Chapter 24

Federal Health and Safety Regulatory Programs

Table of Contents

Federal Health and Safety Regulatory Programs

Main Points

24.1 The overall objective of health and safety regulatory programs is to proactively protect Canadians from risks to health and safety — to catch the problem before it happens, and if it happens, to minimize the consequences.

24.2 The Canadian Food Inspection Agency, Health Canada, Environment Canada, Transport Canada, the Canadian Nuclear Safety Commission and the National Energy Board administer major federal health and safety regulatory programs. We estimate that in 1999–2000 the regulatory programs administered by these organizations spent about $1.2 billion and employed some 12,000 people. They administer about 85 Acts and 250 regulations. Their objectives range from controlling toxic chemicals to maintaining the safety of food, drugs and nuclear power plants.

24.3 The objective of the government's regulatory policy is to promote the design and implementation of effective regulatory programs. Because performance measurement is weak, there is insufficient information to assess the cost effectiveness of health and safety regulatory programs.

24.4 Over the past decade, our audits of federal health and safety regulatory programs have found many instances where the regulatory authorities have not met the expectations of the government's regulatory policy. While effectiveness cannot be judged solely on the basis of adherence or lack of adherence to the policy, well structured programs increase cost effectiveness and reduce the risk of regulatory failure.

24.5 Improving the structure and implementation of federal health and safety programs will require action government-wide and by the responsible regulatory authorities. In particular, we emphasize the need to ensure the following:

- the government explains to Canadians and the federal regulatory and inspection community the priorities for health and safety regulatory programs, particularly the balance the government has reached between the objective of protecting Canadians, addressing budget concerns and meeting economic objectives;

- reliable information is available on the level of risk and the extent to which it is and can be controlled;

- based on priorities determined by risk assessment, regulatory authorities have sufficient financial and human resources;

- the government identifies major health and safety objectives that can only be achieved through interdepartmental co-operation, and authorities assess officials on the achievement of these objectives; and

- the government annually submits reports to Parliament on the overall effectiveness of health and safety regulatory programs, including reports by lead regulatory authorities on the achievement of objectives that require significant interdepartmental co-operation.

Background and other observations

24.6   We undertook this audit to identify the following:

- major trends and challenges faced by health and safety regulatory authorities;

- patterns of recurring strengths and weaknesses in structure and implementation; and

- measures that could be taken to make significant improvements in the structure and implementation of regulatory programs.

24.7   We used key elements of the government's regulatory policy as a basis for organizing information on patterns of strengths and weaknesses. Our findings are based on the results of our current audits of food inspection programs, nuclear power plant regulation, the regulatory regime for biologics of Health Canada, and follow-up audits of animal health and plant protection, safety regulation for the air navigation system of Transport Canada, and onshore pipeline regulation. They are also based on audit findings from previous Reports of the Auditor General and the Commissioner of the Environment and Sustainable Development. As well, we have taken into account the findings of parliamentary committees, government reports and reports of non-government organizations.

24.8   Canadians are concerned about health and safety risks. Crises or regulatory failures heighten these concerns. However, the government cannot eliminate all risks. Canadians need to be provided with understandable information on health and safety risks and consulted on the choices to be made.

24.9   The public's confidence in the government's use of science and technology to protect the health and safety of Canadians has been shaken by recent crises, for example, the concerns about the safety of the blood supply reviewed by the Commission of Inquiry on the Blood System in Canada (Krever Commission). The use of independent expert advisory committees could be expanded to provide advice and enhance the credibility of the regulatory effort.

24.10   Under the Constitution and in practice, the federal government often shares responsibility for the protection of health and safety with the provinces. Co-operation is fast becoming mandatory, rather than a matter of choice. Increasingly, risks are of a global nature, and multinational action is required. Standards and regulatory approaches among countries are being harmonized through trade treaties or international agreements. This trend means that Canadian regulatory authorities need to co-operate to effectively present a Canadian position in international exercises for setting standards. For these reasons, it is in the interest of all parties to work together and to participate in the development of a national health and safety regulatory plan.

The Privy Council Office states that while the government believes its regulatory policy is sound, it shares our Office's concern. It recognizes the need to ensure that regulatory authorities have the capacity to meet the expectations of the policy — to properly develop and to appropriately implement regulations and regulatory programs.

Introduction

24.11 Health and safety regulatory programs deal with issues that have far-reaching implications. The programs are responsible for such matters as maintaining the safety of the blood supply, contributing to the safety of food, and monitoring the quality of air.

24.12 The Canadian Food Inspection Agency, Health Canada, Environment Canada, Transport Canada, the Canadian Nuclear Safety Commission and the National Energy Board administer major federal health and safety regulatory programs. Over the past decade, we have audited most of these programs. We estimate that the spending on these programs was about $1.2 billion in 1999–2000. (Some 12,000 full-time employees developed, implemented or enforced these programs.) This estimate does not include all government spending on health and safety regulatory programs. For example, it does not take into account spending by other agencies, such as the Canada Customs and Revenue Agency, on health and safety inspections or similar activities. As well, it does not include expenditures on supporting corporate administration and policy development. Finally, our estimate does not include the costs incurred by industry to comply with the requirements of these programs and the costs incurred by consumers.

Focus of the audit

24.13 This chapter provides a framework for understanding regulatory programs. It discusses major trends in regulatory approaches and the causes of the difficulties faced by the programs and proposes priorities for improvement. The chapter also identifies recurring patterns of strengths and weaknesses in the structure and implementation of health and safety regulatory programs.

24.14 The government's regulatory policy, including its regulatory process management standards, are similar to those of other member countries of the Organization for Economic Co-operation and Development. We use key elements of the policy as criteria for organizing information on patterns of findings of how well health and safety regulatory programs are being developed and implemented (see appendices A and B). We cover the following issues: risk identification and management, consultation and co-ordination, adherence to the government's regulatory process management standards, human resource management, cost recovery, enforcement and compliance, and reporting on effectiveness.

24.15 Our analysis and recommendations are based on the findings of our current and previous audits, and assessments by Parliament, the Privy Council Office, the Treasury Board Secretariat, departments and authoritative third parties. Our December 2000 Report contains results of our current audits: Chapter 25, Canadian Food Inspection Agency — Food Inspection Programs; Chapter 26, Health Canada — Regulatory Regime of Biologics; and Chapter 27, Canadian Nuclear Safety Commission — Power Reactor Regulation. We also conducted follow-ups of previous audits. Chapter 28 contains follow-ups of the National Energy Board, the animal health and plant protection inspection program of the Canadian Food Inspection Agency, and the commercialization of the air navigation system by Transport Canada. Our findings over the past decade on how well the government has been implementing health and safety regulatory programs are presented on pages 24–21 to 24–28. Exhibit 24.1 lists our current and previous audits of health and safety programs over the past decade.

24.16 We present more details in **About the Audit** at the end of this chapter.

We estimate that major health and safety programs spent $1.2 billion in 1999-2000.

Exhibit 24.1

Our Audits of Health and Safety Regulatory Programs

2000	**Auditor General's Report** Chapter 24, Federal Health and Safety Regulatory Programs Chapter 25, Canadian Food Inspection Agency – Food Inspection Programs Chapter 26, Health Canada – Regulatory Regime of Biologics Chapter 27, Canadian Nuclear Safety Commission – Power Reactor Regulation Chapter 28, Follow-up of Previous Recommendations on Health and Safety Regulatory Programs **Commissioner's Report** Chapter 4, Smog: Our Health at Risk Chapter 5, Partnerships for Sustainable Development: Overview Chapter 6, Working Together in the Federal Government Chapter 7, Co-operation Between Federal, Provincial and Territorial Governments Chapter 8, Working With the Private Sector
1999	**Auditor General's Report** Chapter 11, Agriculture Portfolio – User Charges Chapter 13, National Defence – Hazardous Material: Managing Risks to Employees and the Environment Chapter 14, National Health Surveillance: Diseases and Injuries **Commissioner's Report** Chapter 2, Sustainable Development Strategy Consultations Chapter 3, Understanding the Risks From Toxic Substances: Cracks in the Foundation of the Federal House Chapter 4, Managing the Risks of Toxic Substances: Obstacles to Progress Chapter 5, Streamlining Environmental Protection Through Federal-Provincial Agreements: Are They Working? Chapter 6, Making International Environment Agreements Work: The Canadian Arctic Experience
1998	**Auditor General's Report** Matters of Special Importance Chapter 13, National Energy Board
1997	**Auditor General's Report** Chapter 4, Control of the Transboundary Movement of Hazardous Waste Chapter 19, Transport Canada – The Commercialization of the Air Navigation System Chapter 27, Ozone Layer Protection: The Unfinished Journey
1996	**Auditor General's Report** Chapter 9, Agriculture and Agri-Food Canada – Animal and Plant Health: Inspection and Regulation Chapter 22, Federal Contaminated Sites: Management Information on Environmental Costs and Liabilities
1995	**Auditor General's Report** Chapter 2, Environment Canada: Managing the Legacy of Hazardous Wastes Chapter 3, Federal Radioactive Waste Management Chapter 4, Health Canada: Management of the Change Initiative at Health Protection Branch Chapter 11, Environmental Management Systems: A Principle-based Approach
1994	**Auditor General's Report** Chapter 13, Federal Management of the Food Safety System Chapter 15, Atomic Energy Control Board – Canada's Nuclear Regulator
1993	**Auditor General's Report** Chapter 25, Parliamentary Control Over the Raising of Revenues by Fees Chapter 26, Pulp and Paper Regulations

Exhibit 24.1 (continued)

1990	**Auditor General's Report** Chapter 18, Department of the Environment
1989	**Auditor General's Report** Chapter 17, Federal Regulatory Review Process Chapter 22, Department of Transport – Canadian Coast Guard: Protecting Mariners' and Public's Interest

Observations and Recommendations

Understanding Major Challenges in Health and Safety Regulatory Programs

24.17   Health and safety regulatory programs usually address a broad issue using enabling legislation. For example, the food inspection programs of the Canadian Food Inspection Agency contributes to the safety of food by monitoring a wide range of food products under various federal food statutes. Similarly, Health Canada is responsible for regulating a variety of areas, including biological products such as vaccines, blood, human semen, animal tissue and organ transplants to humans.

24.18   The government's regulatory policy, including its regulatory process management standards, guide the implementation of regulatory programs. Specific regulations are used to implement programs. The authority to make regulations is provided for in the enabling legislation. Regulations may be prepared before or after the proclamation of the enabling legislation. However, they cannot be enforced before proclamation. When authorities wish to make regulations, they must follow the regulatory process management standards. These standards are similar to the principles of the regulatory policy, but are much more detailed. They describe the specific steps that regulatory authorities need to follow to propose, assess and develop a regulation.

24.19   Over time, there have been major changes in the federal regulatory approaches to respond to major changes in technology, significant pressures to maintain economic competitiveness and a growing need to harmonize Canadian regulatory approaches with the requirements of international agreements. Among the emerging major responses to the changes are an emphasis on increased reliance on industry, the greater use of standards set by third parties and the use of internationally accepted standards. In addition, health and safety regulatory programs operate in an increasingly complex environment. For example, they have undergone major changes in organization, there is greater risk of legal liability and there is an increased need for interdepartmental and multi-jurisdictional co-ordination.

Increased reliance on industry

24.20   Traditionally, regulatory programs have been based on regulations that require companies to comply with certain standards of production or service delivery, and on an inspection and penalty system to ensure compliance. The government retained primary responsibility for developing regulations and for ensuring compliance with them. Regulations often specify what is to be inspected, by whom and how. In certain instances, they require both industry and

the government to carry out specific inspections.

24.21 Over time, alternatives to the traditional approach have been developed because of the following concerns:

• inspection programs of the federal government duplicated those that industry established, in part, to ensure their consumer market and avoid major lawsuits;

• the costs to the government and industry of regulations and compliance programs were increasing without an apparent increase in public health and safety;

• regulations were increasingly based on outdated scientific information and were difficult to change;

• new products and services and risks to health safety made the development of appropriate regulations more difficult; and

• industry and advocacy groups wanted ongoing consultation on regulatory approaches and faster responses to their concerns.

24.22 The January 1993 report of the Sub-Committee on Regulations and Competitiveness of the parliamentary Standing Committee on Finance called for greater use of alternatives to regulation. The subcommittee recommended the following:

• the government needs to adopt a policy of decreasing its inspection and monitoring of a regulated company that is certified and is meeting quality management standards; and

• regulated companies need to be allowed options to prove conformance to regulations.

24.23 In response to these concerns and recommendations, the federal government endorsed the use of alternatives to regulation in 1995. Its regulatory policy now requires regulatory authorities to

consider alternatives to direct regulation, such as increased reliance on industry through voluntary industry codes.

