

# **Basic Frameworks for Risk Management**

## **Final Report**

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Prepared by

John Shortreed, John Hicks, Lorraine Craig

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The Ontario Ministry of the Environment



Network *for* Environmental Risk  
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## Objective

This report provides an overview of frameworks for risk management using the NERAM risk management framework as a benchmark for comparison. The report illustrates the design and application of the various components of risk management frameworks by drawing on presentations from the December 6, 2001 NERAM workshop on Basic Frameworks for Risk Management. The report illustrates how a “standard” risk management framework can be adapted to meet the risk management objectives of a range of agencies.

The report provides an evaluation of the Ontario Ministry of the Environment (MOE) Proposed Risk Management Framework for the Air Standard Setting Process in Ontario (MOE, March 2001) through comparison of the existing framework to the NERAM benchmark framework. Strengths, weaknesses and gaps in the MOE framework are identified and discussed.

The report also describes how a risk management framework can support stakeholder consultation processes, as well as new developments in risk management such as the precautionary principle and the population health approach.

### **DISCLAIMER**

**The principles expressed in this document should not be considered to be the official position of the Government of Ontario or of provincial departments and agencies. They are for discussion purposes only.**

## **Risk Terminology (Note: the terms below are identified in the document in italics)**

Source: ISO/IEC Guide 73 (Note: the complete terminology guide can be ordered from IEC at <https://webstore.iec.ch/>)

**consequence** – outcome of an event

**event** – occurrence of a particular set of circumstances

**probability** – extent to which an event is likely to occur

**risk** – combination of the probability of an event and its consequences

**risk acceptance** – decision to accept a risk (Note: risk acceptance depends on risk criteria)

**risk analysis** – systematic use of information to identify sources and to estimate the risk (Note: risk analysis provides a basis for risk evaluation, risk treatment and risk acceptance)

**risk assessment** – overall process of risk analysis and risk evaluation

**risk communication** – exchange or sharing of information about risk between the decision-maker and other stakeholders

**risk control** – actions implementing risk management decisions

**risk criteria** – terms of reference by which the significance of the risk is assessed

**risk estimation** – process used to assign values to the probability and consequences

**risk evaluation** – process of comparing the estimated risk against the given risk criteria to determine the significance of the risk

**risk financing** – provision of funds to meet the cost of implementing risk treatment and related costs (Note: In some industries, risk financing refers to funding only the financial consequences related to the risk).

**risk identification** – process to find, list and characterize elements of risk

**risk management** – coordinated activities to direct and control an organization with regard to risk

**risk management system** – set of elements of an organization's management system concerned with managing risk

**risk transfer** – sharing with another party the burden of loss or benefit of gain, for a risk

**risk treatment** – process of selection and implementation of measures to modify risk

**residual risk** – risk remaining after risk treatment

**source identification** – process to find, list and characterize sources

**stakeholder** – any individual, group or organization that may affect, be affected by, or perceive itself to be affected by, a risk

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## **Executive Summary**

Since incidents such as Bhopal, the Exxon Valdez spill and the Enron collapse, risk management has become a requisite management activity. Like other management activities, risk management helps an organization meet its objectives through the allocation of resources to undertake planning, make decisions and carry out other productive activities. Risk management frameworks are a description of an organizational specific set of functional activities and associated definitions that specify the processes that will be used to manage risks. A good risk management framework should enhance and improve risk management by i) making it more transparent and understandable to stakeholders ii) making its processes more efficient and iii) allowing for sharing of best practice in the implementation of risk identification, risk assessment and risk treatment.

While there are more than 80 frameworks for risk management in existence there is a standard set of basic functions within all risk management frameworks that have been defined in the NERAM benchmark risk management framework. The benchmark framework consists of three basic high level elements: i) operations to reduce risk ii) decision making or corporate management where strategic risk management decisions are made and iii) risk assessment and treatment where risk assessment is carried out and risk management options are identified. These activities are organized in terms of a typical organizational structure including senior management, operations, and policy and program planning. The benchmark framework identifies risk criteria and basic capacity requirements for any risk management function. Each organization must design its own risk management framework, process, roles and responsibilities.

This document captures key concepts and current practice in developing and implementing frameworks for risk management as presented at the December 6, 2001 NERAM Workshop on Basic Frameworks for Risk Management. Presentations by the Ministry of Environment and risk assessment specialists in academia and private consulting illustrate tools and frameworks for population health risk assessment, risk prioritization and air pollution policy development. A multi-stakeholder panel including an environmental non-government organization, industry and government representatives discussed the need to balance science, social and business concerns in risk management and the importance of transparency based on effective stakeholder consultation in ensuring a fair decision-making process. The proposed Ontario Ministry of Environment framework for air standards setting is exemplary in terms of its efforts to build risk communication and consultation into all phases of the decision-making process.

## Introduction

Risk management is becoming an increasingly important activity within firms and organizations. Like other management activities, *risk management* helps an organization meet its objectives through the allocation of resources to undertake planning, make decisions, and carry out productive activities. *Risk management* is unique in that it focuses on uncertainties that an organization faces: uncertainties in the *probability* of occurrence of *events*, uncertainties in the value to the organization of *consequences of events*, and other uncertainties that fall outside the “normally expected” range of variation. Generally *risks* are low *probability*, but high *consequence events* that can cause major disruption to the organization. *Risk management*, like other management activities, must be practical, cost effective, and help the organization survive and prosper. The growth in *risk management* is directly linked to the increasing number of *risks* an organization faces due to more complexity and interactions in the world, greater scrutiny by *stakeholders* and the media, and so forth.

This document is a product of the December 6, 2001 NERAM Risk Management Workshop on Basic Frameworks for Risk Management sponsored by the Ontario Ministry of the Environment. The purpose of the seminar was to foster a common understanding of available *risk management* frameworks through the presentation of various applications of *risk management* frameworks including air standard setting, environmental health risk management, and setting priorities for compliance. Selected material from the workshop is presented in this document to serve as a “primer” on risk management frameworks. This document should be used in conjunction with the NERAM Benchmark Risk Management Framework report (Shortreed, 2001).

Chapter 1 discusses the environment for risk management and provides some basic definitions, to begin the discussion of risk management, risk management frameworks, and risk management systems. The recent ISO/IEC Guide 73 risk terminology<sup>1</sup> is used as a basic set of definitions in this document, and the NERAM Benchmark risk management framework is used as a convenient and comprehensive general framework. For example, the NERAM framework is compatible with the Canadian (CSA, 1997) and Australian risk management standards (AS/NZS, 1999).

The basic elements of any risk management framework are developed in Chapter 2 and illustrated by examples of state of the art frameworks in use around the world, focusing on environmental risk management frameworks. Detailed examples of the elements of risk management are given in Chapter 3 based on the December 6, 2001 Risk Management Workshop presentation.

Chapter 4 of this report introduces principles for the design of risk management frameworks that are derived from elements of the Benchmark Risk Management Framework, but will meet the needs of any particular organization and its risk profile. The framework design principles provide criteria for evaluating risk management frameworks. Chapter 5 reviews the Ontario Ministry of Environment Proposed Risk Management Framework for the Air Standard Setting Process in Ontario (MOE, March 2001) according to the criteria developed in Chapter 4.

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<sup>1</sup> ISO/IEC Guideline terms are identified in italics and defined on page 3.

## Chapter 1 Risk Management Frameworks

This chapter presents an overview of the purpose, function and importance of *risk management* and risk management frameworks in environmental risk management.

### Risk and Risk Profiles

First it is necessary to define *risk* – “*the combination of the probability of an event and its consequences.*”<sup>2</sup> There can be more than one *consequence* from an *event* and the *consequences* can be positive or negative. For safety and environmental risks, most of the *consequences* of interest are negative in value and impact human health in terms of mortality and morbidity risks.

Risks are usually described by a list of risks, arranged in priority order with the largest risks first. For example, the Australian New Zealand standard (AS/NZS, 1999) has a “Risk Register” with the following headings. The example of outdoor air pollution is used to illustrate the headings.

#### **Risk Register (AS/NZS, 1994)**

1. Reference number.
2. The risk: what can happen and how it can happen (i.e. the *Event* part of *risk*). For example, energy production in Ohio produces PM<sub>2.5</sub> which travels to and impacts metro Toronto population.
3. The *consequences* of an *event* happening – *consequence* and likelihood (*probability*) (also assign a numerical or qualitative rating for *consequence* and *probability*). For example, the dirty air from Ohio likely causes health effects in Toronto which are within an estimated range of values. There is considerable uncertainty as to the relative effects of the Ohio generated pollution compared to that produced locally from fixed facilities and transportation.
4. Adequacy of existing controls (*Risk Assessment* using *Risk Criteria*). For example, existing health impacts of air pollution in Toronto are significant, unacceptable and require *treatment* and are the subject of new controls such as “Drive Clean”.
5. Level of *risk* (summary of risk assessment based on numerical or qualitative rating for *consequence* and *probability*). For example, population risks from air pollution from most estimates are high (WHO analyses based on particulate matter estimate that ambient air pollution causes 1.4% deaths globally) and similar to automobile accident deaths (WHO estimates that road traffic injuries account for 2.3% of all deaths worldwide) (WHO, 2002).
6. Risk Priority. For the example, high priority and the risk is increasing.

