

Federal Regulatory Process Management Standards





Federal Regulatory Process Management Standards:

Compliance Guide

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Foreword

This guide, prepared by the Regulatory Affairs Division of the Treasury Board of Canada, Secretariat, is designed to help you assess your compliance with the government's regulatory policy. It gives you tools for evaluating the processes you follow in your department when developing or revising regulations.

Using the guide is not mandatory, nor is the guide prescriptive. It is intended to help you understand the regulatory process management standards, explore alternative ways of meeting them, and satisfy the review and reporting requirements of the Treasury Board.

The guide is divided into two parts. The introduction explains the federal government's regulatory policy framework and the Treasury Board's requirements for departments to review and report on their compliance with standards for managing the regulatory process.

The second part of the guide explains the standards for managing the regulatory process and provides self-assessment checklists to help you determine whether your management systems meet the standards.

Part I Introduction

Framework for the federal regulatory system

The Treasury Board is responsible for developing and issuing the government's Regulatory Policy, which includes the regulatory process management standards. Training courses, seminars and guides are available to regulatory authorities to give them the skills and the flexibility they need to create an effective and efficient national regulatory system. The Policy, training and guides are part of an evolving framework designed to create the best regulatory system in Canada.

By best, we mean a system that

- respects legal and constitutional requirements;
- gives us the most regulatory protection at the least cost to both the private sector and the government;
- promotes a culture of openness and accountability;
- enacts regulations based on input from stakeholders;
- is user friendly, accessible and understandable: and
- is continuously updated and improved.

Key documents explained

The policy: the Regulatory Policy of the Government of Canada, which is designed to ensure that the governement uses its regulatory powers to the greatest net benefit to Canadian society. Regulatory authorities develop, maintain and enforce regulatory programs that follow the Policy.

The standards: the regulatory process management standards which the Treasury Board of Canada, Secretariat developed in 1995, in consultation with departments. They are mandatory "quality assurance" standards for the regulatory process, inspired by the system of ISO 9000 standards. Regulatory authorities must have management systems in place that meet the standards, and must review their performance periodically and report on it to the President of the Treasury Board.

The guides: advisory documents that offer detailed suggestions on developing regulations and managing regulatory programs. Titles include A Benefit-Cost Analysis Guide and Alternatives to Regulation. A list of guides is attached in Annex C to this document.

Federal regulatory policy statment¹

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

Ensuring that taxpayer'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.

Policy requirements

When regulating, regulatory authorities must ensure that

- government intervention is justified, and that regulation is the best alternative;
- · they have consulted Canadians;
- the benefits outweigh the costs to Canadians, their governments and their businesses;
- when managing risks, they allocate resources where they will do the most good;
- they have minimized adverse economic impacts, addressed the special circumstances of small businesses, and considered equivalent means of conforming to regulatory requirements;

- they have respected intergovernmental agreements and coordinated their efforts with those of other governments and agencies; and
- systems and sufficient resources exist to allow them to manage regulatory programs effectively and follow the Management Standards.

Regulatory process management standards

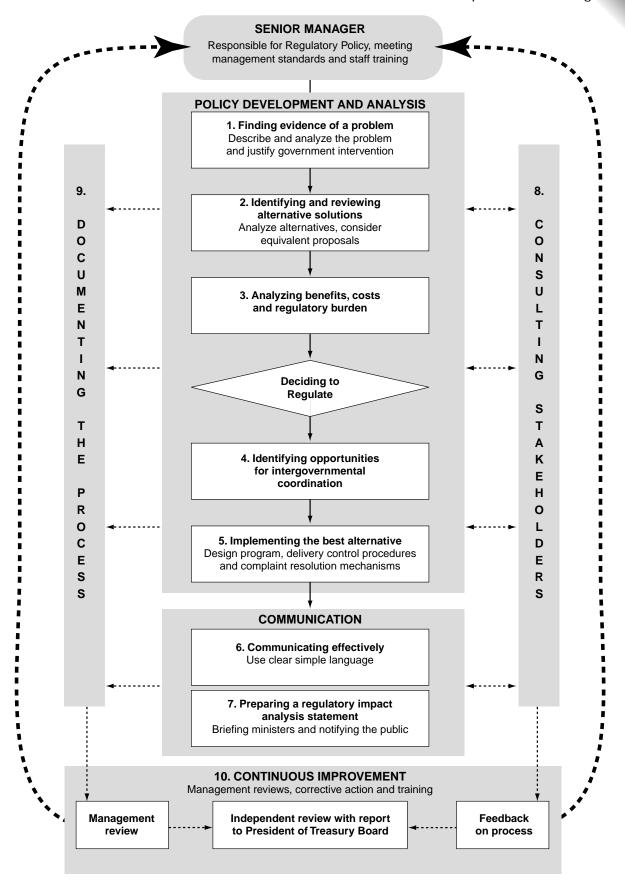
Standards for managing the regulatory process are a new requirement for regulating departments. They are designed to enhance adherence to the Regulatory Policy.

The flow chart that follows illustrates the system for managing the regulatory process. It links the steps involved in managing and continually improving the process for developing regulations.

Departmental compliance with these management standards is expected within the scope of your authority to carry out the various steps involved in developing or amending a regulation. One department may carry out the front-end assessment and analysis of policy alternatives. Another may develop and administer the regulations. Each is responsible for applying and respecting the management standards in their respective roles in the regulatory process.

Efforts in applying the Regulatory Process Management Standards should be proportional to the impact of potential regulatory changes. The greater the impact, the greater should be the effort put into consultations, consideration of alternatives, cost-benefit analysis etc.

Adapted from Regulatory Policy 1995, Treasury Board of Canada, Secretariat, revised November 1995



Summary of the review and reporting requirements

The seven major regulatory departments (see Annex A) will

- implement management systems by December 31, 1996;
- review compliance with the management standards by December 31, 1999;
- report to the President of the Treasury Board on the results of the review; and
- develop, jointly with Treasury Board of Canada, Secretariat, a schedule for subsequent reviews based on risk.

The other regulatory authorities will

- implement management systems by December 31, 1997;
- develop, jointly with Treasury Board of Canada, Secretariat, a schedule of reviews, based on significance of and risk associated with non-compliance with the Regulatory Process Management Standards.

Measurements of significance and risk reflect the magnitude of the possible positive and negative impacts of regulatory programs; the extent to which health, safety and environmental risks are concerned; and the degree of public acceptance. The greater the significance and risk, the earlier the management system controlling a regulation should be reviewed.

Treasury Board of Canada, Secretariat, ensures that regulatory authorities review and report on their adherence to these standards in the appropriate time frame. To achieve this, we will offer guidance and follow up on a timely basis, to ensure that regulatory authorities complete reports and meet deadlines.

Review process

Within the established time frame your organization must review its regulatory process and report to the President of the Treasury Board, that it has met and applied the management standards.

Those conducting the reviews must

- be independent of departmental regulatory units; that is, they must report to a different senior manager;
- be qualified and trained to do this work;
- prepare a review plan setting out scope, approach, criteria and review program; and
- complete all work so that others can draw an appropriate conclusion on the organization's adherence to the Standards.