24.24 Under this reliance approach, it continues to be ultimately responsible for safeguarding the health and safety of citizens. However, the government can devolve to industry, in varying degree, responsibility for establishing product and service standards, for maintaining quality assurance and inspection systems to ensure compliance, and for providing performance reports to assure the government of the integrity of the system and the achievement of goals. The government can verify the information from industry and conduct audits.

24.25 For example, in 1995 the federal, provincial and territorial governments issued a revised version of A Blueprint for the Canadian Food Inspection System. The document states that the longer-term objective is for governments to modify their role by refocussing their activity in the area of quality standards inspection, in favour of an audit of a company's performance against food safety and product identity standards. The federal government is implementing a food safety enhancement program to help "ensure that all processed agri-food products...and the conditions under which they are manufactured lead to the production of safe food." Industry is responsible for controlling and monitoring its critical control points in accordance with an approved plan that meets government standards. The government is responsible for checking the adequacy of the controlling and monitoring done by industry and for verifying its monitoring records. This approach is expected to allow inspectors to focus their efforts on priority areas.

24.26 The policy of shifting from regulatory regimes to reliance on industry has been controversial. Some have expressed general concerns that public health and safety could be compromised because industry would place profit ahead

of public health and safety and that there would be inadequate accountability, credibility and effectiveness. Others have raised concerns about conflict of interest when government recovers costs from industry for providing regulatory services that are supposed to protect the public from negligence by industry.

24.27 There is also concern about using third parties to assess health and safety. In 1998 Health Canada consulted Canadians on how to renew federal health protection legislation. Health Canada asked whether it should be permitted to delegate to an independent third party some of its responsibilities for assessing the safety and effectiveness of products and services sold in Canada. Health Canada's 1999 National Consultations Summary Report indicates that views on this matter are "polarized." Unless stringent precautions are taken, the report concludes that Canadians would view this approach as "an abdication by Health Canada of its responsibilities."

24.28 One argument made to support the shift in responsibilities is that major companies face an increased liability for negligence. As a result of this liability, it is assumed that the interests of the public will be protected because of the need for a company to maintain consumer confidence and avoid lawsuits.

24.29 Legislation and legal precedents create the context for civil lawsuits. In 1994 Health Canada studied the effectiveness of civil lawsuits as a deterrent to the production and supply of hazardous consumer products. The study noted that the increased liability faced by industry may not be a sufficient deterrent because it may be largely hypothetical. Despite legislation in some provinces allowing for class action law suits, citizens may still not have enough resources and opportunities to use the courts to seek redress for industry negligence.

24.30 The study found that civil litigation does not cause manufacturers to adopt measures to avoid injuries where the cost of the measures is greater than the cost of settling civil action for an injury or death. In particular, it found that litigation is least effective for injuries that are small, but affect a large group of people, or for manufacturers without a brand name to protect in Canada or with very limited assets in Canada.

24.31 Because reliance on industry arrangements are relatively new, general conclusions about their effectiveness cannot yet be reached. However, in previous audits we have suggested that the following actions need to be taken for them to work well:

- the government must clearly define the results to be achieved;

- industry must implement a sound program to measure performance and quality on which the government can rely;

- industry must provide the government with comprehensive data for the timely assessment of industry's performance; and

- the government must determine the reliability of this data from industry.

Increased use of standards developed by third parties

24.32 In 1996 the Treasury Board Secretariat initiated the standards and regulatory reform program to encourage departments to participate, where appropriate, in developing regulatory regimes based on standards. This approach has been considered useful to adapt to rapid changes in technology. For example, technology in biologics is moving quickly, and regulations need to be frequently revised.

24.33 Under this approach, responsibility for developing a standard rests with a recognized standards development organization or professional body. The objective is to develop

The policy of shifting from regulatory regimes to reliance on industry has been controversial.

standards that reflect a consensus of interested parties. While the government takes part in developing the standards, it is one of several stakeholders that include relevant professional bodies and technical experts.

The government needs to fully assess the extent to which the standards-based approach can be applied.

24.34   Once approved and published, these standards can be referenced in whole or in part in regulations, making them mandatory rules. Regulatory authorities also can supplement the referenced standards with policies, guidelines and operating procedures according to which manufacturers must meet certain requirements and submit to periodic inspections to ensure compliance. Responsibility for updating the standards rests with the standards development organization, rather than the government. Regardless of the adopted approach, the government remains accountable for the effectiveness of the regulatory regime.

24.35   Proponents believe that a regulatory regime based on standards developed by third parties provides greater flexibility than traditional government-run approaches. In particular, they believe that such a regulatory regime works well when new knowledge or technical advances require immediate changes in a standard. Proponents also feel that standards developed with the consensus of third parties also result in the following:

• the use of clearer and simpler language because these standards are not subject to legal drafting rules;

• greater flexibility in adapting to technological change;

• more acceptance, greater compliance and less need for education and enforcement; and

• greater ease in harmonizing national standards with international standards.

24.36   The government needs to fully assess the extent to which the standards-based approach can be applied

and its effectiveness relative to the traditional approach.

24.37   For example, it is not clear whether there is less or more consultation using the traditional or standards-based approach. A standards-based approach may focus on reaching a consensus among experts and industry and could result in less public consultation than the traditional government regulatory process requires. Also, using a standards-based approach may not always be faster than a traditional approach, and third parties may not wish to undertake a standard setting exercise when there is the potential for significant legal liability.

24.38   Our current audit of Health Canada's regulatory regime of biologics looked at the advantages and disadvantages of using standards developed by third parties. In recent years, Health Canada has consciously moved toward adopting regulatory frameworks based on standards. The Department believes that this approach provides greater flexibility to respond and adapt to rapid advances in technology and to the diverse nature and risks presented by biologics. However, because changes to the standards can only be made by consensus under the auspices of the responsible standards development organization, Health Canada is concerned that it may not be able to make necessary changes when a consensus is difficult to reach. Yet, the Department retains the authority to make a new regulation. Health Canada is considering the option of referencing, where needed, its own technical standards over which it will have complete authority.

24.39   Legal liability for health and safety standards developed by third parties and incorporated into regulations is another issue that has arisen. Standards development organizations may not be willing to tackle a standard that would expose them to significant liability. The experience of Health Canada indicates that when standards development

organizations develop standards that may expose them to significant liability, they may have to carry insurance coverage running into the millions of dollars, and the government would probably have to indemnify them for the losses beyond an agreed amount. The federal government has recently agreed to indemnify a standards development organization by accepting to pay any possible claims that court decisions would impose beyond the amount the organization could bear to pay. However, no contract has been signed with the organization.

24.40 Health Canada is assessing its experience, and we have recommended that it uses the lessons learned in applying future standards-based regulatory regimes.

24.41 The government has also used voluntary industry codes. Industry Canada and the Treasury Board Secretariat provided guidance to federal entities on the use of such standards in Voluntary Codes: A Guide for Their Development and Use. The 1999 Health Canada report indicates that Canadians are skeptical about the effectiveness of voluntary standards. The National Packaging Protocol is an example of a voluntary industry code that the government has used. Approved by the Canadian Council of Ministers of the Environment, the protocol contains targets and a schedule for achieving a 50 percent reduction in waste going to landfill by 2000.

International harmonization of regulatory approaches

24.42 Standards establish accepted practices, technical requirements and terminologies. The government's regulatory policy requires federal entities to determine whether there is an international standard on which they can base a domestic regulation. There are also many international agreements that require Canada to adopt international standards. When departments develop regulations, they need to be concerned about consistency with these standards and standards that could be incorporated into future international agreements. As a result, federal health and safety regulations increasingly refer to standards established by international bodies.

24.43 International agreements often call on signatory nations to use similar standards. This practice harmonizes standards among nations and may be a prerequisite for increasing trade. Protecting the environment often means adopting international standards. As well, the regulation and inspection of food is increasingly part of international trade agreements and economic competitiveness. The Canadian Food Inspection Agency manages about 1,500 international agreements dealing with access to international markets.

24.44 The work on pesticide regulation by the technical working group established under the North American Free Trade Agreement between Canada, the United States and Mexico illustrates the increasing international harmonization of regulatory approaches. The working group addresses trade irritants, builds national regulatory and scientific capacity, shares the review burden and co-ordinates scientific and regulatory decisions on pesticides.

24.45 The working group has formed four subcommittees. One of them, the joint review subcommittee, develops compatible review programs of pesticides to facilitate routine sharing of work on pesticide regulation. In April 1998 the subcommittee completed its first joint review of a pesticide. The activities of the technical working group on pesticides is an example of a means of addressing the problem of scarce expert resources by sharing expertise.

Major changes in resources and organization

24.46 Key health and safety regulatory programs have undergone major budgetary and organizational changes.

Changes in Environment Canada, Health Canada and the creation of the Canadian Food Inspection Agency illustrate these trends.

24.47 Over the three years ending in 1997–98, Environment Canada's budget was reduced from $737 million to $503 million and the Department lost about 1,400 of 5,700 employees.

24.48 The government created the Canadian Food Inspection Agency in April 1997 by consolidating food inspection and quarantine services previously provided by Agriculture and Agri-Food Canada, Fisheries and Oceans, and Health Canada. These departments transferred about $330 million and about 4,500 full-time employees to the Agency. When it was created, the Agency was expected to cut its budget by $33 million over the first three years of operation.

24.49 Health Canada's health protection mandate spans the spectrum of health risks, from therapeutic products to food safety, to environmental safety, to product safety, and to disease risks. In recent years there have been significant fluctuations in resources for health protection as a result of the government's Program Review, program changes, and the introduction of new initiatives and priorities, such as AIDS and cancer research and blood safety. In 1997–98 the Health Protection Branch had expenditures of $146 million and some 2,000 full-time employees, compared with $216 million and about 2,300 full-time employees in 1995–96. For 2000–01, the planned budget for the Branch's activities amounts to some $303 million and about 2,300 full-time employees.

24.50 In July 2000 the Department created three new branches to integrate health promotion and protection activities. The Health Products and Food Branch, Healthy Environments and Consumer Safety Branch, and Population and Public Health Branch are now responsible for the activities of the former Health Protection

Branch and Health Promotion Programs Branch.

Credibility of the use of science by government

24.51 Credible science underpins health and safety regulations. It consists of qualified people carrying out such activities as research in laboratories, establishing technical standards, analyzing databases, inspecting facilities, assessing new technologies and identifying potential threats.

24.52 The government recently published A Framework for Science and Technology Advice: Principles and Guidelines for the Effective Use of Science and Technology Advice in Government Decision Making. This report notes that "recent government decisions in the areas of natural resources management, public health and safety, and other areas have undermined public confidence and contributed to public concern regarding the ability of the federal government to address science-based issues effectively"; for example, the concerns about the safety of the blood supply reviewed by the Commission of Inquiry on the Blood System in Canada (Krever Commission).

24.53 Without credible science, health and safety regulatory programs can be challenged as untrustworthy and subservient to political policy or special interests. As a result, public confidence in and support for regulatory initiatives can be undermined. We discussed the importance of maintaining the credibility of science in government in our October 2000 Report, Chapter 12, Values and Ethics in the Federal Public Sector. We also discussed efforts to enhance the credibility of science in government.

Implementation of the precautionary principle

24.54 The complexity of managing health and safety regulatory programs has grown with the increasing focus on the

Without credible science, health and safety regulatory programs can be challenged as untrustworthy and subservient to political policy or special interests.

precautionary principle for decision making. The description of the principle in the *Canadian Environmental Protection Act* illustrates how the principle is being incorporated into legislation. The Act states that under the Constitution and the laws of Canada, the government must apply "the precautionary principle…where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as reason for postponing cost-effective measures to prevent environmental degradation."

24.55 Among the earliest uses of the precautionary principle (or approach) was its incorporation in the 1987 declaration of ministers on the protection of the North Sea. Variations of this principle now exist in about 10 federal and provincial Acts and agreements. Canada has also made commitments to the principle in about 20 international agreements and conventions. For example, the principle has been incorporated into the 1997 *Oceans Act*, the 1999 *Canadian Environmental Protection Act*, the 1998 Canada-wide accord on environmental harmonization and the 1999 federal strategy to prohibit bulk water removals.

24.56 Implementing the principle is not straightforward. Interpretations vary from those who believe in avoiding risks and fully erring on the side of caution to those who consider risk taking, the cost effectiveness of different levels of control and economic development. Because cause and effect relationships may not be established, the basis for regulating is more complex to define. As well, because these relationships are more uncertain, there is concern that the precautionary principle is a challenge to science-based regulation and to the allocation of resources based on risk assessment.