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| <sup>2</sup> ISO/IEC Guide 73 terminology hereafter shown in italics. See definitions on page 3.



The list of risks are arranged in priority order by the organization's *risk criteria* - "*terms of reference by which the significance of the risk is assessed*". The high priority risks in the risk register are often called the Risk Profile. These priority risks are those considered for additional *risk treatment* - "*process of selection and implementation of measures to modify risk*".

### Risk Management System

A *risk management system* - "*set of elements of an organization's management system concerned with managing risk*" is one component of an organization's management and associated organizational structure. Like the other management components it has elements that include decision-makers, policies, strategic planning, resources, and a unique corporate culture.

The risk management system's function is to establish an organizational structure to:

- establish the *risk criteria*,
- maintain the organization's risk management framework to *identify, estimate, assess, control* and *communicate* about risks,
- make decisions,
- implement *risk controls* to modify risks (usually reduce the negative *consequences* and associated probabilities but may also be to enhance the positive *consequences*),
- develop relationships with *stakeholders*, and
- be responsible for how the organization manages *risks*.

*Risk control* - "*actions implementing risk management decisions*" may involve monitoring, evaluation, compliance with decisions, as well as specific actions to modify risks, such as licensing, laws and regulations, establishment of standards, enforcement, and modification of behaviour.

### Risk Management Frameworks

A *risk management* framework is a description of an organizational specific set of functional activities and associated definitions that define the risk management system in an organization and the relationship to the risk management organizational system. A risk management framework defines the processes and the order and timing of processes that will be used to manage risks. A good risk management framework should enhance and improve risk management by:

1. making it more transparent and understandable to *stakeholders*,
2. by making its processes more efficient, and
3. by allowing for cross fertilization of *risk controls, risk estimation, risk assessment* from others because of standardization of terms, processes, tools, etc.

The latter objective of not reinventing the wheel and borrowing successful methods from others is perhaps the main benefit of a good risk management framework. One other equally important value of risk management is the improved understanding of how the system works.

What a risk management framework is not is important. A framework is not:

- Values to be used in risk management – these are exclusive to the *risk criteria* and are established by the organization.
- Roles and responsibilities of decision-makers, *stakeholders*, regulators, etc. – these are established outside the risk management system and outside the organization through laws, characteristics of organizations, and other societal processes. These are all inputs to the design of the framework.
- A prescription for how the risk management function and processes are done in an organization. These are in accordance with the sequence and pathways of the framework but are basically related to the organization’s culture, technology of their “business”, management structure, and so forth.

Figure 1 illustrates three basic high-level elements in a risk management framework. These are 1) **operations to reduce risk** which includes the ongoing programs and activities performed by an organization to reduce risks to an acceptable and cost-effective level. These activities might include standard setting, performance audits, training and other risk management options; 2) **decision-making** or corporate management, where long term “strategic” decisions are made and responsibility for decisions at the other two levels lies. Activities at this level might include consultation with *stakeholders*, monitoring operations to reduce risk and priority-setting among risk issues; 3) **risk assessment and treatment options** where risk assessment is carried out and risk treatment options are identified. This high level framework provides a “benchmark framework” for evaluation of other risk management frameworks. Figure 2 presents a detailed

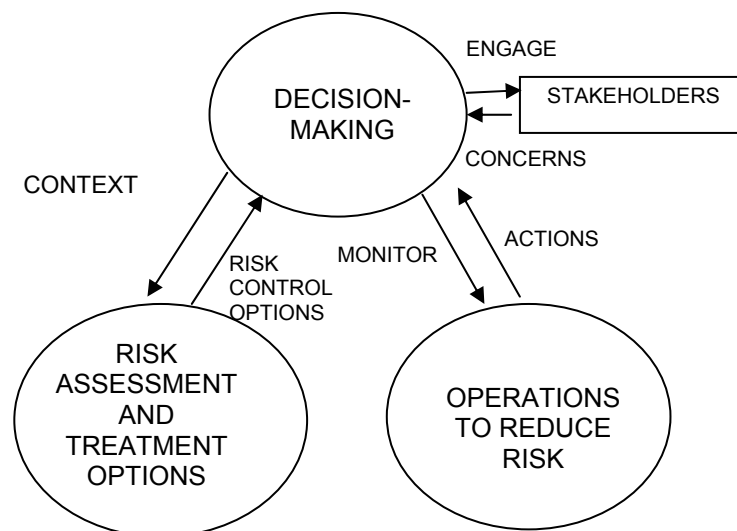


Figure 1: NERAM Benchmark Risk Management Framework

representation of the Risk Assessment and Treatment Options component of the Benchmark Framework. The Figure illustrates the basic functions involved in *risk assessment* and *treatment* and the linkages to the high level risk management framework. This is the traditional “administrative risk management paradigm” developed over the last few decades with traditional of science based regulation. There are three main processes: 1) **Risk Estimation** to estimate the magnitude of the risk (*probability* and *consequences*); 2) **Evaluation** to compare the estimated risk against criteria such as costs, benefits, *stakeholders* concerns; and 3) **Treatment Options** that are developed to reduce the risk to an acceptable level.

A **Preliminary Analysis** of the risk is undertaken prior to consideration of treatment, involving a screening level risk estimation (often called hazard identification or *risk identification*), a preliminary estimation of the *probability* and *consequences* of a risk, followed by an initial *evaluation* of the risks and consideration of the availability of options to *treat* the risk. Following the Preliminary Analysis, decisions can be made to identify priority risks that require more in depth examination. There is an interaction between Preliminary Analysis and the establishment of the context for the risk. Until something is known about a risk it is difficult to establish the appropriate *criteria*, to estimate how much *risk communication* will be needed, and to estimate the resources required for *risk assessment* and identification of *treatment options*.

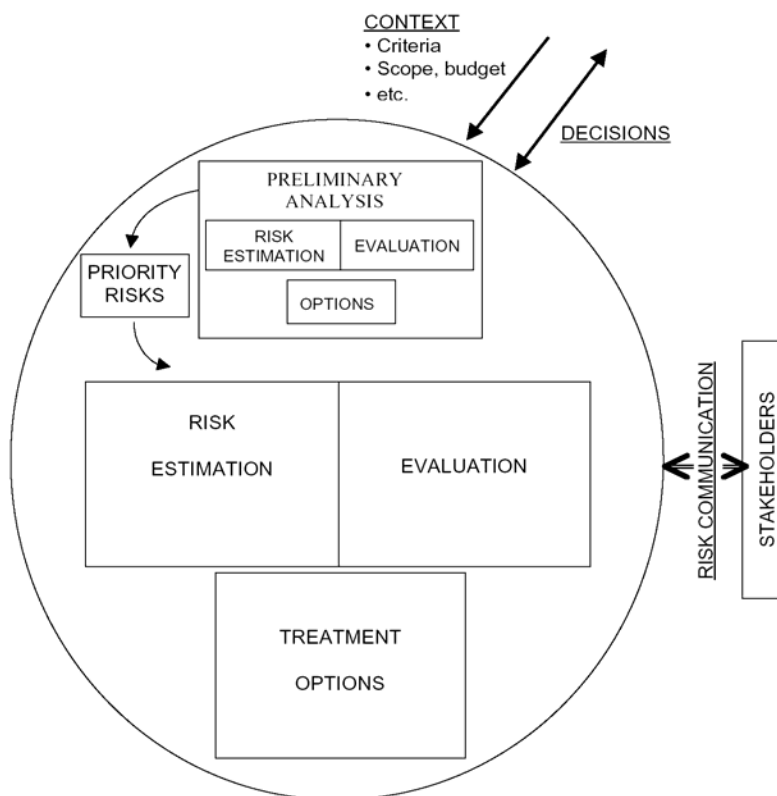


Figure 2: Expanded NERAM Benchmark Framework for Risk Assessment and Risk Treatment Options (details of Figure 1)

### Risk Management in Organizations

The ultimate objective of the management of *risk* is to direct and control an organization's risk. This objective is carried out by a specified set of processes defined in a risk management framework. The objective is supported by the organization's risk management system embodied in their organizational chart of roles and responsibilities.