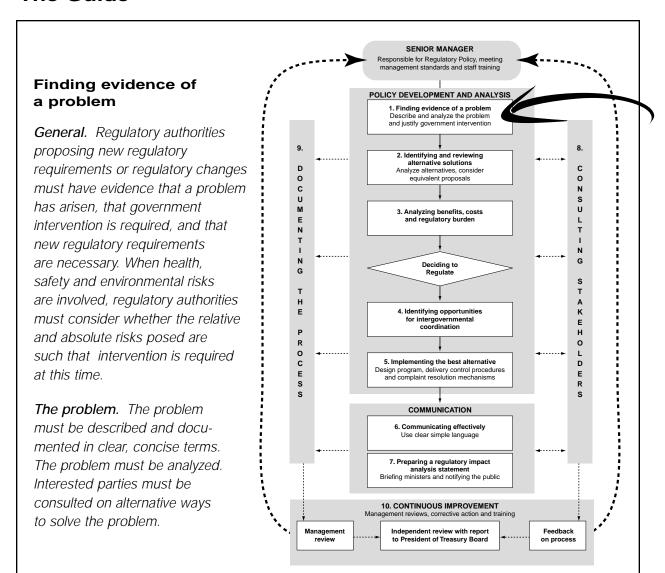
Reports should be clear and complete; state deviations, rationales and recommendations when appropriate; make conclusions regarding adherence to Standards; and include best practices when appropriate.

Working papers should

- substantiate the reported results by providing evidence that the regulatory authority has or has not met a standard, or the rationale for deviations; and
- provide details of any assumptions made, including alternative approaches.

To ensure accountability, managers at the appropriate level should review and sign working papers and reports.

Part II The Guide



Discussion

This part of the standard deals with the preliminary step in government intervention, namely a thorough understanding and definition of the problem. Various players in a situation may create a problem. To solve the problem, government wants to change these

behaviours. It can do so by strengthening the incentives to do the right thing and reducing the disincentives.

Regulation is one policy tool government uses to encourage or change behaviour. However, regulations are expensive to develop and enforce and can create economic barriers for

business. Therefore, government must ensure that it establishes and maintains regulations when a demonstrated need exists and when regulations are the best solution to a problem. This is why you must thoroughly analyze and understand the problem at the outset.

To do this well, authorities should get input from stakeholders on the nature of the problem. If, at the start, people are uncertain about the exact nature of the problem, they will be concerned in the future about the appropriateness of the solution selected. Throughout this document we stress the need for good mechanisms for consulting with stakeholders. We suggest that you start discussing the nature and extent of the problem with stakeholders early in the process, before even beginning to think about how to solve it.

Document the problem and ask the various players in the initiative to confirm the specific wording so there is no room for misunderstanding, and all parties can refer to written material at later stages of the regulatory process.

Self-assessment checklist

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

- ✓ Are procedures in place for monitoring the regulatory environment for potential problems?
- ✓ Is there a system in place to respond quickly to important new problems as they arise?

1.2 All problems detected are properly defined and described.

✓ Are there procedures for ensuring that a problem, that may be addressed by regulation, is clearly and comprehensively described? ✓ Are advisory documents used to help define the problem, such as Assessing Regulatory Alternatives Section 1 (Treasury Board of Canada, Secretariat 1994)?

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

- ✓ Are actual and potential problems analyzed, their risks assessed and affected parties identified?
- ✓ Is public perception of problems part of the systematic analysis, where appropriate?
- ✓ Are available advisory documents used to establish the analytical framework for investigating problems? These documents include:

Technical Guide to Regulatory Impact Analysis, Section 1 (Treasury Board of Canada, Secretariat 1994);

Assessing Regulatory Alternatives, Part 2 (Treasury Board of Canada, Secretariat 1994);

Q850 Risk Management: Guidelines for Decision Makers (Canadian Standards Association, 7th draft, 1996); and

- ✓ Is there a system in place for verifying that authorities adequately evaluate and understand identified problems?
- ✓ Is there a procedure for verifying that all the relevant, cost-effective information on a problem is collected?

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.

- ✓ Are regulatory priorities set for your department or agency as a whole, and are they based on risk management principles and available resources?
- Are the regulatory priorities of your whole organization reviewed and verified on a periodic basis?
- ✓ Is there a process in place for ensuring regulatory development, analysis and resources are focused on the highest priority problems and does this process involve senior management?

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

✓ Are there procedures for carrying out consultations at this stage of the regulatory development process, which confirm the nature of problems and increase the degree of public acceptance of solutions?

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

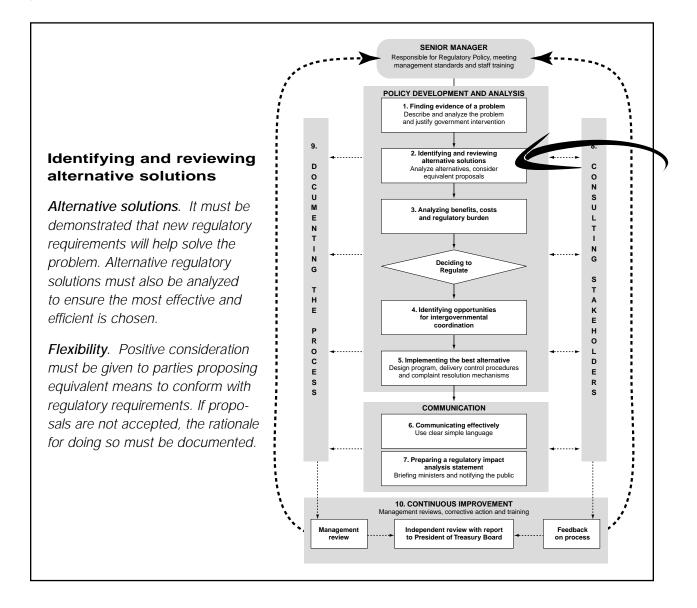
- Are consultations extensive enough for problems with high risks and low public acceptance?
- ✓ Are consultation efforts proportional to the impact of potential regulatory changes?

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

- ✓ Are documents that identify and analyze the problem shared with stakeholders?
- Is the documentation written in a style and language that stakeholders can easily understand?
- ✓ Do all parties agree on the way the documentation defines and describes the problem?

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

- Does the analysis and the results of your consultations indicate that the problem warrants more detailed study?
- ✓ Do you document your definition of the problem, your consultations with interested parties, and the conclusions of your preliminary analysis?
- ✓ Do program managers have sufficient information for determining whether government intervention is justified and if alternative solutions should be explored?



Discussion

You need to be creative when looking for the least disruptive and least expensive way to get the result you seek, and you should not assume that regulations are the only solution. Both regulatory and non-regulatory tools can solve problems or create incentives or disincentives to influence how people or firms act. Sometimes you can best achieve your objective by implementing a combination of regulatory and non-regulatory solutions.

Consider proposals from regulated parties that offer an equivalent way of meeting a regulatory requirement. You must try to accommodate those proposals if you have the legal means to do so, or, consider changing the legal framework.

