Senior Steering Committee on Human Resources was that new mechanisms be adopted and human resource strategies developed to improve the management of science and technology personnel in science-based departments and agencies.

**9.7** In 1994, we pointed out the need to develop a stronger and more effective management capability. Since then, the community has developed a competency profile for science and technology managers. During our consultations, we noted that most science-based departments used their own competency profiles instead of the one developed by the working group. Moreover, their profiles were being used solely to identify training needs and generally not for purposes of manager recruitment, promotion or performance assessment. Present practices suggest a lack of consensus in the community on the management competency profile defined by the working group. This could eventually prevent the integration of recruitment and training activities as well as the reward, promotion and compensation systems envisioned in the *Science and Technology Blueprint for Human Resources Management*.

**9.8** The Treasury Board Secretariat, science-based departments and agencies and the science and technology community have indicated that they are committed to following through on the strategies and plans developed to date.



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# Indian and Northern Affairs Canada

## Funding Arrangements for First Nations: Follow-up

### Chapter 10 – Main Points

**10.1** Indian and Northern Affairs Canada still needs to better match the level of flexibility attached to funding arrangements with the willingness and ability of First Nations to assume responsibility for billions of dollars they receive annually through the Department.

**10.2** The Department is not taking adequate steps to ensure that allegations of wrongdoing, including complaints and disputes related to funding arrangements, are appropriately resolved. Redress (resolution mechanisms) needs to be improved as an element of accountability.

**10.3** The Department has stated that it has slowed the rate at which the Financial Transfer Arrangement (FTA), a new type of funding arrangement, is being implemented in order to address issues concerning the willingness and ability of First Nations to adopt it. The Department still has a long way to go if it wishes to achieve its objective of implementing the FTA as the appropriate funding mechanism to replace other types of funding arrangements. It will need to find ways to expedite the conversion process while improving co-ordination of funding with other federal departments.

#### Background and other observations

**10.4** Funding arrangements are a key element in the relationship between First Nations and the federal government. Parliament appropriates about \$4 billion annually to Indian and Northern Affairs Canada to fund several programs for First Nations communities. The programs include social assistance, education, capital facilities, housing, and economic development for approximately 600 First Nations and other Aboriginal groups.

**10.5** In our November 1996 Report, we made recommendations relating to funding arrangements, including the FTA, and to the co-ordination of funding across federal departments. We also made recommendations on accountability issues and on the suitability of funding arrangements for the needs of the Department and First Nations.

**10.6** This follow-up focusses on the Department's implementation of our 1996 recommendations.

**The Department believes that with respect to redress, the follow-up extends beyond the issues raised in 1996; however, it has acknowledged that continuing effort is needed to improve certain aspects of funding arrangements, including accountability.**

# **Other Audit Observations**

**National Defence and  
Health Canada**



## National Defence and Health Canada

### Non-compliance with conditions and inadequate monitoring with respect to the pre-licensing use of an anti-malarial drug

*National Defence participated in a clinical trial of an anti-malarial drug, but did not follow the study protocol when the drug was administered to Canadian Forces personnel deployed to Somalia. Despite a requirement in the protocol to do so, the Department did not obtain consent from the personnel who received the drug, did not systematically monitor for efficacy, and did not provide to the study sponsor records of the drug's administration or reports of adverse reactions to the drug.*

*Once Health Canada approved the conditions for the clinical trial of the drug, it made no attempt to monitor the study to ensure that the trial was adhering to the protocol with its reporting requirements and procedures to protect patients' well-being.*

*Health Canada is responsible for the regulation and licensing of drugs in Canada. An unlicensed drug may be made available only through special measures, such as a clinical trial when Health Canada has approved the study design and protocol for testing the drug. Some studies test the drug in "real world" conditions and are thus a potentially valuable source of information about adverse drug reactions among specific populations, efficacy problems in certain environments, and so on.*

#### Background

1. Health Canada licenses manufacturers to produce and sell drugs that have been demonstrated to be safe and effective. Only licensed drugs can be sold in Canada, except under specific, controlled conditions. For example, an unlicensed drug may be available through the Special Access Program (whereby Health Canada approves the sale of the drug for a specific patient), or through a "clinical trial", which tests the drug to obtain evidence on its safety, dosage and effectiveness. A clinical trial is conducted under the direction and control of a sponsor (usually the manufacturer), but the study design and protocol must be approved by Health Canada. Once it has approved the protocol and received information about the investigators appointed by the sponsor, the sponsor is responsible for conducting the study and ensuring that the investigators follow the protocol. The sponsor is obligated to inform Health Canada of any serious adverse reactions (other than those already identified) or deaths associated with the drug.