Potential legal liability

24.57 Companies may incur major liabilities due to negligence. Since 1990

the courts have held that regulatory authorities have a "duty of care" and that a high standard of care is necessary to fulfill this duty. As a result, authorities are more exposed to claims for regulatory negligence. Further, if an authority's inspection and enforcement program is not credible, the authority may be found liable for failing to meet its enforcement responsibilities where damage arises as a result of its omissions.

24.58 The federal government has already faced a number of court challenges about health and safety; some concern claims for faulty medical devices and tainted blood. Because it has no government-wide approach to avoid or manage litigation, the government is exposing itself to very high risks. A major effort may be needed to develop awareness of legal risks and to co-ordinate a more proactive and strategic approach to litigation.

24.59 To reduce the risk of regulatory negligence, regulatory authorities need to take a variety of measures to provide an appropriate standard of care. For example, they must ensure the following in given circumstances:

- human resources are sufficient;

- decisions to delegate are well-founded;

- risk management strategies are defensible;

- compliance and enforcement policies standards are practical;

- regulation delegated to industry is properly monitored against objectives;

- testing and approval procedures reflect recent technological standards;

- timely action is taken to prevent public harm; and

- timely advice is given to the public on dangerous products or activities.

Some of the most pressing challenges facing health and safety regulatory programs cut across departmental mandates, political jurisdictions and national borders.

Need for multi-departmental action

24.60 Some of the most pressing challenges facing health and safety regulatory programs cut across departmental mandates, political jurisdictions and national borders. The Treasury Board's 1995 Framework for Alternative Program Delivery recommended that federal departments establish collaborative arrangements with other departments, other levels of government and other sectors of the economy. Since 1995 there has been a significant increase in the number of collaborative arrangements or partnerships between the federal government and provincial governments.

24.61 In collaborative arrangements, parties share power and authority in decisions on program and service delivery and need to reconcile their legislative mandates and approaches to managing people. Because power is shared, the establishment of credible reporting, effective accountability, transparent processes and protection of the public interest become more complicated.

24.62 For example, Environment Canada is responsible for administering or helping to administer over 25 Acts and over 40 regulations. To achieve its objectives, it relies extensively on the co-operation of other government organizations, including Health Canada, Agriculture and Agri-Food Canada, and Transport Canada.

24.63 Not surprisingly, conflicts sometimes exist between these organizations about how to protect the environment, while sustaining economic development and competitiveness. In the 1999 Report of the Commissioner of the Environment and Sustainable Development, we reported that federal departments were divided on the degree and significance of risks posed by some individual toxic substances, the interpretation and application of legislation and the nature of their

respective roles and authorities. We noted that this division has led to indecision, inaction and strained relations among departments and agencies.

Need for multi-jurisdictional action

24.64 In many instances, federal and provincial governments have constitutional powers over the same matter. This situation is especially true for the environment. The exercise of these powers has resulted in a substantial degree of overlap in activities and uncertainty of the limits of each government's jurisdiction. Increasingly, Environment Canada needs to negotiate bilateral agreements with the provinces to enforce its environmental regulations or equivalent regulations. An example of this approach is the collaborative arrangement between the federal, provincial and territorial governments to reduce smog. Collaboration was necessary because one level of government could not solve the problem alone. The development of the arrangement required extensive consultation (see the Commissioner's 2000 Report, Chapter 4, Smog: Our Health at Risk).

24.65 Our Office has extensively reviewed collaborative arrangements. Chapter 5 of the Auditor General's April 1999 Report, Collaborative Arrangements: Issues for the Federal Government, examined the major issues of effective participation in these arrangements. Chapter 23 of his November 1999 Report, Involving Others in Governing: Accountability at Risk, presented a governing framework for collaborative arrangements. Chapters 5 to 8 of the Commissioner's 2000 Report reviewed collaborative arrangements in the federal government; arrangements between the federal, provincial and territorial governments; and arrangements between the public and private sectors.

24.66 Our Report chapters contain the following findings:

- Departments need to define clearly "who does what." Key problem areas include unclear objectives, poorly defined responsibilities, unclear accountability and weak dispute resolution. Good interdepartmental co-ordination is limited by departments' inability to compel other departments to act, except through persuasion and negotiation.

- To be successful, federal-provincial agreements must offer clear benefits, specify roles and responsibilities, and have clear objectives, time frames and expected results. As well, each partner of the agreements needs to produce an early action plan for its own organizations.

Increased public scrutiny

24.67   Industries affected by health and safety regulatory authorities have traditionally monitored and tried to influence regulatory decisions. Organizations representing a variety of different interests in health and environmental issues are watchful. Recently, Canadians have become more aware of the personal implications of regulatory decisions.

24.68   These trends have partly occurred because many health and safety regulatory issues involve rapid and major changes in science and technology and an increased possibility of significant error. As well, there is greater public sensitivity to potential risks. For example, there is now a significant public interest in new health and food technologies and products, such as medical therapies, transplants of animal organs to humans, genetically-modified foods and natural health products.

24.69   The degree of concern also has increased because of recent events: the failure to protect the safety of the Canadian blood supply system; the British experience with mad cow disease; and the Ontario experience of deaths and illness from contaminated drinking water, and of

the closing of several nuclear power plants.

24.70   Access to the Internet also allows for growing scrutiny of regulation and the approval of particular products. Electronic communication also makes it easier to organize associations. As a result, the work of health and safety regulatory authorities can be carefully monitored and lapses can attract major media and public attention.

Extensive requirements of the regulation-making process

24.71   Specific regulations are often used to protect health and safety. Regulations have the force of laws, and they confer legally enforceable rights and impose legally enforceable obligations on organizations and individuals. Regulations are often referred to as delegated legislation because in an Act, Parliament empowers the government to enact specific types of regulations.

24.72   About 85 Acts and 250 regulations are administered by Environment Canada, Health Canada, the Canadian Nuclear Safety Commission, the National Energy Board, the Canadian Food Inspection Agency, and Transport Canada. Their objectives range from protecting the environment to maintaining the safety of food, drugs and nuclear power plants.

24.73   There have been many reviews of the regulatory process and attempts to reform it. The first main documents on problems in the regulatory process include the 1980 report of the House of Commons' Special Committee on Regulatory Reform, the 1979 and 1981 reports of the Economic Council of Canada on reforming regulation, our 1989 Report chapter on the federal regulatory process and the 1992–93 report of the Standing Committee on Finance. These reports contained the following concerns:

- regulations were unnecessarily harming economic performance;

- regulations were not achieving policy objectives;

- regulations were not being implemented with a clear need, accountability and consideration of effective alternatives to regulation;

- regulations were not sufficiently assessed for their economic and social impacts;

- regulations were not developed with sufficient consultation with affected stakeholders; and

- regulations were not effectively enforced.

24.74 In response to these criticisms, the government has made major changes in the process for making regulations. It took the first major measures in 1986. The government developed a regulatory policy and a citizen's code of regulatory fairness, designated a minister responsible for regulatory affairs, and required impact analyses. Furthermore, it established the Office of Privatization and Regulatory Affairs (OPRA) to oversee the regulatory process and published annually a government-wide regulatory plan to identify all proposed regulations.

24.75 The key components of the regulatory policy were clear accountability, public consultation, assessment of regulations to ensure that benefits exceed costs, clear public information on why regulations were needed, evaluation of regulatory programs and a sound legal basis for regulatory action. Exhibit 24.2 identifies the major steps and responsibilities in the making of federal regulations.

24.76 There have been major changes to the administrative oversight of the regulatory process. In 1987 the OPRA had 14 full-time employees and a budget of about $1.9 million. It was dissolved in 1991 and the central oversight process was

significantly curtailed. The responsibility for the regulatory process was no longer vested in one minister and the responsibility for ensuring the reliability of regulatory impact assessment was transferred to departments.

24.77 The Regulatory Affairs Directorate of the Treasury Board Secretariat retained the responsibility for making central policy. In 1994–95 the Directorate had 11 full-time employees and a budget of about $1.14 million. Since, it has published about 40 documents that contain technical and policy advice on managing regulatory programs, assessing alternatives to regulation, conducting regulatory impact analyses and developing new regulatory administrative policies.

24.78 The 1994 Treasury Board Secretariat Regulatory Review reflected the delegation of responsibility to departments and agencies. The Secretariat gave some guidance, but allowed departments to determine their own path of regulatory reform and apply their expertise and experience to their particular problems. In 1997 the government discontinued the publication of the government-wide regulatory plan. Each department now publishes its proposed regulations in the annual Report on Plans and Priorities to Parliament.

24.79 In 1999 the responsibilities for the regulatory policy were transferred to the Regulatory Affairs and Orders in Council Secretariat at the Privy Council Office. The Regulatory Affairs Division supports the Special Committee of Cabinet that reviews regulations. The Division provides analysis, briefing and strategic advice on department and agency regulatory proposals. It also supports the government's regulatory reform and research agendas. In 1999–2000 the Regulatory Affairs Division of the Secretariat had 12 full-time employees and a budget of about $1.23 million.

Exhibit 24.2

Major Steps and Responsibilities in the Making of Federal Regulations

Responsibility	Step
Minister and Department	Scrutinize the need for each proposed regulation.
Minister and Department	Consult stakeholders, assess risks, assess alternatives to regulation, assess cost and benefits, prepare compliance and enforcement plan, and prepare the regulatory impact analysis statement.
Department of Justice	Reviews the proposed regulation to ensure a sound legal basis, and respect for the *Canadian Charter of Rights and Freedoms* and the *Statutory Instruments Act.*
Minister	Formally recommends to the Governor in Council the pre-publication of the proposed regulation.
Privy Council Office	Reviews the proposed regulation for consistency with the federal regulatory policy and broader government initiatives. Prepares information on the proposed regulation for the Special Committee of Council.
Special Committee of Council	Reviews the proposed regulation. If approved, the regulation is pre-published in the *Canada Gazette* for at least 30 days, allowing for scrutiny and comment.
Parliament and stakeholders	Review the proposed regulation.
Minister and Department	Collect, review and assess comments on the proposed regulation. If needed, repeat previous steps in process (e.g., scrutinize the need for the regulation).
Privy Council Office	Reviews the documents that contain stakeholder comments on the proposed regulation and the departmental response to the comments. Prepares information for the Special Committee of Council.
Special Committee of Council	Reviews the proposed regulation and makes a final recommendation to the Governor in Council on whether to approve the regulation.
Governor General	Signs the regulation, which is then registered with the Registrar of Statutory Instruments. The regulation comes into force as soon as it is registered within seven days of final approval. It can only be enforced once it has been published in the *Canada Gazette*, Part II, within 23 days of registration.
Standing Joint Committee for the Scrutiny of Regulations	Reviews the new regulation, reports to Parliament on problems it may contain and proposes, if necessary, that it be repealed.

Source: Government Regulatory Process Management Standards: Compliance Guide

Implementing Health and Safety Regulatory Programs

24.80 Our analysis and recommendations are based on our current and previous audits of health and safety regulatory programs.

24.81 Our findings over the past decade on how well the government has been implementing health and safety regulatory programs are presented on pages 24–21 to 24–28.

Improving Regulatory Programs

24.82 The overall objective of health and safety regulatory programs is to proactively protect Canadians from major risks to health and safety — to catch the problem before it happens, and if it happens, to minimize the consequences. Because performance measurement is weak, there is insufficient information to assess the cost effectiveness of health and safety regulatory programs.

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24.83 It is also important to keep in mind that there are often complementary and compensating factors that offer a depth of protection. For example, the expertise of managers and employees who work at the Canadian Food Inspection Agency, at Health Canada and in the food supply system protects Canadians. Employees of supermarkets and local stores also screen foodstuffs on shelves for spoilage. Equally important are the skills of shoppers and those who prepare food at home and in restaurants.

24.84 However, despite a wide safety net, major regulatory failures can occur, and the results can be significant. The results of not being able to ensure the safety of the blood supply are an example.

24.85 The objective of the government's regulatory policy is to promote the design and implementation of effective regulatory programs. Over the past decade, our audits of federal health and safety regulatory programs have found many instances where regulatory authorities have not met the expectations of the government's regulatory policy. While effectiveness or exposure to risk cannot be judged solely on the basis of adherence to the policies, well structured and implemented programs increase cost effectiveness and reduce the risk of regulatory failure.

Clarifying priorities and values

24.86 Health Canada's 1999 National Consultations Summary Report found that Canadians believe that "health and safety must take precedence over economic and other considerations." However, the government's regulatory policy contains potentially conflicting requirements. The policy requires that costs and economic objectives be considered when developing and implementing regulatory programs. In our view, there is a need for the government to clarify the priorities of the regulatory policy for health and safety regulatory programs and clarify the balance it has reached to protect Canadians and address costs and other objectives.