Regulations written with a lot of prescriptive detail limit the way regulated parties can meet regulatory objectives. In many situations, there may be more than one way to meet these objectives. Avoid writing regulations with a lot of inflexible detail or you may needlessly increase costs, prohibit innovation, and prevent the use of more efficient technologies.

Generally, you should focus instead on desired results or performance requirements, and give regulated parties flexibility in achieving them. Many regulatory authorities are moving to performance-based regulations.

Self-assessment checklist

- 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.
- ✓ Do you consult on alternative ways to solve problems, including non-regulatory solutions?
- ✓ Do you systematically consider alternative instruments for changing behaviours, including regulatory and non-regulatory ones?
- ✓ Do you identify and fully consider noninterventionist alternatives?
- ✓ Do you use the advisory document Assessing Regulatory Alternatives, (Treasury Board of Canada, Secretariat, 1994) to help develop the analytical framework for assessing alternative solutions?
- ✓ Do you use the advisory document Designing Regulatory Laws that Work, (Department of Justice, 1994), or A Guide to the Making of Federal Acts and Regulations, (Department of Justice, 1996) to develop the analytical framework for identifying and assessing the form of regulatory programs?

- ✓ Do you use the advisory document Benefit-Cost Analysis Guide for Regulatory Programs, Chapter 2 (Treasury Board of Canada, Secretariat, 1995) to screen regulatory and non-regulatory alternatives?
- ✓ Are the comparative advantages of alternatives assessed in terms of legality, effectiveness, efficiency, fairness, intrusiveness, visibility, timeliness and responsiveness?
- ✓ Are preliminary assessments done on alternative regulatory solutions in terms of their approximate benefits and costs, their impact on the environment and interest groups, and their ability to solve problems?
- ✓ Is there a system in place to verify that regulatory solutions help solve the problems they are supposed to address?
- ✓ Does management have sufficient information to determine whether the most efficient and effective regulatory solutions are recommended?
- 2.2 Regulatory solutions based on performance requirements are considered as alternatives to prescriptive standards.
- ✓ Does your regulatory process ensure that you consider performance-based regulatory solutions?
- ✓ Is there guidance to help regulators developing regulatory proposals to incorporate performance goals rather than prescriptive requirements?

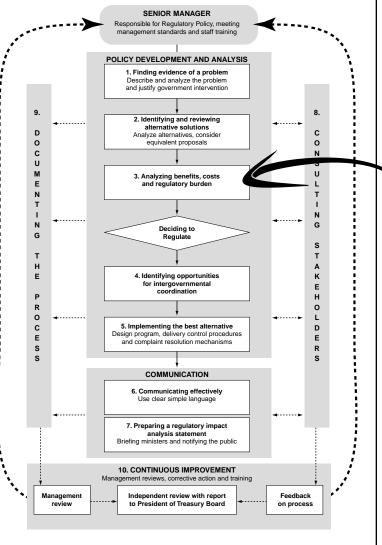
- 2.3 When possible, positive consideration is given to proposals for achieving regulatory objectives by equivalent means. When such proposals are not accepted, the reasons are fully documented and are explained to the proposer.
- ✓ Do senior management and the Minister have clear policies that support flexible regulatory initiatives and responsiveness to legitimate concerns of regulated parties?
- ✓ Are procedures in place for reviewing proposed regulations in terms of their flexibility and their responsiveness to changing technologies, changing regulated parties, and changing market conditions?
- ✓ Do you give high priority to proposals from regulated parties for equivalent means of achieving desired results and do you accept them when appropriate?

- ✓ When you do not accept proposals for achieving regulatory objectives by equivalent proposals, do you document your reasons and explain them to the proposer?
- ✓ Do you systematically encourage regulated parties to identify equivalent means of achieving regulatory objectives and then make these available to others as appropriate?
- ✓ For regulations affecting manufactured products, is full consideration given to using good manufacturing practice standards, which focus on how a product is designed, produced and serviced? Are equivalent proposals from industry in this area considered?

Analyzing benefits, costs and regulatory burden

Benefit-cost analysis. It must be demonstrated that the benefits of regulatory requirements are greater than their costs. When regulations address health, social, economic or environmental risks, it must also be demonstrated that regulatory effort is being expended where it will do the most good. For all regulatory proposals, a benefit-cost analysis must be carried out to assess potential effects, such as impacts on the environment, workers, consumers and other sectors of society. The Business Impact Test, or equivalent analysis, must be undertaken to assess the effect that major regulatory proposals will have on Canadian businesses.

Regulatory burden. It must be demonstrated that adverse impacts on Canada's sustainable development - this concerns the long run capacity of both the economy and the environment to generate well-being, wealth and employment for Canadians - are minimized and



that no unnecessary regulatory burden has been imposed. Information and administrative requirements should be limited to what is absolutely necessary and impose the least possible cost on regulatees. The impact of additional regulatory burden on small businesses in particular must be considered, and the least burdensome but effective alternative for their circumstances should be chosen.

Discussion

You must clearly understand the gross costs of regulations, which are a good measure of a regulation's importance to society as a whole. Conduct benefit-cost analyses on alternative solutions and alternative regulatory proposals, using an effort proportional to the potential

impact of the alternatives. Government resources are becoming more and more limited, so you should make full use of risk management techniques for your regulations to have the greatest positive impact.

In general, do not use regulations to solve problems if the costs that those regulations impose, whether direct or indirect, are greater than the benefits of the regulations. If you use regulations when it is unclear whether benefits exceed costs, then you must fully document your reasons.

For significant regulatory proposals that could have an impact on the business community, use the Business Impact Test (BIT), or equivalent analysis, so that you can understand the specific affects on business operations. The BIT requires a structured dialogue between industry and government; consequently, it is also a helpful consultation tool. Consultation is an important component of the Regulatory Policy.

You must clearly understand what your regulatory proposals will cost those affected. For example, small businesses, such as those employing fewer than 50 full-time employees, have fewer resources than larger companies making it harder to digest and adjust to new rules. You should limit the extra work and expense caused to small businesses and to other regulated parties.

For instance, you can try to align administrative requirements as closely as possible to standard business practices, information systems and accounting procedures, to reduce the need for parallel systems in businesses. Check that your requirements do not contradict those that firms must meet for other authorities or governments. Also, you should explore opportunities for sharing information with other authorities, rather than collecting information for yourself only.

Self-assessment checklist

- 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.
- ✓ Are benefit-cost analyses systematically carried out for regulatory proposals and their alternatives, including the status quo?
- ✓ Are there procedures for ensuring that the amount of analysis conducted is reasonable when compared to the significance of the problem being addressed and the potential impact of solutions being considered?
- 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.
- ✓ Are benefits, both direct and indirect, systematically taken into consideration? Are costs similarly considered? Are the benefits and costs for identifiable and significant groups, such as consumers, labour, or industry, considered?
- ✓ Are impacts on the environment fully considered?
- ✓ Are total gross costs always estimated and documented?
- ✓ Is there a system in place to ensure that affected groups are consulted?