2. As they travel throughout the world and are involved in hostile situations, Canadian Forces members are sometimes exposed to health hazards for which licensed drugs or other protective measures are not available in Canada. These may include diseases, such as malaria, that are not common in Canada or health hazards associated with hostile actions such as biological warfare. As a result, National Defence must sometimes obtain drugs or vaccines through special measures.

3. Canadian Forces members may be subject to discipline under the *National Defence Act* if they refuse to submit to a treatment, drug or vaccine when ordered to do so. National Defence officials told us that it is policy not to seek written, informed consent when preventive drugs or vaccines are prescribed for Canadian Forces members during deployments, since such consent is often not compatible with operational requirements.

4. Mefloquine is an anti-malarial drug that is recommended by the World Health Organization and others for use

against some types of malaria that have become resistant to other drugs. Although licensed in a number of countries since the late 1980s, it was not licensed in Canada until 1993 and in 1992 was available to National Defence only through a Safety Monitoring Study. Use of the drug was conditional on satisfying the requirements of the protocol for the study, including obtaining informed consent.

5. From November 1990 to early 1993, mefloquine was available in Canada only through an “open label, compassionate access” clinical trial called a Safety Monitoring Study, under the sponsorship of the drug’s manufacturer. The objectives of the study were:

- to ensure that the Canadian public travelling to regions where chloroquine-resistant malaria was present had access to mefloquine under controlled conditions; and
- to collect safety data on those travellers.

6. The study was carried out under the direction of 21 principal investigators, who were medical doctors in travel clinics across Canada. The study protocol specified the investigators’ responsibilities, including keeping accurate records on dispensing and reporting all adverse drug reactions. It stipulated that informed consent was to be obtained from all participants and specified that “safety data will be collected and efficacy will be monitored for each subject receiving [mefloquine]”. All data and records were to be provided regularly to the sponsor (the manufacturer).

7. National Defence participated in the study beginning in March 1991, with a physician at an Ottawa hospital as a principal investigator and a Department physician as a co-investigator.

## Issues

### **National Defence did not consistently follow the protocol for the Mefloquine Safety Monitoring Study**

8. From 1991 to July 1992, 96 National Defence officials travelling to Cambodia and Africa were given mefloquine under the provisions of the Safety Monitoring Study. The Department kept records of all but 362 of the 3,500 mefloquine tablets dispensed; obtained consent forms from the travellers; and reported to the study sponsor on the frequency of adverse effects.

9. However, National Defence did not follow the protocol in the fall and winter of 1992–93, when mefloquine was dispensed to approximately 900 Canadian Forces members before they left for Somalia and while there. It did not provide the manufacturer with records of the drug’s distribution, nor did it obtain the consent of those receiving the drug, which was not licensed. Canadian Forces members were given an oral briefing on malaria, mefloquine, and the possible side effects, but did not get the written documentation given to other Department travellers who received the drug. Further, even though all supplies of the drug used by National Defence were labelled “for investigational use only”, the Department did not systematically monitor efficacy or adverse reactions for each person receiving the drug, as required by the study protocol. It relied instead on a disease surveillance system and a periodic report of activities to provide any indication of side effects or other problems with mefloquine.

10. The manufacturer had identified a number of side effects of the drug for which patients were to be monitored, including gastrointestinal, central nervous system and psychiatric disorders. (While severe side effects were rare, mefloquine was not prescribed for pilots or others in occupations “requiring fine co-ordination and spatial discrimination, where the

sudden onset of dizziness/vertigo can be hazardous or life-threatening".) Although 69,000 doses of mefloquine had been provided to the Canadian Forces medical unit in Petawawa in September and October of 1992, information on their use and on adverse reactions or side effects was not reported. Thus, neither the manufacturer nor Health Canada benefited from information that might have been obtained about safety and efficacy of mefloquine.