24.87 Our concern for priorities of these programs stems from the emphasis on economic considerations in the regulatory policy, potential conflicts of interest arising from the cost-recovery policy, and the government's recent focus on client service.

24.88 The regulatory policy emphasizes the need for regulatory authorities to take into account economic considerations. Since 1986 the policy has focussed attention on the importance of limiting the impact of regulation on the economy. In 1996 the Treasury Board Secretariat directed departments to use a business impact test that would determine the impact of regulations on the private sector.

Implementing Health and Safety Regulatory Programs

1. We have used the following major elements of the government's regulatory policy to organize information on the development and implementation of health and safety regulatory programs:

- identification and management of risks to health and safety;
- consultation with citizens on regulatory approaches and with stakeholders on proposed regulatory initiatives and the manner of their implementation;
- adherence to the regulatory process management standards for making regulations;
- management of human resources;
- recovery of costs of services provided to industry that benefit private interests;
- compliance and enforcement of regulations; and
- timely and complete reporting on program effectiveness to Parliament.
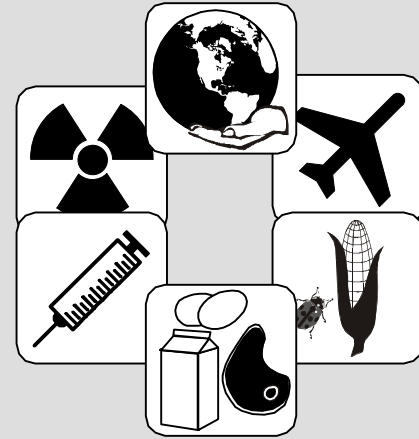
Risk Identification and Management

2. **Background.** The federal regulatory policy requires that regulatory authorities demonstrate that a problem or risk exists and that federal government intervention is justified. Sound procedures to identify and manage risks to human health and safety are needed to implement this policy requirement. Such procedures allow regulatory authorities to ensure that their programs focus on priorities, that government intervention is required and that funds and human resources are allocated to the best advantage.

3. Managing health and safety risks to Canadians is a complex task. While risks can be reduced, they cannot be entirely eliminated. It also is difficult to separate Canadian and international aspects of risks. In addition, the scientific assessment and public perception of risks may differ. The extent of resources allocated to reducing a specific risk is often heavily influenced by the public's tolerance of loss of life or injury.

4. As well, the extent to which risks can be reduced depends on factors such as technology, human and financial resources, availability and dissemination of information, choices made by individuals, genetic and socio-economic factors, competing policy priorities, economic competitiveness and trade agreements.

5. **Risk management process.** In October 1997 the Canadian Standards Association published a national standard for Canada, Risk Management: Guideline for Decision-Makers.

This standard is similar to the processes in the Treasury Board's 1994 risk management policy. The Association's approach combines scientific assessments of risks with extensive stakeholder consultations and public communication.

6. Risk management, broadly defined, includes the following key elements:

- identifying risks, the risk management team and potential stakeholders;
- risk communication;
- assigning responsibility, authority and resources;
- conducting a preliminary analysis to define the scope of required decisions and risk scenarios;
- estimating the frequency and consequences of the risks;
- estimating the level of stakeholder acceptance of risks and the benefits and costs of containing the risks;
- identifying and assessing feasible risk control options, evaluating options for dealing with residual risks and assessing stakeholder acceptance of residual risks; and
- developing an implementation plan, evaluating the effectiveness of the risk management decision process and monitoring the effectiveness of the risk reduction program.

7. **Patterns of findings.** Our audits have regularly raised concerns about significant risk management in health and safety regulatory programs. In certain cases, they have identified

incidents that posed threats to public safety, government personnel and the environment.

8. Our previous audits have found that regulatory authorities were having major difficulties identifying and managing health and safety risks. We found examples of inadequacies in the following:

- risk identification;
- risk assessment methodology;
- information on the extent of risks to health and safety; and
- information on potential liabilities.

9. Our current audits continue to find examples of deficiencies in risk identification and management:

- there is a lack of important information on the incidence of food-borne illness in humans and the prevalence of pathogens in the food supply;
- Health Canada has encountered a number of problems with the surveillance of biological drugs after they have been approved for sale, including the surveillance of adverse reactions and events;
- the Canadian Nuclear Safety Commission needs to strengthen its risk analysis and assessment of licensee performance; and
- the National Energy Board has not assessed the health and safety risks associated with making regulations for onshore pipelines less prescriptive.

10. However, there have been improvements. For example, the Canadian Food Inspection Agency has enhanced its surveillance activities for animal and plant health and is incorporating information gathered from these activities into its risk assessment process. Health Canada has adopted a proactive approach to identifying health and safety risks arising from biologics. Overall, Transport Canada has made satisfactory progress in applying systematic risk analysis for its air navigation regulations and enforcement activities.

11. Government's assessment. In March 2000 the Treasury Board Secretariat consolidated the results of the assessments of comptrollership practices by five pilot departments. The Secretariat's findings are consistent with our own. For example, it concluded the following:

- although risk management is understood intuitively, only a few departments have begun to establish a formal risk assessment framework;

- managers need better tools to assess risks, and there is often little training available; and

- frameworks for the delegation of authority exist, but there is a need to review them in light of greater decentralization.

Consultation and Co-ordination

12. Background. The government has increasingly recognized that it cannot solve problems alone. It has also recognized that wide-ranging consultation is needed to gain the co-operation of affected parties, to develop the most effective regulatory approach and to foster compliance and the achievement of objectives.

13. The 1986 federal regulatory policy stated that Canadians were to be consulted in the making of regulations. This requirement has been reiterated in all subsequent versions of the policy. According to the current policy, regulatory authorities must ensure that "Canadians are consulted and that they have an opportunity to participate in developing or modifying regulations and regulatory programs." This statement sets a clear expectation that Canadians will be consulted on regulatory programs, not just on specific regulations.

14. Patterns of findings. The 1993 report of the Sub-Committee on Regulations and Competitiveness of the Standing Committee on Finance identified consultation as one of the areas that present problems. The subcommittee recommended that there be greater stakeholder involvement in setting regulatory goals and determining the means of achieving them.

15. Overall, we have found that regulatory authorities are investing a lot of time and resources in trying to meet increased public, industry and intergovernmental demands for consultation. In some cases, we have reported that consultation has worked well. For example, in the Auditor General's 1997 Report, Chapter 27, Ozone Layer Protection: The Unfinished Journey, we indicated that stakeholders had expressed a high degree of satisfaction with Environment Canada's consultations.

16. In other instances, consultation could have been significantly improved. Our Commissioner's 1999 Report, Chapter 2, Sustainable Development Strategy Consultations, reviewed the consultation process undertaken by 28 departments and agencies to develop sustainable development strategies. Our review of consultation plans for preparing departmental sustainable development strategies revealed that the objectives of the consultation were generally clear. However, the Commissioner's Report raised the following concerns:

- there were major differences in the quality and comprehensiveness of consultation plans among departments;

- fewer than half of the departments had internal policies or guidelines for consultation;

- departments often did not co-ordinate their consultations with other departments;

- most departments did not consult stakeholders on the design of their sustainable development strategy;

- consultation with other departments was often too late for their comments to be realistically incorporated into any report, other than in a cosmetic fashion;

- few departments evaluated their consultation process; and

- participants received uneven feedback on how their comments were considered.

17. Our current audits continue to find improvements in the consultation process. For example:

- there was extensive consultation on legislative changes relating to the Canadian Nuclear Safety Commission;

- Health Canada has taken steps to identify stakeholders and consult them on proposed changes to regulatory frameworks for some biologics; and

- Transport Canada developed the Canadian Aviation Regulations through a structured, national consultation process.

The Development of Regulations

18. Specific regulations are often used to protect health and safety. The development of regulations is subject to the government's regulatory process management standards. We looked at whether regulatory authorities were following existing standards in our 1989 Report chapter on the federal regulatory process and in our 1993 Report chapters on the development of pulp and paper regulations, the firearms control regulations and parliamentary control over user fees. We did not review these matters in other previous audits or in our current audits.

19. Government self-assessments. In 1995 the Treasury Board Secretariat directed seven major regulatory organizations to implement by December 1996 mandatory quality assurance standards for the regulatory process. These standards were contained in the 1995 Treasury Board's publication, Regulatory Process Management Standards.
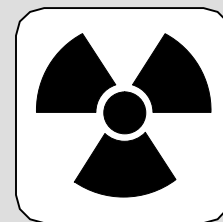
20. These organizations were also required to use the standards to determine their compliance with the government's regulatory policy, and report back to the President of the Treasury Board by 31 December 1999. The Board had received self-assessments from the organizations, including four from organizations that focus on health and safety regulatory programs: Health Canada, Transport Canada, the Canadian Food Inspection Agency, and Environment Canada.

21. The Privy Council Office has had the results of the self-assessments consolidated to assess current capabilities on a government-wide basis (see exhibit below). Overall, the consolidation identifies four areas of strength. The areas demonstrate good to advanced management capability. They include monitoring the regulatory environment, identifying potential problems, consulting and communicating with stakeholders, and ensuring interdepartmental co-ordination.

22. Thirteen areas were identified as "opportunities for further development," including better mechanisms for assessing the need for regulation, better capabilities in cost-benefit analysis, more clarity on the approach to resourcing regulatory programs and better performance measurement.

23. Six of the areas where there are opportunities for further development are rated as being in the "early stages of development" (see exhibit below). These areas include performance measurement and accountability, the ranking of problems and issues in order of priority. The remaining areas fall in between the "early stages of development" and "good management capability."

Highlights of Strengths and Opportunities for Further Development Among Regulatory Authorities

Strengths	Opportunities for further development
• Monitoring of the regulatory environment for gathering intelligence on issues and problems, and identifying potential problems. • Consultations with stakeholders, and strong relationships that exist with stakeholders. • Communications with stakeholders and the range of media used to communicate. • Interdepartmental and intergovernmental co-ordination and harmonization.	• **Better mechanisms for assessing the need for regulation and ranking regulatory proposals in order of priority.** • Stronger linkages between regulatory plans and overall departmental planning. • Improved capabilities to assess regulatory and non-regulatory alternatives. • Better capabilities in cost-benefit analysis, the assessment of the regulatory burden and preparation of the regulatory impact analysis statement. • More clarity in the approach to resourcing the delivery of regulatory programs. • **More training programs for regulatory staff in program areas.** • **Better performance measurement systems and accountability for regulatory programs, with a focus on outcomes.** • **More consistent complaint- and dispute-resolution processes.** • **Improved documentation on the regulatory management program and processes.** • **A more formalized approach to ongoing review and improvement.** • Simplification of the process and guidelines of the regulatory process management standards (RPMS). • More standardized reporting by departments and agencies against the RPMS. • Dissemination of best practices.

Note: Bolded "opportunities for further development" are rated as being in the "early stages of development."

Source: Treasury Board Secretariat, Privy Council Office.

24. Regulatory impact analysis statement. In August 2000 the Privy Council Office completed a review of the usefulness of the regulatory impact analysis for decision making and the development of regulations. The government's regulatory policy requires regulatory authorities to publish information on the proposed regulation in impact analyses. The information is expected to describe the purpose of the proposed regulation, present the results of reviews of a range of regulatory and non-regulatory alternatives, summarize the results of consultations, indicate the benefits and costs of regulating and describe proposed compliance and enforcement policies and measures.

25. The review focusses on six regulations initiated by major regulatory authorities. On the whole, the review concludes that the requirements of the regulatory impact analyses have changed the regulatory process for the better. In particular, the review indicates that for major regulations, a large amount of information is being provided to the public and government decision makers, and consultation is extensive.

26. However, the review cautions that the descriptions of regulations or problems need to be clearer, assessments of regulatory and non-regulatory alternatives and costs and benefits can be significantly improved, and descriptions of compliance policies and approaches need to be more complete. The review also makes recommendations to improve the relevance and usefulness of regulatory impact analysis statements.

27. We are concerned that the quality of cost-benefit analyses or impact assessments still needs major improvement. In 1989 and 1993 we expressed concerns about the quality of these analyses and assessments. These procedures are intended to provide an objective assessment of whether the social and economic benefits of adopting a regulation outweigh the costs. Without this information it is difficult for the public and decision makers to have as reliable a basis as possible for understanding what the regulation will achieve and how much it will cost.