- ✓ Are the long-run impacts of major regulatory proposals² on economic productivity and on the functioning of important ecosystems systematically analyzed?
- ✓ Is the benefit-cost analysis structured according to practised techniques, for example as outlined in the *Benefit-Cost Analysis Guide for Regulatory Programs*, (Treasury Board of Canada, Secretariat, 1995)?
- ✓ Is there a system in place to verify the results of major benefit-cost analyses using third-party reviews?
- 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.
- ✓ Does your departmental regulatory policy require that benefits outweigh costs for both new and existing regulations?
- ✓ Do you fully document your justification for proposed regulatory measures where the benefits do not clearly exceed the costs?
- ✓ Do program managers have access to sufficient information to allow them to make informed decisions about net benefits?

- 3.4 For regulations addressing health, social, economic or environmental risks, the relative net benefits of actions are considered. Those 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.
- ✓ Is there a system in place for assessing the risks posed by problems and for comparing the risks posed by problems, to ensure that effort is focused on the most important problems?
- ✓ Are the risks associated with regulatory proposals systematically assessed, and used as a criterion in selecting costeffective solutions?
- ✓ For regulatory actions that are not your top priority on the basis of risk, do you have a process to fully justify your reasons for proceeding?
- 3.5 Analyses are undertaken on the burden alternative regulatory proposals impose.
- ✓ Are there procedures for ensuring that the burden of regulatory proposals is explicitly considered from the start when developing regulatory proposals?
- ✓ Is the cumulative burden of federal regulations known, so that the total cost of information, administrative, and compliance requirements can be considered when reviewing proposed changes?

² A regulation is classified as **major** if it has a present value of costs greater than \$50 million or if it has a present value of costs between \$100,000 and \$50 million and a low degree of public acceptance.

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

- ✓ Do you have a system for ensuring that you consult small businesses?
- ✓ Are structures of businesses that may be affected by proposed regulatory change well researched, understood and documented.
- ✓ Are impacts on small business addressed as a high priority and special circumstances and needs of small businesses taken into account?

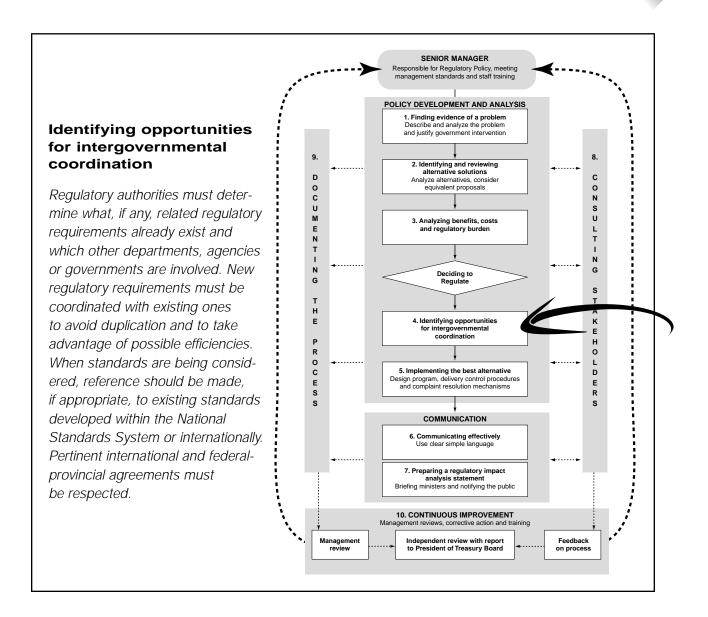
3.7 The Business Impact Test (BIT) or equivalent is used to analyze and compare the anticipated impacts of major, alternative regulatory solutions on business.

- ✓ Is the BIT or equivalent analysis used for proposals with a present-value gross cost of more than \$50 million and those with a lower present-value gross cost that have a low degree of public acceptance? If not, are the reasons why clearly documented?
- ✓ Have you considered impact of the of the regulatory proposal on the workplace using the Workplace Impact Test (WIT) or an equivalent tool?

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

✓ Are measures taken to minimize the burden, to ask only for necessary information, to coordinate information requirements with other government agencies when appropriate, and to minimize costs to business?

- 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 the regulatory burden is kept to a minimum.
- ✓ Is there a system in place to verify that a range of reasonable alternatives to regulations and alternative forms of regulation have been examined and given full consideration?
- ✓ Burden is difficult to assess. Can you verify that both clients and government agree the information on burden is reasonable?
- ✓ For major regulatory proposals, do your procedures require you to thoroughly analyze the benefits and costs, assess risk, consult with stakeholders and analyze the impact of a variety of alternatives before recommending a solution?



Discussion

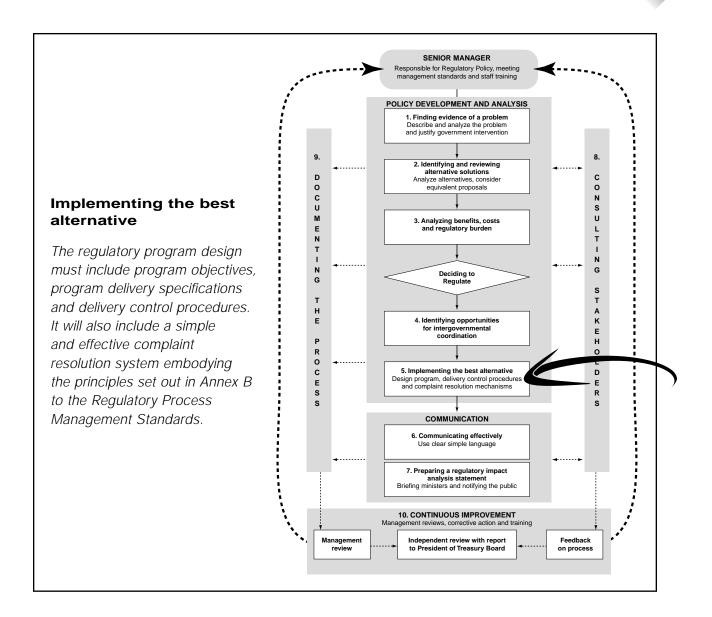
Differing or conflicting regulatory standards at international, federal and provincial levels greatly frustrate regulated parties. You should be aware of what other levels of government are doing and collaborate with them, right from the earliest stage in the regulatory process.

Collaboration can help you find out about different approaches other regulators are using. Before writing new regulations you should also see if there are any existing national or international standards you can use to avoid reinventing the wheel.

Self-assessment checklist

- 4.1 Effective relationships are maintained with provincial and foreign regulators and procedures are in place to obtain information from them as necessary.
- ✓ Are there ongoing communications with regulators in provincial governments and those of other countries in order to understand the nature of regulations in other jurisdictions?
- ✓ Are the advisory documents used when appropriate? For example *Regulatory Cooperation between Governments*, (Treasury Board of Canada, Secretariat 1994) and *International Collaboration: Options for the Regulation of Potentially Dangerous Products*, (Treasury Board of Canada, Secretariat 1992)
- 4.2a The regulatory environment of the problem area is understood, particularly 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 coordinated with existing regulatory requirements, to maximize efficiencies and to avoid overlap and duplication.
- ✓ Do you review proposed regulations for consistency with the requirements of other governments in Canada and abroad?
- ✓ When proposing regulatory change, do you systematically consider the cumulative burden of the regulations of all levels of government on business, especially small business?
- 4.3 Recognized Canadian and international standards are referenced in regulations when appropriate, rather than including a new, duplicate set of standards.