Since incidents such as the Enron collapse, Bhopal, and Exxon Valdez, risk management has become a requisite management activity. It is expected that in the next few years the majority of Canadian companies will have formal "operational risk" management in their organization. Similarly, the federal Treasury Board now requires that risk management be an integral part of the annual budgeting cycle.

Risk management should be a line management function not a staff function since it is just another management activity and because it is integral with decision making. According to Peter Drucker, renowned 'father of modern management,' "a decision that does not involve risk, probably is not a decision." While there often is a staff function it is one of facilitation, integration and enterprise-wide reporting of risks, this is not the design and implementation of risk controls.

For example, in Clarica Life Insurance's enterprise risk return management system the "staff" functions are grouped at the corporate level. With only three positions, their responsibilities include corporate standards, framework, research, provision of tools, consolidation and reporting, education, and sponsorship (Conference Board of Canada, 2002).

Risk has become a positive (opportunity) as well as a negative concept. For example, the ISO/IEC Risk Terminology document opens with the statement "*All types of undertakings are faced with situations (or events) that constitute opportunities for benefit or threats to their success. Opportunities may be realized or threats averted by effective management. There is always a probability of outcomes, both positive and negative, that are not "usual" outcomes and the organization needs to have a management strategy for dealing with these outcomes.*"

Effective risk management is only sustainable in an organization if there is constant attention in the form of audits, reviews, and other forms of monitoring. This is due to the low *probability* nature of risks – they do not happen very often – relative to other management tasks they are easily forgotten and their predominantly negative characteristic makes it easier to leave them for another day. Unless the organization is vigilant, risk management controls, like batteries in smoke detectors, quickly become ineffective.

Each organization must design its own risk management framework, process, roles and responsibilities, documentation, and so forth. However, there are standard risk management functional elements for framework, procedures, etc. which should be used in the design. This ensures that the risk management procedures will be recognizable to others and will improve both effectiveness and efficiency. Chapter 2 outlines selected standard risk management frameworks and their elements.

Key indicators of an effective risk management activity in an organization are:

1. Commitment of senior management
2. Risk controls and programs that are ubiquitous in the organization and well understood
3. A well publicized “Risk Profile” that sets priorities for modifying risk controls
4. Effective risk communication that results in transparency for employees and other *stakeholders*, and
5. Monitoring, review, and performance indicators of the organization’s risks. These include all legal and regulatory requirements.

Finally, risk management must produce a net value for the organization. This value is estimated and reviewed and consists of three basic elements: costs, financial benefits, and trust and respect of *stakeholders* and the public.

## Chapter 2 Risk Management Frameworks and their Elements

This chapter describes the typical functional elements of risk management frameworks as well as categories of *risk criteria* and basic capacities required by an organization for effective risk management. Each organization must design their own framework through the selection and detailed design of elements in their framework. The design of an organization’s framework depends on the nature of risks it must manage, legal and regulatory considerations, available resources, and the relative value of *risk assessment*, operations to modify risks, risk communications, monitoring and review, etc. Chapter 3 provides examples of the framework elements, particularly for environmental risk frameworks. Chapter 4 outlines the risk management framework design guidelines.

Table 1 identifies the basic functional elements in the “benchmark” risk management framework. The benchmark framework is organized in terms of a typical structure of an organization; corporate decision-making (the board and senior executives), operations (line functions, supervisors, area managers, etc.), and policy and program planning (risk assessment and treatment). Table 1 also indicates categories of *risk criteria* and risk management system criteria for each level as well as five basic capacity requirements for any risk management function.

Table 1: Benchmark Framework for Risk Management Decision-Making<sup>3</sup>

MANAGEMENT TASK	FUNCTIONS	CRITERIA	CAPACITY REQUIREMENTS
SENIOR MANAGEMENT  “STRATEGIC”	<ul style="list-style-type: none"> <li>• Decision-making</li> <li>• Monitoring</li> <li>• Stakeholder Relations</li> <li>• Context</li> </ul>	<ul style="list-style-type: none"> <li>• Agency Objectives</li> <li>• Capacity</li> <li>• Trust of Stakeholders</li> <li>• Transparency</li> <li>• Flexible-Consistency</li> <li>• Budget</li> </ul>	<ul style="list-style-type: none"> <li>• Risk Communication and Consultation</li> <li>• Documentation</li> <li>• Best “Practical” Practice</li> <li>• Partners</li> <li>• Staff</li> </ul> <p style="text-align: right;">Each capacity applies to all three function levels</p>
POLICY & PROGRAM PLANNING  “TACTICAL”	<ul style="list-style-type: none"> <li>• Preliminary Analysis (Identification)</li> <li>• Risk Analysis</li> <li>• Risk Treatment Options</li> <li>• Evaluate Risk and Risk Treatments</li> </ul>	<ul style="list-style-type: none"> <li>• Cost-Effective</li> <li>• Stakeholder Acceptance</li> <li>• Uncertainty Explicit</li> <li>• Reasonable Relationship</li> <li>• Precautionary Principle</li> <li>• Comprehensive</li> </ul>	
OPERATIONS  “OPERATIONAL”	<ul style="list-style-type: none"> <li>• Implement</li> <li>• Quality Control</li> <li>• Programs to Reduce Risk</li> </ul>	<ul style="list-style-type: none"> <li>• Achieve Operational Plan</li> <li>• Correct Failures</li> <li>• Continuous Improvement</li> <li>• Customer Satisfaction</li> </ul>	

<sup>3</sup> See Figures 1 and 2 for a graphical presentation of the Benchmark Framework Functions.

This chapter will describe the broad outline of risk management functions and discuss conceptually how they are combined into a “framework”. This chapter will also introduce several frameworks that are representative of the current state-of-the-art and have rather wide application as a way of enhancing the basic conceptualization of a “risk management framework”.

Throughout this chapter and this report ISO/IEC risk terminology is used. For instance Table 2 shows the relationship between this terminology and functional elements in three frameworks introduced in this chapter. The NERAM benchmark framework and the three other frameworks in this table will be used to illustrate the core risk management functional elements. In addition the first framework to be introduced (The British AIRMIC, ALARM, and IRM: 2002 framework) is completely compatible with the ISO/IEC Guide 73.

Table 2: Comparison of Elements of Proposed Benchmark Framework with Steps of Existing Frameworks

<b>Proposed Benchmark Framework Functions</b> (see Figures 1, 2 and Table 1)	<b>CSA-Q850</b> (see Figure 4)	<b>U.S. Presidential/ Congressional Framework for Environmental Health Risk Management</b> (see Figure 6)	<b>Australian/New Zealand Risk Management Standard</b> (see Figure 5)
<b>Decision-making throughout</b>	Four Decision Points	Decision	Decision between Evaluate Risks and Treat Risks
<b>Monitoring</b>	Action/Monitoring	Evaluation	Monitor and Review
<b>Stakeholder Relations</b>	Risk Communication	Engage Stakeholders	Communicate and Consult
<b>Context</b>	Initiation & Preliminary Analysis	Problem/Context	Establish the Context
<b>Preliminary Analysis</b>	Preliminary Analysis	Problem/Context	Identify Risks
<b>Risk Analysis</b>	Preliminary Analysis & Risk Estimation	Risks	Analyse Risks
<b>Risk Treatment Options</b>	Risk Control	Options	Treat Risks
<b>Evaluate Risk and Risk Treatments</b>	Risk Evaluation & Risk Control	Decision	Evaluate Risks & Treat Risks
<b>Implement</b>	Action/Monitoring	Actions	Treat Risks
<b>Quality Control</b>	Action/Monitoring	Action/Evaluation	Monitor and Review

Corporate Decision-making Functions

Risk is inherent in any decision, at any level in the organization. As such the risk management framework closely follows the typical management decision-making structure of:

1. Identify and assess the situation
2. Consider treatment (decision) options
3. Decide
4. Implement management control
5. Monitor decision

Figure 3 shows the 2002 business based risk management framework, a joint venture by the Institute of Risk Management, The Association of Insurance and Risk Managers, and the National Forum for Risk Management in the Public Sector, which are all based in the UK. The standard is available at <http://www.airmic.com/>.



Figure 3: The Risk Management Process (AIRMIC, ALARM, IRM, 2002)



Like all risk management frameworks, it is an arrangement of processes in a linear sequence, but with opportunity for feedback at any time in the process. The framework can be applied to:

- a) annual or other cyclical review, usually as a part of a budgeting process,
- b) a particular issue/project that the organization must deal with, that is raised in the marketplace, by stakeholders, as a result of trends, as an opportunity, etc.
- c) a crisis situation

This is a “business” risk management framework, using ISO/IEC Guide 73 terminology that mirrors both the traditional health and safety risk management framework and the usual management decision process. It starts from the Organization’s Strategic Objectives as expressed in the Risk Management Policy, described as “*an organization’s approach to and appetite for risk and its approach to risk management...set out the responsibilities...legal requirements...commitments for the chief executive...allocation of appropriate resources...role of the board...role of Internal Audit ...*”

The framework does a *Risk Assessment*, composed of *Risk Analysis* (in turn being *Risk Identification*, *Risk Description*, and *Risk Estimation*) and *Risk Evaluation*. The framework then has a formal step of reporting both opportunities and threats to decision-makers, who must decide if *Risk Treatment* is needed (i.e. if the risk is acceptable or not with existing Risk Controls), then decides on the level of *Risk Treatment*. The report of the decision-making includes discussion of the *Residual Risk*.