28. Report of the Public Policy Forum. In February 2000 the Public Policy Forum released a report, Managing Regulation: Policy, Practice and Prognosis. The report presents the results of a multistakeholder roundtable in the fall of 1999 on the federal government's regulatory process and its implementation. The stakeholders included 15 industry associations, five federal departments and agencies, two provincial governments and the Consumers' Association of Canada.

29. According to the report, there is a general consensus that the regulatory policy is sound, but a "disconnect appears to exist between the Policy and its implementation across government departments and agencies."

30. In particular, stakeholders at the roundtable stated the following:

- the regulatory development process often lacks fairness;
- the techniques of regulatory impact assessment, such as cost-benefit analysis, tend to be misused or manipulated to support a position;
- the process is too slow, procedural and rigid;
- there is still a tendency for the government to regulate, not to find alternative solutions;
- the widespread practice of regulation by negotiation and bargaining raises concerns over the consistency of laws and rules.

Human Resources

31. Background. The regulatory policy requires that regulatory authorities "when managing risks on behalf of Canadians, …must ensure that limited resources available to [the] government are used where they do the most good." This requirement is difficult to achieve when risk assessment is weak.
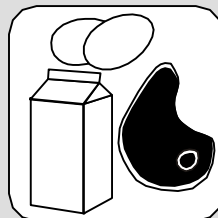
32. The primary human resource challenge facing health and safety regulatory programs is obtaining sufficient funds to hire staff and determining the type and number of staff and their competencies. The programs also need to maintain a sufficient number of inspectors who are well trained in the most up-to-date methods and technologies and led by people with a broad understanding of the work they do. About 5,000 inspectors work in health and safety regulatory programs. Most of them work at Health Canada, the Canadian Food Inspection Agency, and Transport Canada.

33. Pattern of findings. Our previous audits have often found instances of insufficient resources to carry out responsibilities. For example, we found that there were insufficient resources to do the following:

- to oversee in the long term the radiation safety program and nuclear safety compliance;
- to deal with new issues in the national energy sector; and
- to apply and maintain specialized knowledge and technical expertise in deep geological disposal of radioactive waste.

34. Our current audit findings indicate that the Canadian Nuclear Safety Commission, the regulatory regime for biologics of Health Canada and the Canadian Food Inspection Agency are experiencing or will experience some major staffing problems.

35. The situation in Health Canada illustrates the problems and their consequences. Following the 1997 report of the Commission of Inquiry on the Blood System in Canada (Krever Commission), the government announced in 1998 that it would invest $125 million over the next five years to strengthen Health Canada's blood safety program, including regulatory and surveillance programs for related biologics. The government also gave the Department the authority to start hiring 84 full-time employees in 1998-99 and up to a total of 133 by 2002-03.

36. The Department indicates that it has yet to fill 30 of 94 positions allocated to the Therapeutic Products Programme in 1999-2000. Vacant positions were identified as either "staffing in progress" or "staffing to be initiated" and pertained to compliance and enforcement investigations, pre-market and post-market reviews, post-market surveillance, regulatory research and policy development. According to the Department, these shortfalls were the result of a number of factors, including lengthy staffing processes, the unavailability of qualified candidates, non-competitive salaries and the unwillingness of potential candidates to work in biologics in a post-Krever environment.

37. The staffing problems have a significant impact on the Department's ability to manage the workload of pre-market reviews of new biological products and conduct post-market assessments. The result is a significant backlog of new biological drug submissions, failure to meet established performance targets and incomplete post-market assessments. These problems are expected to worsen with the implementation of proposed changes to the regulatory framework for clinical trials. The present 60-day default period for approval will decrease to only 30 days for many clinical trial submissions. While authority was given to increase staff levels, Health Canada expects that it will have difficulty obtaining additional qualified resources in the immediate future. At the current level of staffing, it is estimated that this change will further increase the backlog of new biological drug submissions.

38. Other regulatory authorities are also experiencing difficulties. The Canadian Food Inspection Agency estimates that by 2006, 734 of its indeterminate employees will be eligible to retire, including about a third of inspectors and veterinarians. The Agency is already having some difficulty recruiting for some positions.

39. While the Canadian Nuclear Safety Commission has set priorities and developed a number of important human resource policies and practices, it also faces difficulties in hiring scientific and technical staff. Despite management's initiatives, the present vacancy rate is high, and positions are vacant for long periods. In addition, the employee population is aging and could suffer from a loss of leadership and experience.

40. Government's assessment. The government's assessment of human resource issues in regulatory organizations is consistent with ours. The government has identified major risks in retaining and recruiting inspectors. The Committee of Senior Officials has assessed the government's capacity to carry out its core regulatory and inspection functions. The committee's November 1999 report, A Public Trust: Keeping Canadians Safe and Healthy, identifies a number of key problems facing these functions. It reveals an aging population, many vacancies, few recruits and high attrition rates in some key areas. The data shows that these problems will become more serious in the next few years.

41. The committee's report notes the following:

- The workload of inspectors has increased dramatically, and the cost of training inspectors is high. For example, Transport Canada can spend up to $150,000 and take up to two years to fully train an inspector.

- The government is competing for scarce human resources in a highly competitive market. Key specialists in some diseases command salaries of over $200,000 in private practices. In areas such as aviation and marine engineering, the wage gap between the public and private sectors now exceeds 40 percent. It is unlikely that the government will be able to bridge gaps of this magnitude.

- Career progression is done through promotions to management, but this path is not always the best one for scarce expertise.

- There is concern for the status of personal liability of inspectors and the damage that their decisions could cause. Uncertainty has made some inspectors adopt an extremely conservative approach to risk management.

42. The report notes that the regulatory and inspection community is much older than the public service as a whole and that it has a high departure rate due to high retirement eligibility. As well, based on historical trends, significant non-retirement departures can be expected. Recruits are almost entirely from outside the public service, which maximizes competition with industry. Due to unique accreditation requirements, there is also low mobility between regulatory programs.
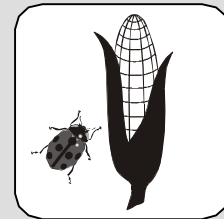
43. The report notes that by 2008, about 40 percent of the regulatory and inspection community will be eligible to retire, compared with 33 percent for the public service as a whole. However, it points out that certain inspection groups have a higher rate of projected retirement eligibility. For example, the rate for the group that deals with the food standards regulation is about 48 percent.

44. The report also notes that the role of inspectors has changed significantly. Traditionally, government inspectors examined processes and products, assessed their safety and took required action or designed the rules that must be followed to reduce risks to acceptable levels. Now they educate industry, encourage change, monitor activities and enforce regulations. This current role aims to build expertise in industry and to increase the probability that industry will operate within regulations.

45. The report points out that the new educational and monitoring functions are far more complex for the inspector. The inspection community has found it difficult to interpret the meaning in their operational context of the client service vocabulary, which has been prevalent in the government. Competencies now required of inspectors also include a range of soft skills to teach, monitor activities, encourage changes in attitude and develop new competencies in the industry client.

Cost Recovery

46. Background. Health and safety regulatory programs recover a portion of their operating costs from regulated industries. Information indicating the proportion of program funding that is based on cost recovery is not readily available. We estimate that health and safety regulatory programs collected about $154.6 million in 1997-98. Depending on the legislation, these funds can be re-spent by regulatory authorities, or they become part of government general revenues.

47. In 1999-2000, the Canadian Food Inspection Agency collected about $54 million (or 13 percent) of its total expenditures of about $416 million. It is authorized to re-spend these funds. Health Canada's Therapeutic Products Programme, which regulates drugs and medical devices, recovered about $40 million (or 63.5 percent) of its total expenditures of $63 million. All of these funds are re-spendable by the department.

48. In 1997-98, the National Energy Board recovered about $24.7 million (or 88 percent) of its total expenditures of some $28 million. These funds became part of the government's general revenues. The Atomic Energy Control Board, now the Canadian Nuclear Safety Commission, collected $30.8 million (or about 70 percent) of its total expenditures of $43.8 million. These funds also became part of the government's general revenues.

49. The federal government states that it will only initiate cost recovery for an activity that is legitimate and necessary, that is not available in the private and voluntary sectors, and that offers identifiable recipients direct benefits beyond those received by the general public. In 1994 the government made cost recovery a priority for departments and agencies. It undertook this initiative, while cutting spending to eliminate the deficit. Fees were introduced for many services previously offered at no cost.

50. Ministers are responsible for implementing and amending user charges in their area of responsibilities. By linking service costs to the fees it charged, the government expected that industry could scrutinize fees to ensure that they were fair and that the services were being delivered efficiently. The President of the Treasury Board is the point of contact for clients who feel that departments have not given them a fair hearing in the fee-setting process.
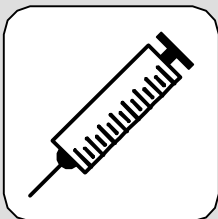
51. The objectives of the cost-recovery policy are the following:

- to promote the efficient allocation of resources;

- to promote an equitable approach to financing government programs, mandatory or otherwise, by fairly charging clients or beneficiaries who benefit from services beyond those enjoyed by the general public; and

- to earn a fair return for the Canadian public for access to, or exploitation of, publicly owned or controlled resources.

52. The policy requires that departments and agencies do the following:

- undertake meaningful consultations with clients throughout the fee-setting process, including the conduct of impact assessments and establishing a dispute-resolution process;

- follow appropriate costing and pricing practices;

- treat all user charge revenues as public funds; and

- spend these revenues only with the prior approval of Parliament and the Treasury Board.

53. Pattern of findings. We have reported to Parliament a range of major concerns about the implementation of the cost recovery policy. We reviewed the implementation of user fees in our 1993 Report, Chapter 25, Parliamentary Control Over the Raising of Revenues by Fees. More recently, we comprehensively reviewed the management of user fees by Agriculture and Agri-Food Canada, the Canadian Grain Commission and the Canadian Food Inspection Agency. The findings in our September 1999 Report, Chapter 11, Agriculture Portfolio — User Charges, illustrate our concerns.

54. The concerns that we reported included instances of the following:

- inadequate legislative frameworks;

- inconsistent cost identification and allocation methods;

- a lack of specific and enforceable guidelines to price services;

- unclear definitions of private and public benefits;

- a lack of co-ordination by central federal agencies;

- a lack of consolidated information for planning and reporting;

- a lack of information on user charges to concerned parties, including fee revenues not published in the annual budget;

- inadequate impact assessments;

- a lack of an open, clear and independent appeal process for those affected by user charges; and

- a need for broader consultation on service charges to take into account the interests of the public and of those who pay fees.

55. As part of the current audit of Health Canada's regulatory regime for biologics, we examined cost recovery for reviewing biological drugs. Since 1994-95 the Department partially recovers from the manufacturer the costs of reviewing biological drugs for market approval. The drug industry expected that cost recovery would help the Department meet established performance targets of shorter duration. However, we did not find clear objectives linking cost recovery and shorter approval times. For new biological drugs approved in 1999, the Department took an average period of 328 days (compared with a performance target of 180 days) to review priority-status submissions and 545 days (compared with a performance target of 300 days) to review non-priority status submissions.

56. In its recent evaluation of the cost-recovery initiative, the Department found that it is difficult to separate public and private benefits of cost recovery for biological drugs.

57. Report of the Standing Committee on Finance. In June 2000 the House of Commons' Standing Committee on Finance published its review of cost-recovery in government, Challenge for Change: A Study of Cost-Recovery. The committee examined whether the Treasury Board's cost-recovery and charging policy is being implemented consistently in the government and whether the Board's policy is sound. The concerns of the committee are similar to ours.

58. The committee found that the policy generally conforms to sound economic practices. However, government departments are not implementing the policy consistently, and central supervision and dispute resolution is ineffective or absent. The committee raised concerns that user fees are perceived as a tax, rather than prices for services, and that departments do not seem to be following the guidelines originally set out in the cost-recovery program.

59. The committee also reported that some groups are concerned about the potential threat to the integrity of regulatory programs because of the reliance of regulatory authorities on cost recovery for funding.

60. The committee concluded that a government-wide assessment of the cost and benefits of user fees is needed. Treasury Board Secretariat officials told the committee that a review of the cost recovery policy is under way and should be completed by the winter of 2001.

Compliance and Enforcement

61. Background. Regulations set legal process or requirements for industries involved in activities that affect health and safety. To be in compliance, a company must meet these requirements. To ensure compliance, regulatory programs need to ensure that those who must comply with the laws understand what is expected of them and that the laws are enforced in a fair, predictable and consistent way. Regulations have to contain provisions that are consistent, understandable, measurable and enforceable.