- ✓ Are there procedures to identify equivalent regulatory standards of major trading partners and to ensure they are considered when developing Canadian regulations and standards?
- ✓ Where proposed Canadian standards differ from those in other countries, is the difference justified and fully documented?
- 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 coordination.
- Are interagency agreements designed to anticipate and foster regulatory coordination?
- ✓ Do you have a system for verifying that other governments are achieving their agreed-upon obligations when different levels of government share regulatory responsibilities?
- 4.5 Regulatory personnel are familiar and up-to-date with international and federal-provincial trade agreements and respect their obligations. They understand and respect other pertinent agreements.
- ✓ Does your management system ensure that your regulators are familiar with their obligations under international (such as the World Trade Organization and North American Free Trade Agreement) and Canadian agreements (such as the Agreement on Interprovincial Trade)?
- ✓ Are proposed technical regulations systematically reviewed to ensure fairness in the treatment of products from different jurisdictions?



Discussion

Framework for Managing Regulatory
Programs, a document published by the
Regulatory Affairs Division of Treasury Board
of Canada, Secretariat, discusses in more
detail ideas such as program objectives, specifications for delivering programs and procedures for controlling program delivery. We
encourage you to read this document.

For both the regulation you are enacting and the larger regulatory initiative of which it is a part, you should have a detailed and precise statement of the *general objectives* of the program, as well as the more specific goals that the program is meant to achieve.

Specifications for delivering programs will describe how your activities will meet your program objectives.

Ensuring compliance with regulations is an objective common to all regulatory programs, and the Regulatory Policy stresses it. For this reasons, we expect the specifications for delivering programs to include a compliance policy. Its complexity and scope will depend on the nature of the regulation. For more substantive regulations, the compliance policy will be a comprehensive and detailed plan of the methods you will use to get people to comply with the law.

This plan must be well-crafted, given recent judicial pronouncements that redefine the potential liability of government agencies for failing to enforce regulations.

You should apply the enforcement provisions of regulations reasonably and responsibly, with penalties proportional to the seriousness of the infraction. Fair and appropriate redress mechanisms should be in place, giving people a reasonable opportunity to respond to demands, assessments, or allegations of wrongdoing.

Procedures for controlling program delivery allow you to ensure that your activities help you meet your goals. These procedures

- identify key activities in different parts of your program;
- analyze these key activities and identify characteristics or indicators that you should measure and control to ensure that you reach your regulatory objectives;
- define methods for evaluating the chosen characteristics; and
- change or control the characteristics.

Self-assessment checklist

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

- ✓ Is the advisory document *Framework for Managing Regulatory Programs*, (Treasury Board of Canada, Secretariat, 1992) used?
- ✓ Are there procedures to ensure that clear and comprehensive regulatory program objectives and goals are developed?
- ✓ Do the regulatory program goals explicitly incorporate improved efficiency, enhanced service delivery and regulatory reform?
- ✓ Is there a system in place for measuring whether goals are being met?

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

✓ Does the compliance policy support the implementation of the objectives and goals of the regulatory program?

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

- ✓ Does the compliance policy clearly specify enforcement standards? Is there a system for ensuring that these standards are being met?
- ✓ Is there a system for ensuring that regulations are enforced reasonably and responsibly?
- ✓ Are reviews of compliance procedures used to minimize the potential liability of the government?

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

- ✓ Do you clearly articulate compliance and enforcement policies and make them accessible to regulators, regulated parties, program beneficiaries and the Canadian public?
- 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.
- ✓ Do you have a mechanism for reviewing the compliance specifications of regulations?
- ✓ Are punishments proportional to the infraction?
- ✓ Is there an information system that provides intelligence on the state of compliance with key regulatory activities and are there adequate procedures for handling cases of non-compliance?

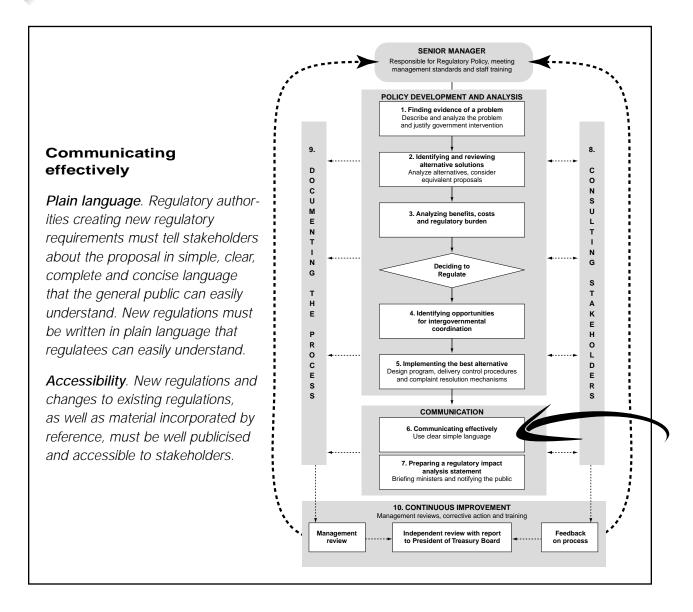
5.6 Regulatory programs have procedures for controlling program delivery.

Are service standards developed for program commitments, including measures of accessibility, completeness, response times and accuracy?

- ✓ Are services evaluated against the standards to help improve service where necessary?
- ✓ Are there controls for ensuring that program activities meet program objectives.
- Are there adequate resources for the program and are program personnel adequately trained?
- ✓ Are performance indicators systematically used to measure the results of interactions with clients, for example, when monitoring compliance or managing complaints?

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

- ✓ Is there a complaints management system in place? Is it accessible, available in both official languages, simple, timely, fair, confidential, effective, and capable of giving feedback to the regulatory program? (Refer to principles in Annex B.)
- ✓ Can the system for managing complaints handle international and intergovernmental complaints related to assessing products' conformity to standards and other regulations?



Discussion

If you can describe the problem and the alternative solutions in clear, simple language, it will show your audience that you have a well thought-out approach. It will also make it easier for your audience to understand and respond to your request.

Making regulations easier to read and understand are some of the benefits of using plain language techniques to write regulations.

However plain language is not a practical option in all cases. You cannot, for example, insert a plain language amendment into a conventionally drafted regulation. However, you should write new regulations in plain language or take advantage of major amendments to put a regulation into plain language.

Before they become law, new regulations generally appear twice in the Canada Gazette; that is the minimum requirement for communicating new regulations to interested parties.

Depending on the circumstances, you can use any combination of information dissemination tools, including newspapers, trade journals, newsletters, and, increasingly, more modern tools such as the Internet to inform those who must obey the new regulation.

Self-assessment checklist

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

- ✓ Are there people involved in developing regulations who are trained in writing plain language documents?
- ✓ Do you use the advisory documents to write in plain language? For example Developing Regulations: The Basic Steps in the Plain Language Approach (Field-tested Edition) Department of Justice and Treasury Board of Canada, Secretariat (1996) or Plain Language, Clear and Simple, (Multiculturalism and Citizenship Canada, 1991).
- ✓ Is there a system for verifying that the final regulation is understood by those affected?
- ✓ Do you have a system for reviewing and confirming public documents related to regulation development are understood by the consultees?