The framework shows the possible feedbacks in the process as “modifications”. Finally there is a formal Audit and Monitoring activity. The framework is unusual in that formal *risk communication* and the role of the *Stakeholders* is not formally recognized. Nevertheless it does represent a formal framework adopted by a variety of professions in one country – not an insignificant achievement.

The standard in Figure 3 uses a risk description method that is similar to the Australian-New Zealand standard described below. It also uses a “matrix” method for classifying risks in terms of *probability* and *consequences* similar to the approach described in Chapter 3. This matrix is unusual in that it is used both for threats and for opportunities. In some standards this matrix method is used as a form of preliminary analysis with more detailed *risk estimation* methods done for priority risks, but in this standard the method is the full extent of the *risk estimation* methods.

The “business” framework in Figure 3 differs from the traditional “technical” risk management framework in that it explicitly considers “*residual risk reporting*” so that *risk financing*<sup>4</sup>, transfer of risk through insurance, and other *residual risk* issues can be considered.

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4 According to ISO definition, in some industries, risk financing refers to funding only the consequences related to the risk and not the risk management

Figure 4 illustrates the Canadian Risk Management Standard (Guide) Q850 (CSA, 1997). It is a generic standard and was the first to formally introduce the ideas of:

1. Explicit decision-making at most steps in the process, including the decision option of “end” consideration of a risk.
2. *Stakeholders*, stakeholder analysis, and introduction of stakeholder needs, issues, and concerns in the *risk evaluation*, etc.
3. Explicit introduction of *risk communication* at each functional step in the framework.
4. Initiation step where the technical and administrative risk management “process” is designed and resourced. Initiation is a function in the organization’s risk management system.
5. Preliminary Analysis, which is a screening level risk analysis and *risk evaluation* (both together are called *risk assessment*). This is illustrated in the benchmark framework in Figure 2.
6. Documentation needs and the creation of a “risk library” for any application of the process.

This standard was a milestone and the Australian-New Zealand standard issued in 1995 was revised in 1999 to incorporate some of these ideas and extend them in terms of the concept of “Context” and other innovations.

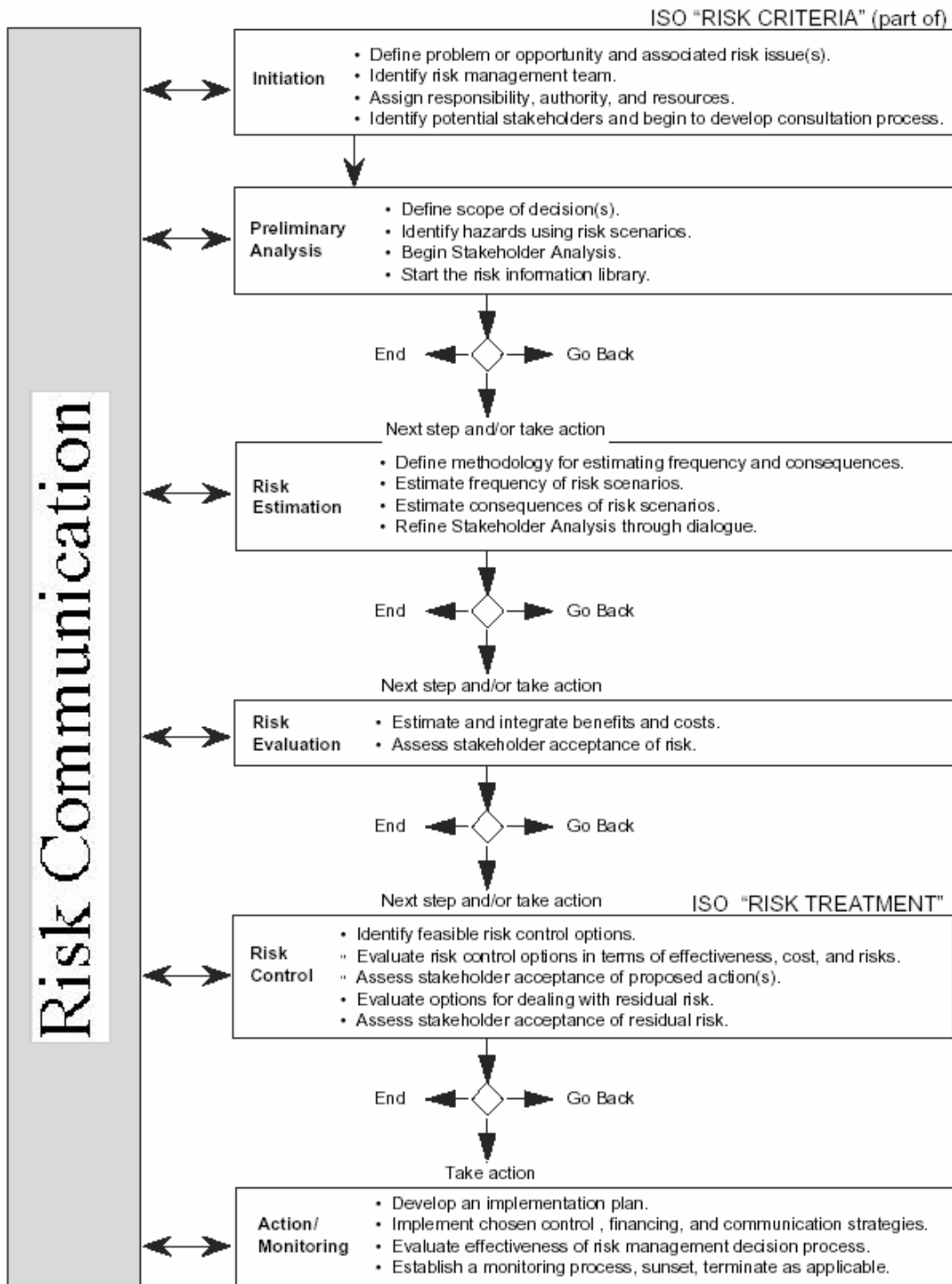
The Canadian standard in Figure 4 now has some non-standard (ISO) terminology, for example, *Risk Control* is now *Risk Treatment* after implementation, and *Risk Treatment* is the process of finding a treatment to modify the risk that the decision-makers deem acceptable<sup>5</sup> However, most of the terminology is similar to ISO/IEC Guide 73.

The role of the decision-maker is shown at 4 points in the framework, after the completion of major functional processes, such as *risk estimation*, *risk evaluation* and *risk treatment* (shown as *risk control*). Between preliminary analysis and *risk estimation* there is a decision as to which of the many risks identified (and given a preliminary assessment) are priority risks which need further attention. Figure 2 illustrates this for the benchmark framework.<sup>6</sup>

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<sup>5</sup> This is analogous to the field of medicine where treatments are the available therapeutic options for disease management, while risk controls are the specific care plan the physician has selected from the available treatment options.

<sup>6</sup> The number of priority risks is typically 1/10<sup>th</sup> or less of all risks that have been identified – with this decision typically 90% of all risk scenarios are assigned “end.” (Peter Schroeder, Zurich RE, Personal communication)



Source: CSA, July 1997. Risk Management: Guideline for Decision-Makers (CAN/CSA-Q850-97) Canadian Standards Association.

Figure 4: Steps in the Q850 Risk Management Decision-Making Process - Detailed Model

The decision-making may be delegated to other managers or may be incorporated into standards and “prescribed” treatments in laws and regulations. Many regulations and their associated administrative application have the same structure as the decision diamond in Figure 4. A risk may need a prescribed control if it meets certain requirements (take action), it may not need to be regulated if these requirements are not met (end), or a risk may have uncertainty in the requirements and have to “Go Back” to get more information which is typical, for example, in multi tiered approaches to decommissioning of polluted sites. The benchmark framework incorporates the structure of the decision function directly from this Canadian risk management standard.

Figure 5 illustrates the Australian-New Zealand standard framework of functional processes (AS/NZS, 1999). It has a core set of functions that mirror those in Figure 3, with slightly different terminology, including the idea of extensive feedback loops and continuous monitoring. Like the Canadian framework, it explicitly identifies the “communicate and consult” function.