62. The complexity of enforcement depends on the nature of a regulation. The age of a law or regulation often determines the quantity and quality of compliance information that is available. Some regulations cover an ongoing activity in a specific area, such as the production of pulp and paper. Other regulations may refer to more transient activities that are more difficult to monitor, like the transport and disposal of hazardous waste. Lastly, regulations can impose complex technical requirements; the procedures to verify compliance with these requirements can also be complicated.

63. Compliance and enforcement also are areas significantly affected by technological changes, pressures from economic

competitiveness, insufficient human resources, public scrutiny and reliance on collaborative arrangements with the provinces and territories.

64. Inspection programs verify compliance with the laws and their regulations. A plan identifies the type and frequency of inspections and monitoring activities that have to be conducted. The plan usually considers priorities, historical problems, operational factors and regional variability. Inspections can also take place in response to specific incidents.

65. Departmental policies or procedures list a number of actions that can be taken to remedy situations of non-compliance. These actions range from verbal and written warnings to criminal prosecutions. According to the report of the Committee of Senior Officials, A Public Trust, regulatory authorities are increasingly focussing on achieving compliance by seeking conformity with the law through educational programs, the encouragement of technology transfers and self-evaluation.

66. Pattern of findings. Our previous audits revealed recurring weaknesses in compliance and enforcement, including the following:

- unclear objectives for compliance with legal and policy requirements;

- inadequate identification of the regulated community, an ineffective process for determining the companies to inspect, and inconsistent inspection coverage of the regulated community;

- a lack of using risk assessment to focus inspection activities;

- inadequate information on the incidence of non-compliance and related consequences;

- inadequate implementation of audit and inspection programs with results fed into performance measures;

- insufficient random inspections to detect and prevent incidents of non-compliance;

- over-reliance on voluntary compliance with limited verification to demonstrate that this reliance is justified; and

- an absence of national reviews to ensure that different regions use consistent procedures.
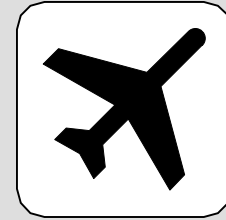
67. Our current audits continue to find deficiencies in ensuring compliance with health and safety regulatory requirements. For example, the Canadian Nuclear Safety Commission's compliance and enforcement framework is incomplete. It needs to promptly develop outstanding regulatory documents and implement its compliance and enforcement policy.

68. For problems of non-compliance, the Canadian Food Inspection Agency's policy requires that inspectors take action to ensure compliance in the shortest time frame and to prevent the problems from recurring. Our review of a sample of cases noted that the compliance actions were not sufficient to achieve the Agency's goal because of limitations in legislation or a failure by the inspector to take more serious compliance action.

69. Our audit of Health Canada's regulatory regime for biologics contains findings about establishments that process and distribute semen for assisted conception. These findings illustrate the risks posed by incomplete inspection approaches. In June 1996 Health Canada implemented regulations governing these establishments. However, it started to monitor and inspect them only in March 1999. Although an accreditation process and inspection regime was intended to be part of the 1996 regulatory framework, these activities did not occur. There were no plans established before 1999 for the inspection of semen processing facilities, nor were there any standard operating procedures for inspection.

70. In March 1999 problems identified by an Ontario human semen bank initiated a national investigative inspection by Health Canada of all known semen establishments that following summer. The Department found that 43 of the 51 establishments under investigation did not fully comply with the regulations. Of these 43, 17 did not perform the required tests for specific infectious diseases and more than half did not maintain sufficient records for Health Canada to

determine that they had done the required tests. As a result, the Department detained much of the semen supply for assisted conception in Canada, which created considerable anxiety among recipients.

71. Although problems continue to exist in health and safety regulatory programs, there have been improvements. In April 1999 Health Canada established a program to inspect all known semen establishments, and it began to formulate and test standard operating procedures for investigative inspections. In addition, the Department has given formal training to compliance officers to ensure that they have the necessary knowledge and skills to do their work. At the Canadian Food Inspection Agency, four of the five alternative service delivery arrangements for animal and plant health have devoted considerable attention to monitoring, controlling and auditing compliance. Transport Canada's Air Navigation Services and Airspace Branch has completed over 150 audits and inspections to date and identified 130 findings and observations. The Branch's enforcement actions have included counselling, monetary penalties and license suspensions.

Reporting on Effectiveness

72. Background. The Treasury Board requires departments to prepare performance reports in the fall of every year. The reports, as part of the government's Main Estimates, are tabled in the House of Commons and referred to the appropriate standing committee. They are intended to provide information on achieved results. Some federal entities have legislated reporting requirements, such as the Canadian Food Inspection Agency which is required to report performance in its annual report.

73. Pattern of findings. Our previous audits of reporting on the effectiveness of health and safety regulatory programs identified serious weaknesses, such as the following:

- a lack of specific requirements for reporting;
- an inconsistency and incompleteness of data;

- an absence of common protocols to measure and estimate incidents to make results comparable;
- an insufficient verification of actual results; and
- a lack of performance indicators to support statements of achieved results.

74. Our audits also identified instances where Parliament was not adequately informed:

- On the results of national efforts on smog reduction, Parliament did not receive meaningful, comprehensive and timely information about action on the promises made to Canadians in 1990.
- On the results of agreements under the *Canadian Environmental Protection Act*, Parliament received incomplete and outdated information.
- On the achievement of program objectives for the disposal of hazardous waste, Parliament did not receive information on actual spending, achieved or likely achievable results and constraints.
- On federal food safety activities, Parliament did not receive a description of the objectives of the federal food safety system, the roles of involved departments, and the results achieved;
- On the animal and plant health inspection program, Parliament received inadequate information to understand and assess the program's performance and response to serious outbreaks of diseases and pests.
- On nuclear power plants and licenses for prescribed substances and radioisotopes, Parliament received limited information on licensing actions and the number of compliance inspections.

75. Our current audit findings continue to find deficiencies in reporting on effectiveness. For example, The *Canadian Food Inspection Agency Act* requires the Agency to prepare a corporate business plan and an annual report to Parliament. The business plan must specify objectives and expected performance against these objectives. The 1997-2000 plan contains only limited information on milestones, time frames, expected level of effort, and measures of goal achievement. The information provided is not adequate because it does not allow Parliament and the public to determine how well the Agency is performing.

76. The Canadian Nuclear Safety Commission, like other nuclear regulators, has had difficulty in reporting performance. While its annual report contains many measures, the Commission needs to develop meaningful performance expectations and report measures within a clear context and strategy.

77. Transport Canada has made progress in reporting on effectiveness by publishing annual reports of the Air Navigation Services and Airspace Branch. However, significant deficiencies exist in ensuring the quality of the safety data. In 1997 we indicated that Transport Canada should conduct formal reviews of the quality of the air safety data that it receives from NAV CANADA. The Department has still not conducted or planned any formal review of such data.

78. The incident rate for losses of separation (the spacing required between aircraft) is a primary indicator of safety performance for an air navigation service provider. To be useful for both management and accountability purposes, it is critical that this data be timely and correct. The Department has not yet reconciled the reports of the Civil Aviation Daily Occurrence Reporting System (CADORS) with data from the incident-reporting system operated by the Transportation Safety Board of Canada. Further, the Department's audit regime for NAV CANADA does not include tests of the completeness and accuracy of the CADORS reports by reference to primary sources (radar and voice tapes). An other jurisdiction that has carried out these tests has found that self-reporting systems tend to understate the occurrence of incidents.

24.89 This economic emphasis also appears in the most recent revision of the policy in November 1999. The policy requires regulatory authorities to minimize adverse impacts on the capacity of the economy to generate wealth and employment and to impose no unnecessary regulatory burden. In addition, the authorities must ensure that information and administrative requirements are limited to what is absolutely necessary and that they impose the least possible cost; the special circumstances of small businesses are addressed; and parties proposing equivalent means to conform to regulatory requirements are given positive consideration.

24.90 The study of cost recovery by the Standing Committee on Finance raises a concern for the effect of cost recovery on the priorities of health and safety regulatory programs. The concern is that the government's policy on cost recovery to fund regulatory efforts may be creating a potential conflict between the public interest and the interest of private organizations that are paying fees to help fund regulatory programs. For example, the committee was told about concerns regarding the effect of cost recovery on the drug review process. The Auditor General told the committee that "as there is a greater dependency on fee recovery, a client-provider relationship could be established, and in some areas that may not be entirely healthy." He indicated that there is a need for direction on how to avoid potential conflict of interest.

24.91 The government has focussed on introducing the concept of client service as a public service value. A Public Trust: Keeping Canadians Safe and Healthy, the November 1999 report of the Committee of Senior Officials, reviews the consequences of this concept for the inspection and regulatory community. The report notes that adoption of the concept

"has been driven by a wide range of government initiatives and directives, providing a pervasive message to all public servants." It also reviews the difficulties that the community encountered in implementing this direction. The report concludes that a key issue for the community was "the need to shift the language for this group away from the 'client service' vocabulary, towards a discussion of 'Protecting the Public Interest'." The clarification is also needed because government is often both a regulator and, directly or indirectly, a promoter of the industries that it regulates.

24.92 Our October 2000 Report, Chapter 12, Values and Ethics in the Federal Public Sector, and the 1996 Report of the Task Force on Values and Ethics in the Public Service (Tait Report) raise concerns about giving client service equal or more emphasis than the public interest.

24.93 By clarifying the priorities of its policies, the government may also address the continuing concerns that stakeholders have about the regulation-making process. While transparency in decision making is required, the government needs to determine whether these concerns stem from its cost-recovery policy and its consultation process, which is encouraging expectations that cannot be met. For example, it needs to ensure that it is not raising the expectation that regulatory authorities are accountable to industry and other stakeholders.

24.94 **The federal government should explain to Canadians and the government's regulatory and inspection community its priorities for health and safety regulatory programs, particularly the balance that the government has reached to protect Canadians and address budget, social, economic and trade objectives. The government should revise its regulatory policy and other policies to reflect this emphasis.**

Many of the difficulties faced by regulatory authorities can be attributed to a lack of comprehensive systems to identify risks.

24.95 Many of the difficulties faced by regulatory authorities can be attributed to a lack of comprehensive systems to identify risks. Surveillance systems need strengthening and important baseline data needs to be collected, while safeguarding the privacy of individuals. Expert advisory committees can be used as a supplement to direct surveillance or as a substitute in situations where little data exists, such as the effects of new biotechnologies.

24.96 Without these improvements, it will be difficult for regulatory authorities to scientifically assess risk, conduct cost-effective audits and inspections, determine the human resources they need or allocate staff, and assess whether they are achieving objectives or whether their inspection programs are working. As well, the authorities' exposure to liability will become more difficult to manage.

24.97 In the absence of data from surveillance systems to focus the allocation of resources, authorities may have to respond to funding reductions by spreading the cuts across activities. New regulatory problems may further strain resources, for example, the monitoring of new medical and biological technologies, such as transplants of animal tissue to humans and the prevention of microbial contamination of food.

24.98 The lack of a sound risk identification system means that health and safety regulatory programs are vulnerable to crises and public outrage at regulatory failures. It may also make it more difficult to effectively apply the precautionary principle. As well, there is no solid basis for discussions with industry or special interest groups.

24.99 Government initiatives to improve risk management are in their preliminary stages. The 1997 Report of the Independent Review Panel on Modernization of Comptrollership in the Government of Canada identifies risk management as one of the key elements of

modern comptrollership. In 1998 the Treasury Board Secretariat prepared an action plan to develop a "results-oriented approach to risk management."

24.100 The Privy Council Office is leading a task force to design a comprehensive framework for the application of the precautionary principle. The objective of this initiative is to improve the predictability, credibility, and consistency of precautionary approaches, which would ensure adequate, reasonable and cost-effective application of the principle. This framework is needed to guide regulatory authorities on how to incorporate the precautionary principle into their risk identification and management procedures. Seven interdepartmental working groups have been established to look at key issues, such as the scientific basis for applying the principle, transparency, accountability and public involvement. The Privy Council Office expects to present an endorsed government position on the precautionary principle by the spring of 2001.

24.101 The Department of Justice is responsible for a legal risk management initiative. The objective of its work is to develop a framework for managing litigation that will minimize overall costs to the government. From the fall of 2000 to 2003 the Department is designing and implementing a framework and identifying the need for further work.

24.102 These initiatives will help upgrade policies on risk identification and management in the government. However, we believe that without a major effort to improve surveillance systems and obtain baseline data, the initiatives will not be successful. The development of more reliable and comprehensive databases on the prevalence of health and safety risks will require substantial human and financial resources. To this end, the Privy Council Office, the Treasury Board and the regulatory authorities could jointly

identify necessary improvements and resources.