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.

- ✓ Are there communications guidelines for regulators?
- ✓ Do you have procedures for ensuring that you know who your client group is for regulatory initiatives, and that you know what communications methods you need to use to keep them up to date on your regulatory plans?
- ✓ Do your procedures clearly state that proposals for new and changed technical regulations that may affect international trade must be prepublished in the Canada Gazette for at least 75 days?
- 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.
- Do communications plans include actions for advertising the nature and implications of significant new regulations?
- ✓ Do you explore new avenues for communication with clients?

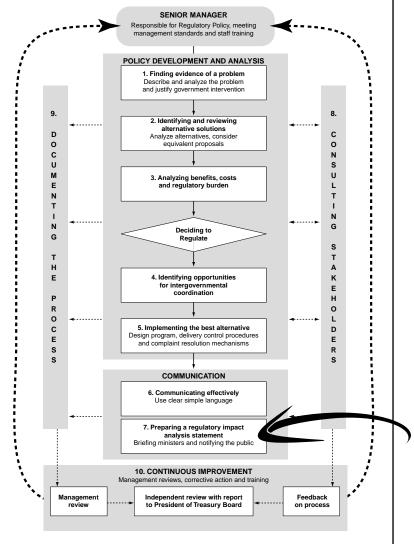
6.4 Managers verify that regulatory information is clear and accessible to interested parties.

- ✓ Are there procedures in place to give management assurances that affected persons know about and understand proposed regulatory requirements?
- ✓ Is feedback on the accessibility of regulation-related information solicited from clients?

Regulatory impact analysis statement (RIAS)

When a regulatory impact analysis statement is required, the document must

- describe the problem and explain why regulation is required;
- provide a clear and precise description of the regulatory proposal;
- outline the alternatives considered and the reasons for choosing to regulate;
- describe the major anticipated impacts;
- summarize the consultations undertaken; and
- explain the procedures and resources that will be used for compliance and enforcement.



Discussion

When you recommend a regulatory solution to Ministers, you need to prepare a regulatory impact analysis statement (RIAS). It is used by Ministers to approve regulations. A companion guide to this one provides assistance to regulators on how to obtain ministerial approval for the various types of federal regulations.

It is called *Federal Regulatory Process*. *Procedures for submitting regulation for ministerial approval* (Treasury Board of Canada, Secretariat, 1996 draft).

The RIAS must also be published in the Canada Gazette to notify stakeholders of what the government is going to do. The RIAS describes the regulatory proposal, how Canadians have been consulted, the benefits and costs of the proposal, and what other alternatives were considered.

The Treasury Board of Canada, Secretariat, has also published a guide for writing RIASs and courses are available on this subject.

Self-assessment checklist

- 7.1a RIASs are prepared when regulations are to be written or amended as part or all of the recommended solution to a problem.
- 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.
- ✓ Is the advisory document used, Regulatory Impact Analysis Statement: Writer's Guide, (Treasury Board of Canada, Secretariat 1992)?

- ✓ Are there people involved in developing regulations who are trained in writing RIASs?
- ✓ Do you have a system for ensuring that the RIAS comprehensive and complete?
- ✓ Are RIASs written in plain language that the general public can easily understand?
- ✓ Do your procedures require that you discuss all draft RIASs with Regulatory Affairs at Treasury Board of Canada, Secretariat, before going for Ministerial approval?
- ✓ Do you systematically seek feedback from clients on the usefulness of RIASs published in the *Canada Gazette*?

Consulting Stakeholders

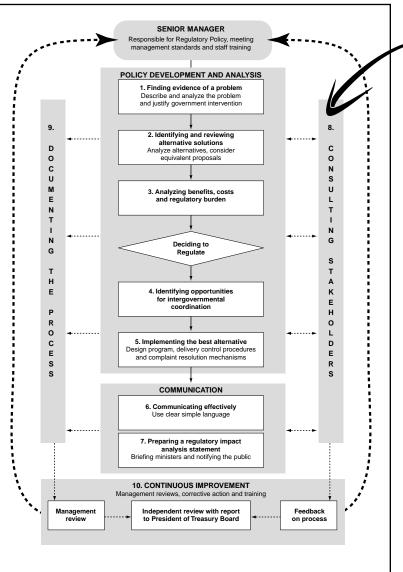
Full consultation and notification.

Regulatory authorities proposing new regulatory requirements, or changes to existing regulatory requirements, must carry out timely and thorough consultations with interested parties. The consultation effort should be proportional to the magnitude of the impact of the proposed regulatory change. Notice of proposed regulations and amendments must be given so that there is time to make changes and to take comments from consultees into account.

Timeliness of consultations.

Consultations should begin as early as possible in order to get stakeholder input on the definition of the problem, as well as on proposed solutions.

Consultation process. Regulatory authorities must clearly set out the processes they use to allow interested parties to express their opinions and provide input. In particular, authorities must be able



to identify and contact interested stakeholders, including, where appropriate, representatives from public interest, labour and consumer groups. If stakeholder groups indicate a preference for a particular consultation mechanism, they should be accommodated, time and resources permitting. Consultation efforts should be coordinated between authorities to reduce duplication and burden on stakeholders.

Regulatory authorities should consider using an iterative system to obtain feedback on the problem, on alternative solutions and, later, on the preferred solution.

Discussion

Full consultation with stakeholders is a critical element of the Regulatory Policy. It appears in many of the management standards because input from people affected by regulations improves the regulations. The best timing for consultations varies. It can be at the legislative change stage, if the major impacts will come from the law rather than the regulations themselves. Timing is left to your discretion.

Timeliness is part of the standard. In many cases as early as possible means as soon as you have a problem and are considering a regulatory solution. Input from stakeholders can be very useful in defining the problem and its environment. Consultation that you start when you have already defined the problem and chosen a preferred solution is not timely.

The Treasury Board of Canada, Secretariat, through its quality service initiative, has prepared a guide on client consultation and the Privy Council Office has published a set of guidelines on best consultative practices.

Final regulatory decisions should reflect the contributions of participating groups or explain why they do not.

You should use the Business Impact Test (BIT) or equivalent for consultation with businesses on major regulatory initiatives. You can use the BIT to record detailed anticipated impacts of regulatory proposals, and as a consultation tool when discussing problems, alternatives and solutions.

Self-assessment checklist

- 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.
- ✓ Is there a written consultation policy?
- ✓ Do you use advisory documents when structuring the consultation process? For example Consultation Guidelines for Managers in the Public Service (1992), Practical Guide to Public Consultations (1993), Privy Council Office or Quality Services Guide 1: Client Consultation (Treasury Board of Canada, Secretariat, 1995).
- ✓ Do you have procedures for consulting with participants on the consultation itself, including the timing, the method, the issues and the way in which input will be incorporated into the final regulatory recommendations to government?
- ✓ Does management verify that suitable consultations are carried out?

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.