The Australian-New Zealand framework introduced the concept of “Context” which is a further development of the Canadian “Initiation” step. Context provides the essential linkage between decision-makers and the technical or scientific analysis of risks. It is described as a process to “Establish the strategic, organizational and risk management context in which the rest of the process will take place. Criteria against which risk will be evaluated should be established and the structure of the analysis defined.”

The Australian framework also makes explicit the idea of *Risk Criteria* or “*terms of reference by which the significance of risks is assessed*” (ISO/IEC definition). These criteria can be quite broad and include qualitative and quantitative criteria, including absolute limits, social preferences, cultural, economic, and political criteria. The benchmark framework incorporates the Context and Risk Criteria concepts directly from this standard.

The Australian framework clearly separates out the assessment of the risk with already existing controls and then if the remaining *residual risk* is not acceptable, additional *treatment* options are evaluated to make the *residual risk acceptable*.

The Australian-New Zealand standard also developed the concept of risk communication into “communicate and consult” and made it clear that any risk communication has to involve the decision-maker, an idea which was incorporated into the ISO/IEC definition and the benchmark framework.

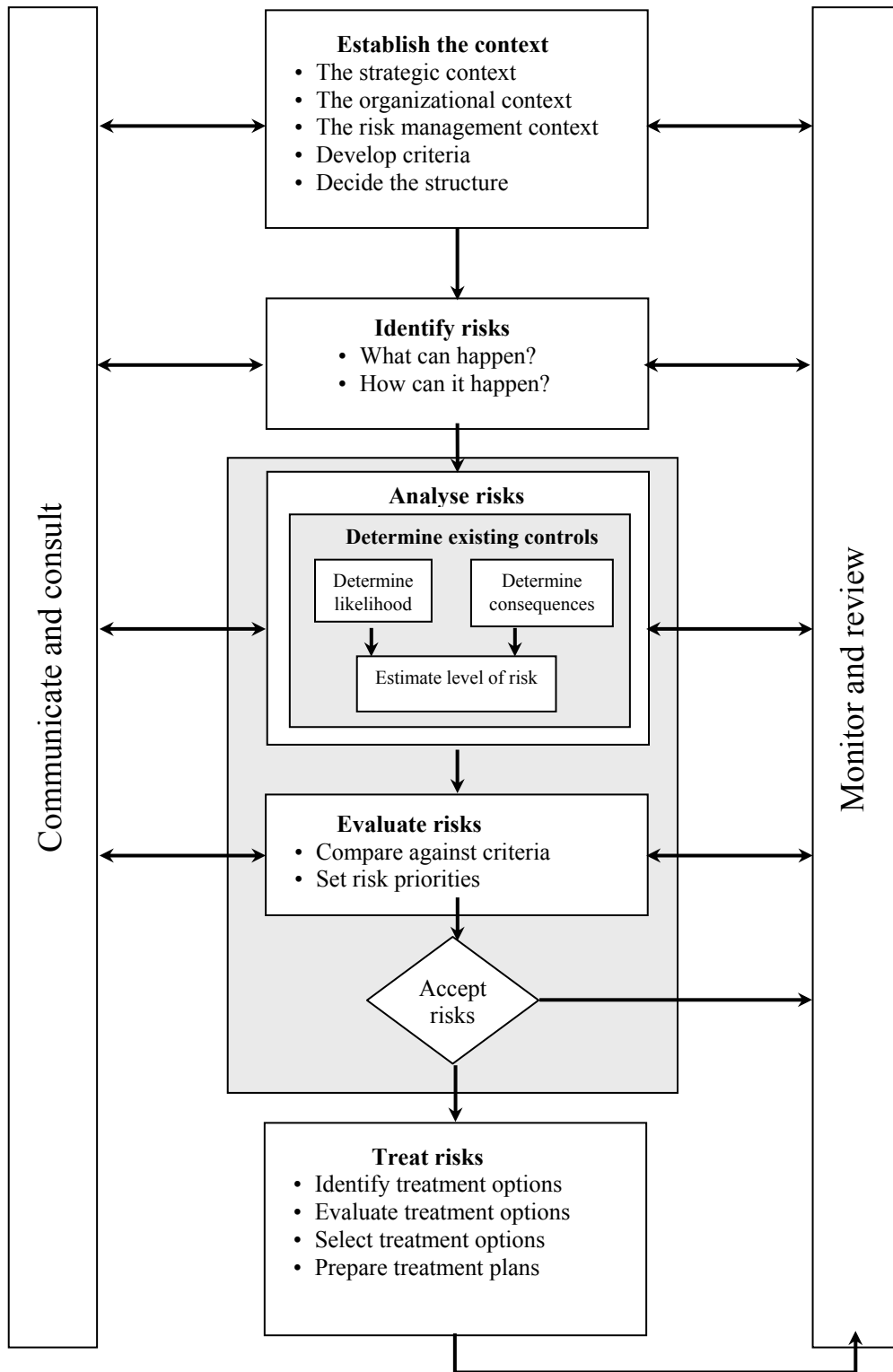


Figure 5: Australia/New Zealand Risk Management Standards (AS/NZS 4360:1999).

The Australian framework is supported by extensive guidelines in appendices and stand-alone documents that provided checklists and other tools for implementation of the framework. For instance, Appendix D of the framework gives “Generic sources of risk and their areas of impact” which can be used as a basis for *risk identification*. Appendix C lists some 16 classes of stakeholders. Appendix H provides a “Risk Register” form that is generic and can be used directly for any application. This form is comprehensive, for example, there are headings; “person responsible for implementation”, “timetable for implementation”, and “How will this risk and the treatment options be monitored?”.

Figure 6 shows the US Presidential Congressional 1997 Commission framework for Environmental Risk Management. Figure 6, when translated to standard ISO/IEC terminology, is also Health Canada’s risk management framework for health risks (Health Canada, 2000) and the Province of Quebec’s framework.

The US framework is circular and has “decision” arrows linking all steps, emphasizing the feedback and unique design aspects of risk management – each risk management process needs to be specially designed for the problem and its characteristics using standard functional elements. The US framework is described as “holistic,” being focused on health outcomes, and stressing multiple interventions and strategies for risk treatments that include mixtures of public and private interventions, less dependency on command and control mechanisms, and so forth. This is a key contribution of this series of frameworks, which moved from stressing a prescribed administrative and technical process to stressing population health outcomes in an open process with active involvement of stakeholders. The objective was a framework that would find the best and most effective answer.

The US framework also emphasizes the role of Stakeholders, similar to the Canadian standard stakeholders may be involved in all steps and are shown as central to the framework. The monitoring function with evaluation of outcomes and audits of the whole process were important additions to the previous HC framework of 1993. One objective of the new framework was to achieve a more open and transparent process for risk management of health issues.

The US framework, unlike the benchmark framework, does not separate out the elements of the risk management framework into the levels of a typical organizational chart. Issues of risk criteria, documentation, etc. are not shown directly in the framework. The framework does introduce the concept of “context” similar to the Australian-New Zealand framework. In general, the framework is comparable to the other frameworks for the core aspects of *risk assessment*, *risk treatment*, *risk communication*, decision-making, monitoring, etc. This framework is a more conceptual framework which needs to be operationalized by a specific organization.