24.103 As part of the effort to enhance the capability of regulatory authorities to identify and manage risks, we believe that there now is a need for providing organizational stability and rebuilding programs based on risk assessments. In recent years some major health and safety regulatory programs have seen their funding reduced. They also have undergone major reorganizations to improve their effectiveness. In many instances, these changes have been accompanied by loss of expertise due to downsizing. Further, health and safety regulatory authorities face a major loss of staff in the near future, and they may have great difficulty in competing with the private sector for new expertise.

24.104 The federal government should ensure that regulatory authorities have a sound capability to identify risks to health and safety, in particular effective surveillance systems, databases and risk assessment methodologies.

24.105 The federal government should strengthen health and safety regulatory programs by basing the allocation of funding and staffing on risk assessments.

24.106 The federal government should take major steps to help regulatory authorities manage the difficult human resource issues that they face.

Safeguarding the credibility of science in government

24.107 The public's confidence in government's use of science and technology to protect the health and safety of Canadians has been shaken by recent crises. The continued lack of sound impact assessments of proposed and existing regulations also undermines the credibility of government science. Without credible science, health and safety regulatory programs can be challenged as untrustworthy sources of information and subservient to political policy or special interests.

24.108 To enhance the credibility of regulatory efforts, the government has established advisory committees of independent experts to provide advice. For example, the Canadian Biotechnology Advisory Committee advises ministers on the ethical, social, economic, regulatory, environmental and health aspects of biotechnology and examines the potential benefits and risks of emerging biotechnology. It also raises public awareness and engages Canadians in discussions on biotechnology. In establishing the committee, the government pointed out that "advisory committees are increasingly the way of the future in biotechnology, and Canada joins forward-thinking countries such as the [United States, the United Kingdom] and the European Union, in adopting this approach."

24.109 These committees help to enhance the credibility of science in government (see our October 2000 Report, Chapter 12). They could also be used to advise parliamentarians, ministers and departments on identifying priorities and objectives for risk reduction, developing or improving risk assessment methodologies, assessing the effectiveness of regulatory programs, and other matters.

24.110 The credibility of science in government has also been damaged because the government has not established effective recourses for scientists to voice concerns in good faith. These recourses are needed when a scientist believes that regular departmental mechanisms are insufficient and that the public's health and safety is at risk. In September 2000 the Federal Court, referencing a Supreme Court decision, decided that public servants can publicly express concerns when the government is engaged in illegal acts or if government policies jeopardize the life, health or safety of the public. The court raised

The public's confidence in government's use of science and technology to protect the health and safety of Canadians has been shaken by recent crises.

two caveats: the criticism should not have an impact on a public servant's ability to perform effectively, and other avenues of redress have to be exhausted.

24.111 We believe that public servants should not be put in the position where they believe that their only recourse is to express their concerns publicly. Matters of ethical concern need to be effectively and honestly addressed in an organization. But to do so, the avenues must be clear, effective and trustworthy. We suggested in our October 2000 Report, Chapter 12, that the government establish recourse mechanisms to allow for public servants to intervene in good faith. We believe that such mechanisms will enhance the credibility of health and safety regulatory programs.

24.112 To enhance the scientific independence and credibility of health and safety regulatory programs, the regulatory authorities should expand the use of independent expert scientific advisory committees.

24.113 The federal government should revise the requirements of its regulatory policy to incorporate the best practices of using these committees.

24.114 The federal government should establish standards for conducting risk analysis, particularly for measuring and comparing risks.

24.115 The federal government should ensure that regulatory impact assessments are conducted objectively, using the best available procedures.

24.116 The federal government should establish avenues for recourse to allow employees of federal health and safety regulatory authorities to voice concerns in good faith about risks to health and safety.

Increasing public dialogue

24.117 The government cannot eliminate risks entirely. In some areas, individuals may choose to expose themselves to risks and, government intervention to protect them may be unwanted or may violate their legal rights. Nonetheless, public concern for health and safety risks plays a major role in regulatory decisions. Crises or regulatory failures heighten these concerns.

24.118 It is important to recognize that the concern of citizens and experts for risks may differ. In general, expert assessment of risks is based on several, often unstated, assumptions that include the following:

• public policy focusses on reducing risks to an acceptable level;

• statistics on the level of death and injury may be used to define acceptable levels of risk; and

• public policy focusses on the allocation of scarce resources to save the most lives and avert the most injuries, starting with the most serious.

24.119 In contrast, public concern for risks usually involve assessments that use more personal factors. The focus is on the actual or potential death or injury of family and friends, not statistics. The public asks whether the death or injury was preventable, and if so, why did the responsible authority, often the government, not take the necessary preventive action.

24.120 The increasing adoption of the precautionary principle reflects public pressure on the government to prevent, eliminate or reduce risks, even though scientific evidence may be incomplete and major costs may be incurred.

24.121 Because of the potential differences between public and expert assessments of risks and the growing use of the precautionary principle, the government needs to clearly explain its regulatory policies to Canadians. In recognition of the need to be more transparent and to involve Canadians in

government decision making, the Privy Council Office and the Treasury Board Secretariat are preparing a new policy on consultation and citizen engagement. Solving health and safety regulatory problems requires more citizen engagement.

24.122 To help Canadians make choices, the government needs to give them general information on the nature of risks, its definition of risk management, the way it is applying the precautionary principle, and how it is maintaining the credibility of science-based regulation. The government also needs to explain that focussing on one set of risks may involve the diversion of financial and expert resources from other regulatory tasks perceived as equally important.

24.123 For specific risks, the government will need to focus on "risk communication" — providing information, particularly when there is an imminent risk to health and safety, on the scientific data available, the potential for injury or loss of life and the costs and benefits of government intervention.

24.124 For example, it is envisioned that the Canadian Biotechnology Advisory Committee will publish documents on specific topics of interest, particularly in newly developing areas, to give Canadians factual, balanced information. As well, the committee will be expected to ask Canadians for their views on specific issues during public consultations.

24.125 The government may also have to address increasing demands for consultation on approvals for individual products, rather than consultation only on regulations that apply to a group of products. Meeting the demands for such consultation will require difficult trade-offs between ensuring health and safety and slowing down the regulatory process.

24.126 The federal government should effectively consult Canadians and provide them with information on what is involved in reducing health and safety risks and what the government means by risk management and the precautionary principle.

Increasing accountability for interdepartmental co-operation

24.127 The 1995 Report of the Clerk of the Privy Council to the Prime Minister on the Public Service of Canada recommends more effective ways to manage working relationships between departments.

24.128 The report noted that the public service must develop ways to better address horizontal, cross-cutting issues, including implementing the right system of incentives and accountability — one of the major challenges. Finding ways to effectively address horizontal issues is a difficult task. The report observed that public service practice in this area has not lived up to the concepts of interdepartmental collaboration that are professed, and a better job must be done.

24.129 We have described an accountability framework for partners that work to meet common objectives (see our Commissioner's 2000 Report, Chapters 5 to 8, Partnerships for Sustainable Development). The framework includes credible reporting, effective accountability mechanisms, transparent processes and protection of the public interest. We have noted that productive working relationships are not easily developed or maintained. They require special effort by all parties.

24.130 Increasingly, it is being recognized that unilateral action of one department cannot solve many major regulatory problems in health and safety. Departments share responsibilities for many regulations. The achievement of one entity's objectives depends on the co-operation of others. For example, the Biotechnology Ministerial Co-ordinating

Increasingly, it is being recognized that unilateral action of one department cannot solve many major regulatory problems in health and safety.

Committee addresses issues that cut across the mandates of seven federal ministers.

24.131 The responsibilities of ministers and their departments are stated in legislation. However, there is also a responsibility to serve the broader public interest. As the 1996 Report of the Task Force on Managing Horizontal Policy Issues concludes, "it is these collective responsibilities, which transcend individual mandates, that challenge ministers and their departments to look beyond their narrow interests and to recognize the interdependence of many policy issues."

24.132 The task force recognized that a significant cultural shift would be needed to manage issues where the achievement of objectives depends on interdepartmental co-operation. In the report, it indicated that this undertaking "requires a long-term commitment and consistent actions supporting co-operation, collegiality, and collaboration within and across government. If priority files are managed horizontally, there will be a shift in the Public Service culture towards horizontal approaches. If they are not, real and lasting change is unlikely."

24.133 To encourage this cultural shift, the task force recommended the following:

- senior management and central agencies need to ensure that support for interdepartmental collaboration and teamwork is consistently part of their communications and is reinforced in planning and decision making;

- performance contracts and appraisals of executives and policy staff need to include a section on teamwork and the promotion of team-based approaches as an ongoing priority; and

- an aptitude for and experience in collaborative policy development need to be recognized as an important criterion for promotion and recruitment, particularly at senior levels.

24.134 Many major objectives of health and safety regulatory authorities can only be achieved with interdepartmental co-operation and action. Therefore, we believe that these authorities are good candidates for implementing the recommendations of the task force and for developing the right system of incentives and accountability called for by the Clerk of the Privy Council.

24.135 The government could begin by identifying objectives that require significant co-operation among departments to be achieved. A significant part of appraising the officials of these regulatory programs could include whether or not they have reached these joint objectives. As well, the government could annually report on the overall effectiveness of regulatory programs.

24.136 The federal government should identify major health and safety objectives that, to be achieved, require significant interdepartmental co-operation and ensure accountability for achieving them.

24.137 The federal government should submit an annual report to Parliament on the overall effectiveness of health and safety regulatory programs and the extent to which they have the necessary financial and human resources. This report should include an assessment by lead regulatory authorities on the achievement of objectives that require significant interdepartmental co-operation.

24.138 The performance of senior managers of each contributing regulatory authority should be assessed based on the extent to which joint objectives are achieved.

Encouraging federal-provincial co-operation

24.139 Under the Constitution and in practice the federal government often shares responsibility for the protection of health and safety with the provinces. The

problems in achieving co-operation and accountability at this level are well known. It is for the most part a political challenge.

24.140 However, co-operation is fast becoming mandatory, rather than a matter of choice. Increasingly, risks are of a global nature and multinational action is required. Standards and regulatory approaches among countries are being harmonized through trade treaties or international agreements. This trend means that Canadian regulatory authorities need to co-operate to effectively present a Canadian position in international exercises for setting standards. For these reasons, it is in the interest of all parties to work together and to participate in the development of collaborative arrangements on national health and safety issues. The trend also means that the process of risk identification, cost-benefit analysis and impact assessment has to begin well before international standard setting exercises if Canadian representatives are to be provided with the best objective information. It is also important that departmental experts be present at these exercises.

24.141 The federal government should develop collaborative arrangements with the provinces and territories to reduce risks to the health and safety of Canadians and assess the achievement of joint objectives. The arrangements should also allow for the effective development of a Canadian position in international work-sharing and standard-setting exercises.

Conclusion

24.142 Health and safety regulatory programs are encountering major challenges. They have undergone major reorganizations, funding reductions that have been partly reinstated, and they face major problems in retaining and recruiting

needed expertise. They also operate in an environment of increasing legal liability, greater reliance on third parties to set regulatory standards and a growing need to ensure that Canada's approach to regulation is consistent with international trends.

24.143 At the same time, the credibility of regulation based on science is being questioned because of recent major regulatory failures and may be in increasing conflict with the growing application of the precautionary principle.

24.144 In this environment, we are concerned about our recurring findings that health and safety regulatory programs are encountering major difficulties in meeting the expectations of the government's regulatory policy. To meet these expectations action is required government-wide as well as by regulatory authorities. This chapter focussed on the need for government-wide action.

24.145 The government needs to explain how it is balancing the objective of protecting the health and safety of Canadians with other social, economic and trade objectives. Major improvements in the structure and implementation of health and safety programs are needed government-wide. For example, the government needs to identify and manage risks to health and safety, ensure that sufficient expertise is available, provide sound assessments of the impact of proposed major and existing regulatory actions, promote joint accountability for significant objectives that require interdepartmental co-operation, and report on the effectiveness of the programs.

Privy Council Office's response:
Protecting the health and safety of Canadians is a core responsibility of the government. This responsibility is exercised through statutes adopted by Parliament which state the government's obligations, objectives and standards in this regard.

Major improvements in the structure and implementation of health and safety programs are needed government-wide.

The government adopted the regulatory policy to support ministers and Cabinet in making informed decisions on the development and implementation of regulations which are in the best interests of Canadians. The principles and requirements stated in the regulatory policy have been applied by the government, subsequently endorsed by the Organization for Economic Co-operation and Development, and followed by other jurisdictions in formalizing their own regulatory governance regimes.