- ✓ Do your procedures require that interested parties be clearly notified of consultations sufficiently far in advance?
- ✓ Do your procedures leave enough time between the close of consultations and the submission of recommendations to Cabinet, for you to consider and incorporate input from consultations?

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.

- ✓ Does your consultation policy encourage participants to discuss the nature of the problem, as well as solutions?
- ✓ Do consultations uncover additional possible solutions to problems and help to assess the impacts of each?
- ✓ Does the consultation agenda permit those affected to comment on the final proposed solution?

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

✓ Are there procedures for ensuring that the amount of consultation is reasonable when compared to the significance of the problem being addressed and the potential impact of the solutions being considered?

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.

- ✓ Is the consultation process open, transparent and carried out with mutual respect for the legitimacy and point of view of all participants?
- ✓ Do your consultation procedures ensure that you identify and invite the right people to participate in the consultations?
- ✓ Does the consultation process involve interested parties who can contribute to solutions or who are affected by the problem?

8.6 Alternative consultation methods are used when appropriate, especially if proposed by the people we are consulting.

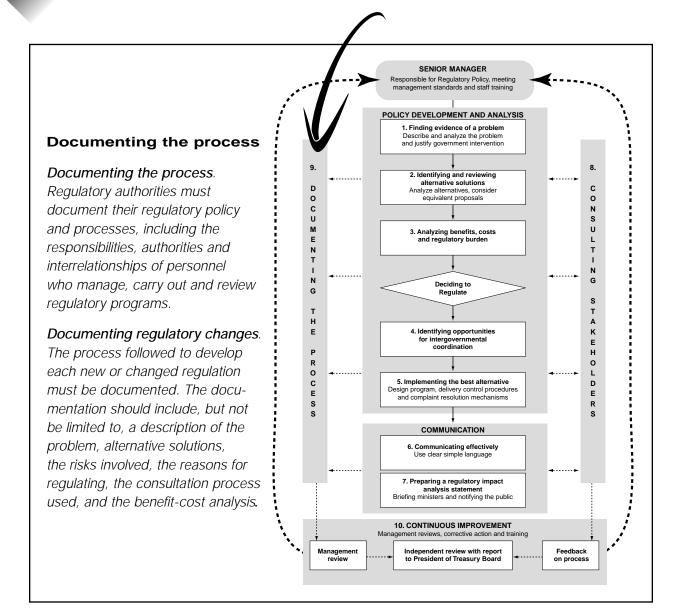
- ✓ Does your consultation policy/approach help you meet the needs of consultation participants who may have limited resources or expertise to participate fully?
- ✓ Do you consider innovative consultation methods when potential participants make suggestions or when they have difficulty participating in traditional ways?

8.7 An Impact Test or an equivalent is used to consult with on major regulations.

- ✓ Does your policy require you to use the Business Impact Test or an equivalent to consult with industry on major regulatory issues?
- ✓ Does your policy require you to use the Workplace Impact Test or an equivalent to consult with labour representatives and workers on major regulatory issues?

- 8.8 Those you consult are approached more than once, as necessary, when situations change, when new issues arise or when consultations are out of date.
- ✓ For more complex regulatory proposals, are the people you consult involved on an ongoing basis as you define the problem more clearly and introduce various regulatory and non-regulatory solutions?
- ✓ Does your consultation process require you to determine whether the public will accept the proposed solution? If the public does not accept it, do you justify the proposed measure?
- 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.
- ✓ Does your consultation process ensure that the comments of participants are considered when developing regulatory proposals?

- ✓ Do you tell participants about decisions you make while developing regulations? Do you give them an opportunity to comment on such decisions?
- ✓ Is feedback on the results of consultations given to participants?
- 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 coordinated when appropriate.
- ✓ Is intelligence gathered on related consultation efforts by other federal departments or other levels of government, and is there a coordinated effort to reduce consultation burden whenever possible?



Discussion

You must write down how you do what you do by keeping up-to-date procedures manuals, so that your employees know what is expected of them and have clear instructions on how to do various tasks.

Documentation is also the record of what you have done. You should keep track of steps in the decision-making process and clearly indicate responsibilities and accountabilities. Without such a record it is difficult to review past actions, to learn from them, and to improve the system for managing your department's regulatory process.

By properly documenting your work, you will also be able to show that you have complied with the Regulatory Policy. Records should be easily accessible.

Self-assessment checklist

- 9.1 The departmental regulatory process is documented and includes objectives, responsibilities, authorities and review requirements.
- ✓ Are departmental regulatory policies written down and available?
- Does the policy clearly identify the senior manager responsible for regulatory activities?
- ✓ Are the lines of authority, the roles and responsibilities, the accountabilities and the relationships of personnel involved in managing the regulatory process clearly documented and available to those working in the system?
- ✓ Are there clear policies or other statements to employees that demonstrate that senior management and the responsible minister fully support the government's overall approach to regulation?
- 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.

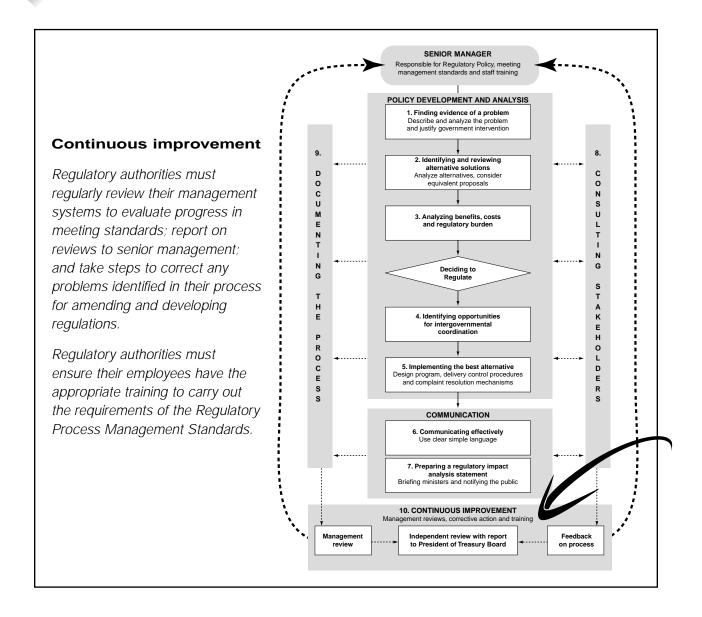
- Are there procedure manuals for regulation-related activities?
- ✓ Are the procedures up-to-date? Do they reflect legislative changes? Do they refer to the 1995 amendments to the Regulatory Policy?
- ✓ Do procedures include references to advisory documents?

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

- ✓ Do your procedures require you to document your decisions throughout the regulatory development process?
- ✓ Is there a system in place to validate the documentation?

9.4 The process for each regulatory initiative is adequately documented. Reasons for not following the Regulatory Policy are documented whenever that occurs.

- ✓ Are there procedures for ensuring you document your regulatory initiatives. These documents should include a description of the problem, alternative solutions, the risks involved, the reasons for regulating, the consultation process used, the benefit-cost analysis, and the gross costs of the regulatory action?
- ✓ When developing a regulation, do you record the assumption you make?
- Is the documentation adequate to provide evidence you have complied with the regulatory process management standards?