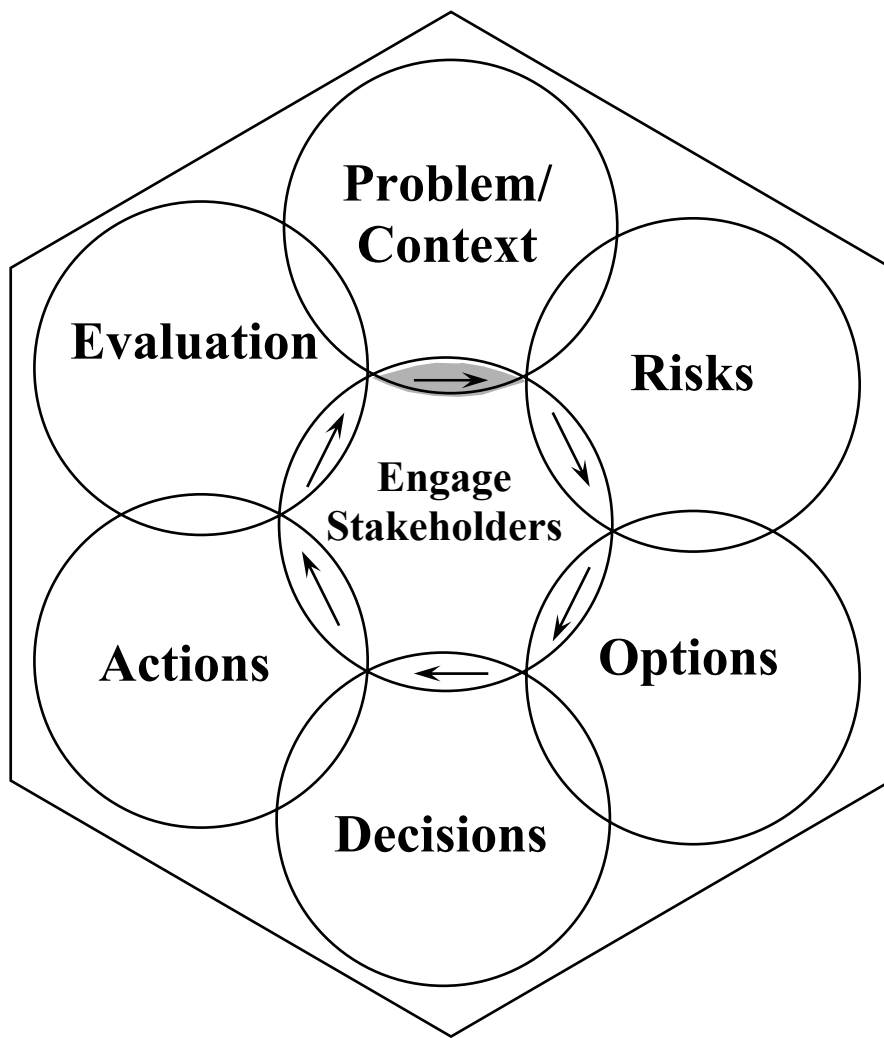


Figure 6: US Presidential/Congressional Commission on Risk Assessment and Risk Management: Framework for Environmental Health Risk Management (1997).

### Other Risk Management Standards

The purpose of this section is to examine some recent international standards and other existing mainstream risk management standards to confirm that the NERAM benchmark risk management framework is comprehensive, generic and state of the art.

NERAM conducted a comprehensive analytical review of more than 45 risk management frameworks in a study for the Federal/Provincial/Territorial Committee on Environmental and Occupational Health (Jardine et al., In Press). The NERAM benchmark framework for risk management was developed as a part of this study and during this development all the

frameworks were “translated” into standard ISO terminology and any additional definitions in the benchmark framework. The benchmark framework analysis functions, listed in Table 1, were comprehensive and included all of the functional elements found in the 45 frameworks. This provides some confidence that the benchmark framework is a generic framework that can be adopted to specific risks and particular organizations.

Japan issued standard “JIS Q 2001:2001 – Guidelines for development and implementation of *risk management system*”, using the ISO terminology for risk management system as well as other terms. Figure 7 shows the concept of the risk management system as an integral part of an organization’s structure established to maintain risk management activities and the associated system that carries out those activities. The standard is compatible with the benchmark framework. There are two basic advances in the standard, the first is the formal definition and development of the risk management system (as opposed to the usual development of the risk management framework) and the second advance is the linkage of the risk management system directly to Total Quality Management concepts, including continuous improvement. In the details of the standard there is a focus on prevention of the events following the 1995 major earthquake when some 5,000 firms and organizations were unable to quickly restart operations.

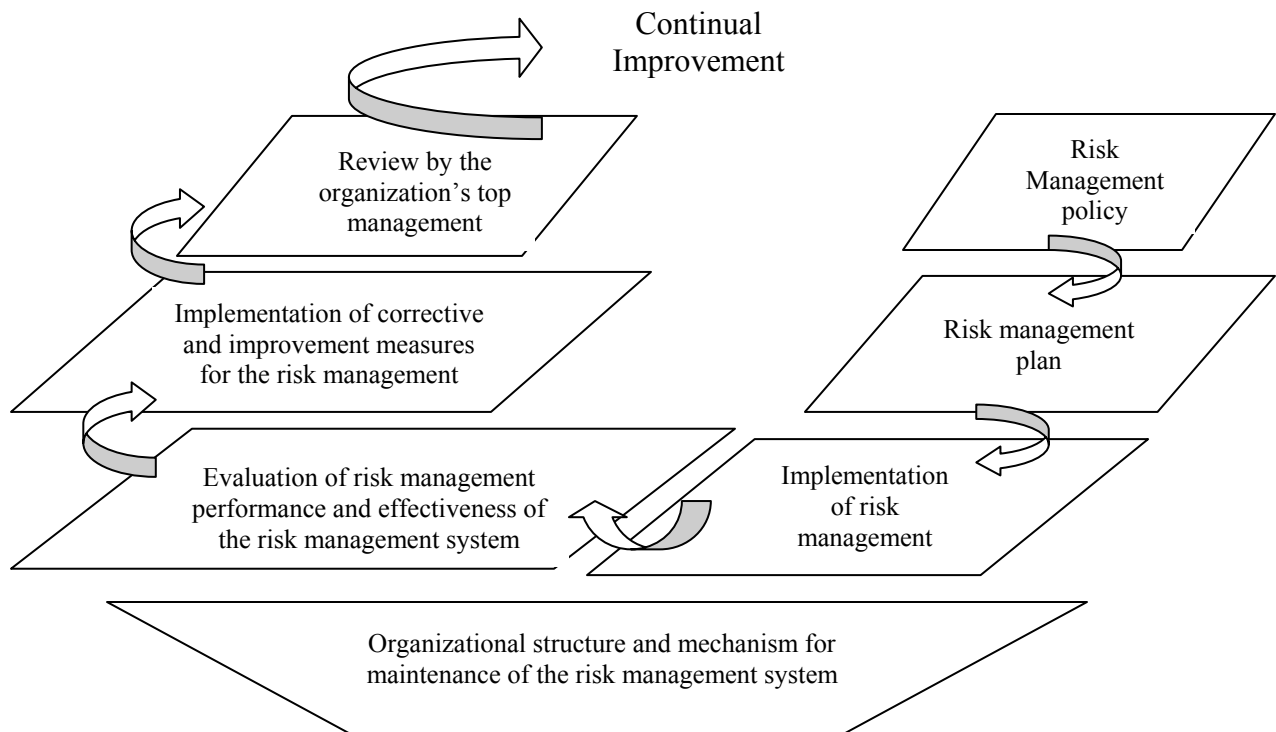


Figure 7: The Japanese Industrial Standard Risk Management System (JSA, 2001)



The British Standard was issued in 2002 as “BSI Technical Committee MS/2 – Part 3: Project Management – Guide to the management of business related project risk (Figure 8).” The standard is similar to other risk management frameworks, particularly the Australian New Zealand standard and the UK standard in Figure 3. It is basically a generic “business” standard and is fully compatible with the NERAM benchmark standard. One advancement contributed by the standard is illustrated in Tables 3 and 4, which show the concept of hierarchical decisions in an organization and how this is translated into strategic, tactical, and operational decision making. This concept is identical to that of the benchmark framework as illustrated in Table 1 and Figure 1. This is the first framework to show explicitly how risk management can, in a general way, be organized in a complex organization. The standard also presents a restatement of the ALARA (As Low As Reasonably Achievable) principle for positive as well as negative *consequences* of risks.