While it believes the regulatory policy is sound, the government shares the Auditor General's concern and has recognized the need to ensure that regulatory authorities have the capacity to meet the expectations of the policy — to properly develop and to appropriately implement regulations and regulatory programs. As evidenced in this audit, the government already has identified many of the issues raised and undertaken significant good work to address these shared concerns. In particular, the government is committed to strengthening risk management, monitoring and reporting on the effectiveness of federal regulatory programs, and ensuring the continued integrity of our health and safety programs.

The government is pleased with the recognition by the Auditor General of the

good practices which exist within departments and agencies. The government will build on this work by continuing to identify and disseminate best practices in such areas as managing risks; using advisory committees and a range of public policy instruments; measuring outcomes; and communicating and consulting with Canadians.

Clear and appropriate lines of accountability exist for reporting through Parliament to Canadians on the effectiveness of federal health and safety programs. Each minister is accountable to Canadians, through Parliament, for the effective and efficient operations of his or her portfolio, and each minister reports to Parliament on their department's or agency's plans, priorities and performance.

Through the Speech from the Throne and federal budgets, the government has articulated a comprehensive set of policies and measures aimed at "building a higher quality of life for all Canadians". Well-designed and well-managed regulations are in everyone's interests, and can contribute to this goal. For this reason, the Government of Canada is constantly seeking ways to improve the effectiveness and efficiency of its regulations and regulatory programs and welcomes this contribution of the Auditor General.

About the Audit

Objectives

We undertook this audit to identify trends in approaches to health and safety regulatory programs and the challenges they face. We also wanted to assess the pattern of findings of current and previous audits of how well the government has been implementing health and safety regulatory programs. Our third objective was to make recommendations that would strengthen the broad structure and implementation of the programs.

Scope

Our findings are based on the results of our current audits of food inspection programs, nuclear power plant regulation, the regulatory regime for biologics of Health Canada, and follow-up audits of animal health and plant protection, safety regulation for the air navigation system of Transport Canada, and onshore pipeline regulation. They are also based on audit findings from previous Reports of the Auditor General and the Commissioner of the Environment and Sustainable Development. As well, we have taken into account the findings of parliamentary committees, government reports and reports of non-government organizations.

Criteria

We used key elements of the government's regulatory policy and the regulatory process management standards to organize patterns of findings on how well the government is developing and implementing health and safety regulatory programs. We looked at the following issues: risk identification and management, consultation and co-ordination, adherence to the government's standards, human resource management, cost recovery, enforcement and compliance, and reporting on effectiveness.

Based on the government's policies, we expected the government and lead health and safety regulatory authorities to ensure that they do the following:

- reliably identify, manage and communicate risks;
- sufficiently consult Canadians and stakeholders and co-ordinate their efforts with other departments;
- adhere to the government's regulatory process management standards;
- obtain sufficient human resources;
- reasonably implement the government's cost-recovery policy;
- enforce regulations; and
- reliably report to Parliament on the effectiveness of regulatory programs.

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Appendix A

Government of Canada Regulatory Policy, November 1999

Policy objective

To ensure that use of the government's regulatory powers results in the greatest net benefit to Canadian society.

Policy statement

Canadians view health, safety, the quality of the environment, and economic and social well-being as important concerns. The government's regulatory activity in these areas is part of its responsibility to serve the public interest.

Ensuring that the public's money is spent wisely is also in the public interest. The government will weigh the benefits of alternatives to regulation, and of alternative regulations, against their cost, and focus resources where they can do the most good.

To these ends, the federal government is committed to working in partnership with industry, labour, interest groups, professional organizations, other governments and interested individuals.

Application

This policy applies to federal regulatory authorities.

Policy requirements

When regulating, regulatory authorities must ensure the following:

- Canadians are consulted and have an opportunity to participate in developing or modifying regulations and regulatory programs.

- Authorities can demonstrate that a problem or risk exists, federal government intervention is justified and regulation is the best alternative.

- The benefits outweigh the costs to Canadians, their governments and businesses. In particular, when managing risks on behalf of Canadians, regulatory authorities must ensure that the limited resources available to government are used where they do the most good.

- Adverse impacts on the capacity of the economy to generate wealth and employment are minimized and no unnecessary regulatory burden is imposed. In particular, regulatory authorities must ensure that information and administrative requirements are limited to what is absolutely necessary and that they impose the least possible cost; the special circumstances of small businesses are addressed; and parties proposing equivalent means to conform to regulatory requirements are given positive consideration.

- International and intergovernmental agreements are respected, and full advantage is taken of opportunities for co-ordination with other governments and agencies.

- Systems are in place to manage regulatory resources effectively. In particular, regulatory authorities must ensure the following:
  - the regulatory process management standards are followed;
  - compliance and enforcement policies are articulated, as appropriate; and
  - resources have been approved and are adequate to discharge enforcement responsibilities effectively and to ensure compliance where the regulation binds the government.

- Other directives from Cabinet concerning policy and law making are followed such as the Cabinet Directive on Law-Making and the Cabinet Directive on the Environmental Assessment of Policy, Plan and Program Proposals and the Cost Recovery and Charging Policy.

Appendix B

Federal Regulatory Process Management Standards: Compliance Guide

1.   Finding evidence of a problem

1.1   Policies, procedures and practices are in place to ensure detection of actual or potential problems.

1.2   All problems detected are properly defined and described.

1.3   Problems are analyzed to fully understand their nature and implications.

1.4   The absolute and relative health, safety and environmental risks associated with potential problems are assessed and compared, and risk management principles are used to set priorities for regulatory changes.

1.5   Interested parties are consulted on the nature of the problems and on potential solutions.

1.6   Consultation is proportional to the degree of risk and public acceptance associated with the regulatory actions proposed.

1.7   Documentation is concise and affected parties can understand it easily.

1.8   Government intervention is justified as a result of problem identification and definition, analysis and consultation.

2.   Identifying and reviewing alternative solutions

2.1   The analyses of alternative solutions show that new regulatory requirements, be they new regulations or changes to existing ones, will help solve the problems.

2.2   Regulatory solutions based on performance requirements are considered as alternatives to prescriptive standards.

2.3   When possible, positive consideration is given to proposals for achieving regulatory objectives by equivalent means. When such proposals are not accepted, the reasons are fully documented and are explained to the proposer.

3.   Analyzing benefits, costs and regulatory burden

3.1   Benefit-cost analyses are carried out on possible solutions to identified problems. The analytical effort is proportional to the related risks being addressed.

3.2a   The benefit-cost analysis considers both direct and indirect benefits and costs, and considers impacts on the environment, government, business, workers, consumers and other sectors of society. The total gross costs of regulatory proposals are estimated.

3.2b   The impacts of potential solutions on sustainable development are assessed and recommended solutions balance environmental, economic and societal goals.

3.3   Regulatory proposals are brought forward when benefits clearly outweigh costs. When this is not the case, a full explanation and justification is given for exceptions.

3.4   For regulations addressing health, social, economic or environmental risks, the relative net benefits of actions are considered. [Regulations] with the greatest net benefit are the regulatory proposals brought forward first. When this is not the case, a full explanation and justification is given for exceptions.

3.5   Analyses are undertaken on the burden [that] alternative regulatory proposals impose.

3.6   The specific effects of regulatory burden on small business are considered, and their particular circumstances and business practices are taken into account.

3.7 The [business impact test] or equivalent is used to analyze and compare the anticipated impacts of major, alternative regulatory solutions on business.

3.8 Recommended solutions minimize the regulatory burden and impose the least costly information and administrative burden on those regulated.

3.9 There is a verification system to ensure that all feasible alternatives to regulations are fully considered; that full consideration is given to equivalent means of achieving regulatory objectives and to performance-based options; and that the regulatory burden is kept to a minimum.

4.   Identifying opportunities for intergovernmental co-ordination

4.1 Effective relationships are maintained with provincial and foreign regulators and procedures are in place to obtain information from them, as necessary.

4.2a The regulatory environment of the problem area is understood; particularly, [it is known] what regulations exist, which levels of government are involved and who the responsible regulatory authorities are.

4.2b Regulatory solutions are developed with the existing regulatory environment in mind and are co-ordinated with existing regulatory requirements to maximize efficiencies and to avoid overlap and duplication.

4.3 Recognized Canadian and international standards are referenced in regulations when appropriate, rather than [supplemented with] a new, duplicate set of standards.

4.4 Interdepartmental and intergovernmental agreements clearly define the roles and responsibilities of each party, the objectives of the regulatory program, enforcement policies, and mechanisms to promote inter agency co-ordination.

4.5 Regulatory personnel is familiar and up-to-date with international and federal-provincial trade agreements and respects their obligations. [It] understands and respects other pertinent agreements.

5.   Implementing the best alternative

5.1 Regulatory programs have specific and clearly documented objectives and goals.

5.2 Compliance policies support the implementation of the regulatory objectives and goals.

5.3 The compliance aspects of major regulatory proposals are designed to minimize the liability of the government.

5.4 Those whose actions are subject to regulations are identified and informed of their responsibilities.

5.5 Compliance objectives are clearly defined and appropriately reflected in operational plans and budgets. Plans and performance expectations are communicated to all enforcement personnel. Fair redress mechanisms exist. Regulatees and products from different jurisdictions are treated equally.

5.6 Regulatory programs have procedures for controlling program delivery.

5.7 Complaint management systems with fair redress mechanisms are in place as appropriate.

6.   Communicating effectively

6.1 Consultation documents and information about the regulatory proposals are clear and all those who may be affected can understand them easily.

6.2a All those potentially affected by a regulatory proposal are given adequate notice of it.

6.2b Regulated parties and others affected by regulations are given adequate information so that they can fully understand the regulations, the regulatory programs and any associated material of direct relevance.

6.3a Information about regulations and proposed changes to regulations appears in the types of media that groups affected by the regulation most often use.

6.3b   The regulatory authority is proactive in reaching its clients and explores new and emerging ways of communicating.

6.4   Managers verify that regulatory information is clear and accessible to interested parties.

7.   [Preparing a] regulatory impact analysis statement (RIAS)

7.1a   RIASs are prepared when regulations are to be written or amended as part of the recommended solution to a problem [or as the whole solution].

7.1b   RIASs are concise, clear and complete. They include information on the problem, the rationale for a regulatory solution, the recommended solution, alternatives that have been considered, the consultation process, and the compliance and enforcement mechanisms to be used.

8.   Consulting stakeholders

8.1a   There are procedures in place for developing and maintaining appropriate relationships with target populations, professional bodies and industry associations to ensure effective and efficient discussion and resolution of issues.

8.1b   There are documented procedures for carrying out consultations, including how consultees are to be identified, contacted and encouraged to participate.

8.2   Interested parties are given clear notification of consultation activities in sufficient time for them to prepare and deliver their input. For complex regulations, consultations start as soon as a potential problem is identified.

8.3   Defining the exact nature of the problem is part of the consultation agenda. Consultations cover alternative regulatory and non-regulatory solutions and the final solution.

8.4   Consultation effort is in proportion to the importance and impact of proposed regulatory changes.

8.5   Consultations clearly identify who should be consulted and what methods should be used to consult with different interest groups. All major interested parties are invited to participate in consultations.

8.6   Alternative consultation methods are used when appropriate, especially if proposed by the people [being] consulted.

8.7   [A business] impact test or equivalent is used [for consultations] on major regulations.

8.8   [Consulted parties] are approached more than once, as necessary, when situations change, when new issues arise or when consultations are out of date.

8.9   All input to consultations is considered and the reasons for not incorporating major suggestions are documented. Feedback is provided to those who contribute to the consultation process on how their ideas are used.

8.10   There is an awareness of the consultation efforts of all levels of government in the areas that are addressed by the regulatory authority, and consultations are co-ordinated when appropriate.

9.   Documenting the process

9.1   The departmental regulatory process is documented and includes objectives, responsibilities, authorities and review requirements.

9.2a   There are procedure manuals for the regulatory process management system.

9.2b   There are procedure manuals for all but the most insignificant regulatory programs.

9.2c   Procedures are kept up-to-date.

9.3   Decisions are clearly documented throughout the process, and an appropriate level of management approves and verifies documents.

9.4   The process for each regulatory initiative is adequately documented. Reasons for not following the [federal] regulatory policy are documented whenever that occurs.

10.   Continuous improvement

10.1   Internal management reviews of the regulatory process are conducted on a regular basis.

10.2   Regulatory program designs are periodically reviewed, and improvements are made as a result.

10.3   There is a system for verifying that managers address problems identified in reviews or by clients.

10.4   There is a system for verifying that staff is suitably trained in regulatory development skills and [that] training is provided when appropriate.

10.5   There are procedures for training staff to ensure that sufficient and properly qualified personnel is available.