Discussion

The standards lay out the requirements for managing the regulatory process well, but are also consistent with overall good management practices. As part of these practices, you should conduct regular internal assessments of performance and policy compliance. This will give senior managers the information

they need to verify that your organization is meeting the requirements of the Regulatory Policy and to implement corrective action if necessary.

The President of the Treasury Board is accountable for the regulatory policy and management standards. As discussed in the introduction, you are responsible for arranging

reviews and sending a copy of the review report to the President of the Treasury Board. By continuously improving your system for managing the regulatory process, you will improve your regulatory program. Continuous improvement will also help you assess your compliance with the Regulatory Policy, determine whether you meet the standards and satisfy the review and reporting requirement of the Treasury Board.

Managing the regulatory process and managing regulatory programs themselves require competent, capable people. With changing technology and evolving business practices, personnel must stay up-to-date with the environment they regulate.

Self-assessment checklist

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

- ✓ Does your management system include regular assessments on whether your regulatory process complies with the regulatory process management standards?
- ✓ Do staff independent from the departmental regulatory units conduct these reviews?
- ✓ Do you use the *Manual on Review,*Internal Audit and Evaluation, Part 1,

 (Treasury Board of Canada, Secretariat,
 1994) used to structure the review process and identify performance measurements?

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

✓ Are risk-based reviews of regulatory programs conducted to determine whether the activities meet the program objectives and service standards? ✓ Are assessments by clients and staff systematically sought and used?

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

- ✓ Are assessment results part of regular management reviews? Are they used to develop recommendations to improve adherence to the standards?
- ✓ Is there a system for ensuring that the results of regulatory program reviews are used to help reach goals and improve services in a timely manner?
- ✓ Does senior management verify that all policy requirements are met and initiate corrective action if needed?
- ✓ Do you use feedback from the complaint resolution system to improve regulatory programs and services?
- ✓ Is there a system to verify these recommendations are implemented?

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

- ✓ Are there policies and procedures for assessing what competencies are required for each job, for assessing the competencies of incumbents and new recruits, and for training personnel when there are knowledge and skills gaps?
- ✓ Can managers verify whether any particular job is done only by trained people?

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

- ✓ Are there sufficient resources to train people involved with regulatory programs?
- ✓ Do your procedures ensure that all employees involved with regulatory issues are aware of the goals of regulatory programs, the role and activities of each part of the operation, the government's overall policy on using regulatory power, and their personal responsibility for helping to meet these goals?
- ✓ Do employees receive training in new techniques and activities before they are required to use those skills on the job?
- ✓ Do you make staff aware of, and provide access to the advisory documents of Treasury Board of Canada, Secretariat, training opportunities provided by the Interdepartmental Best Practices Committee, the Canadian Centre for Management Development and others; and other sources of information?

Annex A Seven major regulatory departments

The following departments must have systems that meet the standards by December 31, 1996, and must arrange a first internal review by December 31, 1999:

- Agriculture and Agri-food
- Environment
- Health
- Industry
- Transport
- Revenue
- Fisheries and Oceans

Annex B Principles for resolving complaints

These principles are designed to ensure that the complaint resolution mechanisms of federal regulatory authorities are simple, clear and well-known.

Such mechanisms should help authorities quickly resolve complaints about program implementation, and increase client satisfaction with federal government regulatory programs and services. Complaint resolution mechanisms that provide information to management will help regulators identify areas where they could improve government services, and will also improve the delivery of regulatory programs and services.

Principles

Federal regulatory authorities must have complaint resolution mechanisms that

- are easily accessible and well-publicized;
- are available in both official languages;
- are simple to understand and use;
- allow speedy handling, with established time limits for action, and that keep people informed of the progress of their complaints;
- ensure a full and fair investigation of complaints;
- respect people's desire for confidentiality;
- provide an effective response and appropriate redress to complainants; and
- provide information to managers so they can improve services

Annex C: Guides and publications

- Assessing Regulatory Alternatives (1994) ¹⁶
- Benefit-Cost Analysis Guide for Regulatory Programs (1995) ^{2 3}
- Colloquium on Risk Management (1994) 28
- Competitiveness and the Design of Regulations (1992) ^{1 2}
- Consultation Guidelines for Managers in the Federal Public Service (1992) ² ⁴
- Designing Regulatory Laws That Work (1994) ⁷
- Developing Regulations: The Basic Steps and the Plain Language Approach Field-tested Edition, (1996) ¹
- Enlightened Practices in Regulatory Programs – Volume 1, Volume 2 (1993, 1994) ^{1 2 6}
- Federal Regulatory Plan ^{1 2}
- Federal Regulatory Policy 1995 1 2 6
- Federal Regulatory Process Management Standards: Compliance Guide (1996) ^{1 2}
- Federal Regulatory Process: Procedures for Submitting Regulations for Ministerial Approval (1996 draft) ^{1 2}
- Framework for Managing Regulatory Programs (1992) ^{1 2 6}
- A Guide to the Making of Federal Acts and Regulations (1996) ⁷
- International Collaboration: Options for the Regulation of Potentially Dangerous Products (1992) ^{1 2 6}

- Managing Regulation in Canada (1996) 12
- Manual on Review, Internal Audit and Evaluation (1994) ²
- Plain Language, Clear and Simple (1991) ⁵
- Practical Guide to Public Consultations (1993) ⁴
- Q850 Risk Management: Guidelines for Decision Makers, 7th draft, (1995) ⁹
- Quality Services: Guide I, Client Consultation (1995) ²
- Quality Services: Guide XI, Effective Complaint Management (1996) ^{1 2}
- Reforming the Federal Regulatory Process in Canada 1971-1992 by W.T. Stanbury ¹
- Regulatory Cooperation Between Governments (1994) ^{1 2}
- Regulatory Review Report 1992-1994 ¹
- RIAS Writer's Guide (1992) ²
- A Strategic Approach to Developing Compliance Policies (1992) ^{2 3}
- Service Standards: A Guide to the Initiative (1996) ²
- Technical Guide to Regulatory Impact Analysis (1994) ¹
- Using the Business Impact Test Effectively (1994) ^{1 2}

They are available as follows:

Regulatory Affairs*
 Treasury Board of Canada, Secretariat
 140 O'Connor Street, 11th Floor
 Ottawa, Ontario K1A 0R5
 Telephone: (613) 952-3459
 Fax: (613) 957-7875

E-mail: RADDAR@tbs-sct.gc.ca

- Available on the Internet at http://www.tbs-sct.gc.ca
- Consulting and Audit Canada (CAC)
 (613) 996-1458 sells this publication
- 4 Communications and Consultation (PCO) (613) 957-5706
- Canada Communications Group Tel: (819) 956-4802

Fax: (819) 994-1498

- ⁶ Available on diskette from Regulatory Affairs
- Department of Justice (Administrative Law Section) (613) 941-1978
- 8 Institute on Governance (613) 562-0090
- Ganadian Standards Association 1-800-463-6727
- * Department and agency officials should call their departmental/agency regulatory coordinator (name and phone available from Regulatory Affairs)