**11.** National Defence officials told us they did not follow the protocol because they believed at the time that they had received authorization from Health Canada to follow a different set of procedures that would not require informed consent. However, no such authorization was obtained, nor have we been provided with any evidence that such authority was sought, or even discussed in National Defence, with Health Canada or with the manufacturer. National Defence attributes this confusion to a lack of communication between two of its directorates.

**12.** In an attempt to minimize the likelihood of non-compliance with the *Food and Drugs Act* and Regulations, in July 1998 National Defence established a position with responsibility for all regulatory issues relating to unlicensed medical products. This position serves as a single point of contact between the Department and Health Canada's Health Protection Branch.

**Health Canada took no steps to ensure the mefloquine study protocol was followed by National Defence**

**13.** Health Canada officials told us that although they had approved the protocol for the Mefloquine Safety Monitoring Study, they took no steps to ensure that it was followed. They said that monitoring the conduct of the study was

the responsibility of the manufacturer, as the sponsor of the study.

**14.** Health Canada has the right, under the Food and Drug Regulations, to request copies of the records of a study and to terminate the study if it believes it is not being conducted properly. However, it has no procedures for monitoring the conduct of these studies or clinical trials.

**15.** We found that National Defence was not the only participant in the study who failed to provide the manufacturer with information about patients and the dispensing records of the drug. The manufacturer's final report on the study (April 1993), which included the results reported by all 21 principal investigators, stated that the inability to obtain the actual number of patients receiving mefloquine made it necessary to estimate the number on the basis of pills dispensed. The report noted that:

- 501,424 pills had been shipped to all investigators in the study but there were records for only 331,695 (66.2 percent); and
- there were an estimated 38,747 patients, but records for only 25,235 (65.1 percent).

**16.** Mefloquine has been available in the U.S. and Europe since the late 1980s, and was licensed in Canada in January 1993, and available on the Canadian market in March 1993. However, not until October 1994, when the use of the drug by Canadian soldiers in Somalia became an issue in the media, did Health Canada ask the manufacturer for copies of the records on the 69,000 doses of mefloquine provided to National Defence in 1992. The manufacturer did not have any such records, although the study protocol called for them to be provided to the manufacturer every six months; it passed the request on to National Defence. When the Department could not provide the information, Health Canada took no action.

## Conclusion

17. National Defence did not consistently keep essential records or follow required procedures to fulfil its obligations as a participant in a clinical study of an unlicensed drug. As a consequence, the integrity of the Mefloquine Safety Monitoring Study may have been compromised and potentially valuable information about the safety or efficacy of the drug under “field” conditions was not gathered. We have noted that, as a result of this situation, National Defence has implemented measures to increase monitoring and improve documentation when using unlicensed medical products.

18. Where unlicensed drugs are dispensed through clinical trials, Health Canada has the responsibility to review and approve the trial design and protocol. It needs to assure itself that the conditions of clinical trial protocols are met in order to preserve the integrity of the process and to satisfy conditions set out under the Food and Drug Regulations. “Open label” trials provide an opportunity to test the safety and efficacy of drugs in “real world” situations and thus to identify potential hazards or problems that may not surface under laboratory conditions. They

represent a potentially valuable source of information about the drug and its use.

***National Defence’s response:** Despite the shortcomings identified in this audit observation, cases of potentially lethal malaria were prevented and the health and safety of Canadian Forces personnel were not compromised. At the time of the Somalia deployment, mefloquine was already licensed in 29 countries, including the United States, and the drug had an established record of safety and efficacy. This record is further supported by the recommendations of the World Health Organization and by Health Canada’s granting of a Canadian licence in January of 1993, which coincided with the arrival of the main body of Canadian troops in Somalia.*

***Health Canada’s response:** It is Health Canada’s policy that the monitoring of study protocols rests with the sponsor of the clinical trial (usually the manufacturer), as well as associated institutional research ethics boards, and data safety monitoring committees. Physicians conducting clinical trials do so under provincial/territorial jurisdiction and processes are in place to monitor the compliance of medical professionals with established practice protocols.*

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