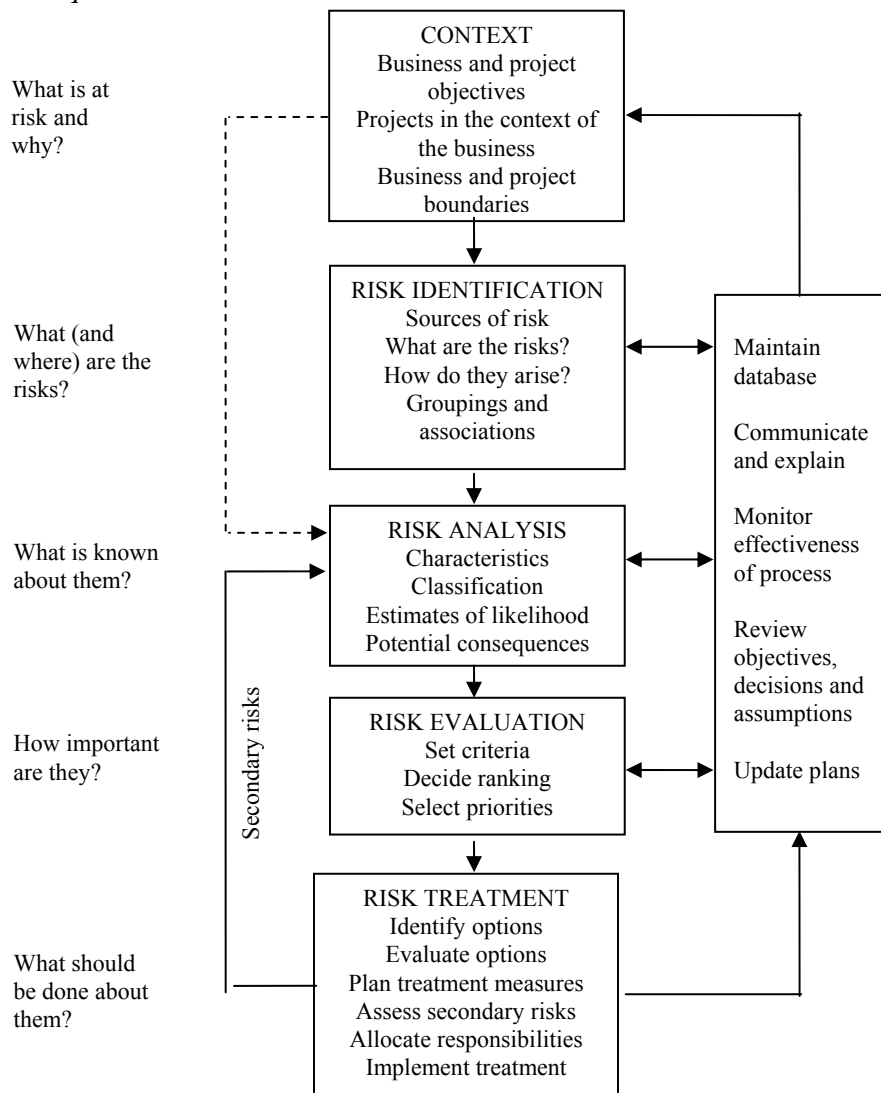


Figure 8: The risk management process (BSI, 2000)

Table 3: Decision making levels (BSI, 2000)

Decision making level	Examples of decision making
Strategic	Establishing/confirming goals, means, constraints, key risks, stakeholders and setting in context for tactical and sometimes operational decisions for each activity/project.
Tactical	Choosing how to deploy the most appropriate means for attaining goals and managing tactical risks within the restraints set at strategic level.
Operational	Implementing tactical choices and managing operational risks.

Table 4: Examples of decision makers (BSI, 2000)

Decision making	For the business	For the project	For the sub-project
Strategic	Non executive and executive senior management	Project sponsor	Project manager
Tactical	Middle management	Project manager	Sub-project management
Operational	Operations manager	Project team and suppliers	Sub-project team and suppliers

Treasury Board of Canada, in 2001, issued an “Integrated Risk Management Framework” to provide generic guidance for risk management frameworks in a variety of government agencies and ministries. The framework consists of 9 steps, or functional activities, (translated into ISO terminology): 1) identify risk areas, 2) set the context; 3) *identify risks*; 4) *estimate risk probabilities and consequences*; 5) *assess risks* and select priority risks; 6) establish *risk criteria*; 7) *risk treatment* options; decide on risk treatments (*risk evaluation* and *acceptance*); 8) implement *risk controls*; 9) monitor and repeat steps as required. Again, once translated, it is clear that this framework is composed of basic functional activities identified in the NERAM benchmark framework in Table 1. The Treasury Board framework also identifies the role of the precautionary principle that is identical to that in the benchmark framework.

The Australian National Health and Medical Research Council (Sinclair et al. 2002) has developed a risk management framework for water supply systems. It is composed of 12 elements, the first of which is “Commitment to Drinking Water Quality Management”. The framework is a risk management framework in a Quality Management format, as indicated by the Japanese standard. The first 6 and last 2 elements mirror the functions in the NERAM benchmark framework but the interesting contribution of the framework is in the middle 4 elements, which correspond to the “capacity” elements of the NERAM framework. The 4 Australian “capacity” elements (referred to as supporting requirements) are (in the benchmark terminology): *risk communications* and consultation; staff awareness and training; best practical practice (i.e. research and development); and documentation. These represent 4 of the 5 capacity elements shown in the benchmark framework with only “partners” not represented, however, in the development of the drinking water framework there was extensive work on all the necessary partnerships required for a successful development and implementation of the framework.

Finally, the European Cooperation for Space Standardization adopted in 2000, “ECSS-M-00-03A - Space project management - Risk management”. The standard is available at [www.ecss.nl](http://www.ecss.nl).

It is an interesting example of a detailed framework design for a specific purpose. It follows almost exactly the NERAM benchmark functional activities, but it is included here because of the richness of the development and integration of the detailed framework. For example, it is only one part (03A) of one of 8 management standards that are coordinated with 8 engineering standards and 9 product quality assurance standards. A short review of this standard will illustrate the level of detail that is needed in specific applications of the generic benchmark risk management framework.

### Discussion of Frameworks and Summary

There has been a continuous development of risk management frameworks – where the framework is an arrangement of activities or processes that assist and inform decision-makers about the risks in question, the assessment of the risk, the views of stakeholders, possible treatments available and the likely risk reductions and *residual* risks that will result. In addition, the frameworks provide for implementation of the decisions and monitoring to see if the estimates of risk reductions, acceptance by stakeholders, etc. were realistic.

The development of frameworks has resulted in a common generic framework that can be applied: to a project, to review an ongoing program, to manage a crisis, or other aspects of risk decisions. The generic framework now includes functional activities or processes that establish the context of the decision, that include communication and consultation with stakeholders, that are more open and transparent, that can search for innovative risk reduction strategies, and generally are sufficient for most risk decision issues.

The NERAM benchmark framework can represent the generic framework as it incorporates the latest ISO/IEC risk terminology (which makes clear the high degree of agreement there is between existing frameworks) and also has all the elements found in other frameworks. The NERAM benchmark framework is basically a catalogue of functional elements that can be included in a risk management framework. However, as indicated in Chapter 1, the basic elements of a risk management framework for a specific organization must be designed for that organization so that it meets the requirements of the organization’s culture, the characteristics of the technical, physical, economic, temporal, and other dimensions of the risk, and the stakeholders’ requirements.

In summary, there has been a rapid development of risk management frameworks in the last few years. There is a common generic framework, which can be represented by the NERAM benchmark risk management framework. While the core elements of risk management frameworks are now basically fixed there is considerable development in terms of linkages to Total Quality Management, in expansion to include specification of the risk management system, in attention to the capacity requirements for risk management, and in terms of details of specific design of frameworks for specific risks and organizations.

The design and evaluation of risk management frameworks is discussed in Chapter 4. Chapter 3 will present some applications of frameworks to environmental issues to illustrate typical methods and tools as well as typical inputs and outputs of the basic actions or processes of *risk identification*, *risk estimation*, *risk evaluation*, and so forth.

### Chapter 3 Review of Approaches in Selected Agencies

The purpose of this chapter is to illustrate the functional activities of the benchmark risk management framework through examples presented at the December 6, 2001 Ministry of the Environment/NERAM seminar on Basic Frameworks for Risk Management. The purpose of this seminar was to foster a common understanding of available Risk Management Frameworks (RMFs) and how these concepts are applied in leading jurisdictions around the world. The speakers were from a variety of sectors including academia, government and non-government organizations to illustrate risk management concepts in setting priorities for protecting the public interest, safety and the environment, including the positive impact of the economy on population health.

The presentation material focuses on two major components of the Benchmark Risk Management Framework illustrated in Figure 9 below i) **Context** and ii) **Risk Assessment**. These two components inform decisions to reduce risk – in the case of the Ontario Ministry of the Environment, implementation of the framework will result in policy decisions to reduce risk, for example, the setting of revised air quality standards to protect public health and the environment.

**Context** provides the essential linkage between decision-makers and the technical or scientific analysis of risks. It is described as a process to “Establish the strategic, organizational and risk management context in which the rest of the process will take place.” **Criteria** against which risk will be evaluated should be established and the structure of the analysis defined.

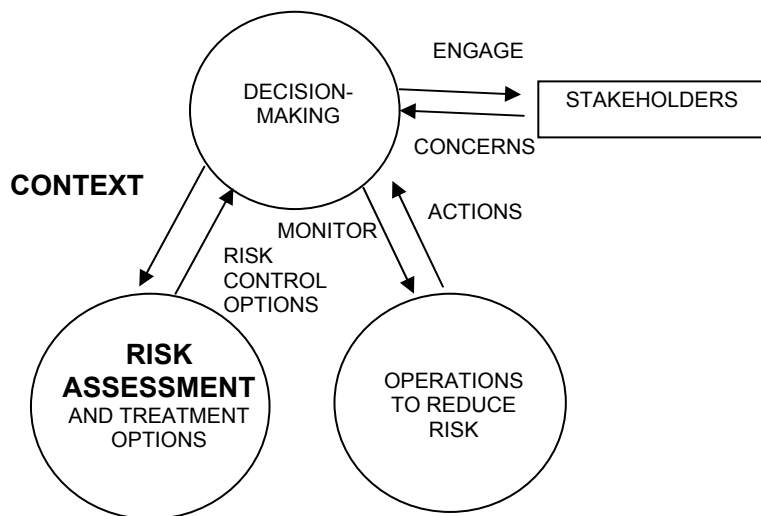


Figure 9: Benchmark Risk Management Framework

These elements of the Benchmark Risk Management Framework are identified in this document **in bold** text and the standard ISO/IEC risk management terminology on page 3 is identified in ***bold italics***.

This chapter concludes with perspectives from a multi-stakeholder panel discussion (at the December 6 workshop) on issues and challenges faced in implementing risk management in organizations.

### **i) Context**

Consideration of the “context” of a risk problem early in the risk management process is a discrete step in the benchmark risk management framework and the US and Australian/New Zealand frameworks. This reflects a recognition of the complexity of risk situations and the need to consider broader dimensions of the risk problem including the organization’s goals, values and capabilities. The scope and depth of the review of the risk is defined in this step to consider whether the review will entail organization-wide issues or be limited to a specific program or process. Bob Breeze, Associate Deputy Minister of the Ontario Ministry of Environment addresses Context for decision-making in describing the basic strategic policy environment for corporate management of Air Pollution Standards within the MOE.

*Criteria* for specific risk issues are determined in the Context function, and refer to the terms of reference by which the significance of the risk is assessed. Mr. Ken Ogilvie, Executive Director of Pollution Probe discusses the application of the Precautionary Principle as a *risk criteria* in the context of risk management decision-making for environmental pollutants.

#### Context for Environmental Risk Management in the Ontario Ministry of Environment

Mr. Breeze, described the context for Environment Risk Management within the Ministry. His presentation identified actions towards implementing a risk management approach following the recommendation of “*Managing the Environment*”- an independent review of best environment practices in leading jurisdictions (Executive Resources Group, 2001).

The “Managing the Environment” report identified several recent strategic shifts in policy:

- High level, government-wide vision and goals with implementation shared across different Ministries,
- Strategies to promote continuous improvement in environmental performance and accountability across all sources of pollution,
- Place-based approach with boundaries that make environmental planning sense and facilitate total cross-media, cumulative approach,
- Comprehensive, flexible set of regulatory and non-regulatory compliance tools and incentives, and
- An approach based on shared responsibility with regulated community, Environmental non-government organizations (ENGOs), public and scientific/technical community.

The use of science-based risk assessment in itself is not new to the Ministry of the Environment. Indeed, its roots can be traced back to the formation of hazardous contaminant standards in the early 1980's. The use of risk management as a central tenet of decision-making at the executive level is a new initiative.

Mr. Breeze identified three implementation measures that were currently being initiated to apply this vision:

- The formation of a cabinet committee on the environment, and a new position of Associate Deputy Minister to lead the implementation of the vision that works across all Ministries in provincial government.
- Strong investigation and enforcement remain critical to effective environmental management. The ministry's Environmental SWAT Team (Soil, Water, Air Team) uses detailed risk assessment to identify high risk groups for inspection and enforcement.
- Development of a risk management framework for air standards in collaboration with *stakeholders* including ENGOs, the public and industry.

Establishing Context in Risk Management: An Environmental Group's Perspective on the Precautionary Principle

Mr. Ken Ogilvie, Executive Director of the environmental non-governmental organization Pollution Probe, proposed a modification to regulating environmental pollutants based on application of the "Precautionary Principle."

Mr. Ogilvie addressed the issue of managing the large inventory of chemical substances already in existence and the potential for environmental and health impacts. He noted that there are scientific risks, business risks, and political risks. He commented that a balanced decision involves consideration of all these aspects and a regulatory process cannot rely solely on the results of scientific assessments. The precautionary principle is most important when there is a potential to have serious and irreversible impacts on public health and the environment. For example, Genetically Modified Organisms, MMT, beef growth hormone, mad cow disease, lead, green house gases, and phthalates in toys are all issues for which application of the Precautionary Principle is the prudent course of action if scientific evidence cannot be provided.

***Risk Criteria*** (part of **Context**) includes the Precautionary Principle as a risk criterion to be established by the decision-maker.

The argument is made for modifying existing ***Risk Criteria*** to give more weight to the Precautionary Principle and also to require governments and industry to act when this principle applies.

"In Pollution Probe's opinion, the value judgments inherent in taking precautionary principle decisions are of fundamental importance and should set the context within which scientific and economic criteria are applied to managing toxic substances. Value judgments cannot be reduced to a set of decision criteria that scientists can apply on their own before the risk management stage of the RA/RM process." (Ogilvie, 2001)

He suggested that the general positions of stakeholders on the precautionary principle are as follows:

- Health Canada implements health standards and regulates issues on the basis of “no significant risk” or that the risk is within acceptable levels.
- Industry wants to reduce risk to economically manageable levels.
- ENGOs work on the principle of risk avoidance, not how to manage it after the fact.

The precautionary principle fits, in part, into a risk management framework. However, the environment community sees it as an “overarching principle” that should guide risk management and decision making in general. Industry wants “science-based risk assessment” to be the starting point for invoking the precautionary principle (Note: “traditional science” and “precautionary science” are not always the same thing in the view of ENGOs). Industry wants peer review of risk assessments done by scientists, and then move to the risk management stage in which industry supports consultation with stakeholders. However, industry doesn’t like “reverse onus of proof” and does not support “duty to act”. Health Canada supports traditional science-based risk assessment, but don’t want to involve the public in the risk assessment process. The Royal Society of Canada expert panel report on the future of food biotechnology recommended the involvement of other disciplines and experts than just scientists in the risk characterization and risk assessment process. They supported the idea that the precautionary principle means involving other qualified people to inform and validate the assumptions and value judgments made in risk assessment.

Mr. Ogilvie advocates for more public debate on societal values and their implications for the definition and implementation of the precautionary principle. In addition, he suggests further discussion of the ethical consideration of the “Duty to Act” inherent in applying the principle. These questions and considerations are very important to developing a risk management system that is open and fair to all stakeholders.



## ii) Methods and Tools for Risk Assessment

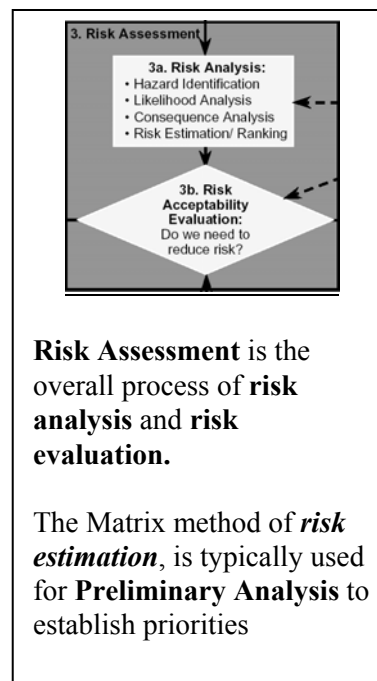
### Matrix Methods for Risk Estimation

Dr. John Hicks of Ryerson University and Ms. Helle Tosine, Director of Inspections, Investigations and Enforcement (II&E) Secretariat presented applications of the matrix method as a tool for evaluating and prioritizing risks in the risk assessment step of a risk management framework. Matrix methods are usually semi-quantitative methods for risk assessment and as a preliminary analysis may lead to more quantitative methods. In some cases further detailed and more comprehensive risk assessment is not required.

Dr. Hicks presented a practical *risk evaluation* system that has been used to prioritize chemical and technological risks in large companies. Ms. Tosine presented the application of a risk ranking matrix to establish compliance inspection and program enforcement priorities for the Ministry of the Environment Environmental SWAT Team. The risk assessment method within Ontario's II&E Risk Management Process is as follows:

- 1) **Hazard Identification:** The first step is to identify what can go wrong in terms of potential hazards and undesirable *events*, or deviations from what is intended that can lead to adverse impacts. In the case of industrial risks this may include the health risk associated with emissions of air pollutants from a facility upon a nearby residential location, or contamination of groundwater systems by an accidental discharge from a chemical storage facility.
- 2) **Likelihood Analysis:** The *probability* or likelihood of occurrence of each risk scenario is estimated. The *probability* is usually defined in terms of events per year (e.g. everyday occurrence, once every five years, etc.). Each organization should establish definitions of the likelihood categories to reflect the needs of the organization and the nature of its activities.

Dr. Hicks provided the following example of an *event* frequency classification system:



**Risk Assessment** is the overall process of **risk analysis** and **risk evaluation**.

The Matrix method of **risk estimation**, is typically used for **Preliminary Analysis** to establish priorities

Table 5: Event Frequency Classification System

<b>Weight</b>	<b>Possibility</b>
Frequent (5)	1 or more events per year (e.g. exposure to petroleum fumes, engine oil spill)
Probable (4)	12 or more events per 10 years (bout of food poisoning, minor auto collision)
Occasional (3)	1 or more events per 30 years (train derailment/chemical spill in urban location)
Remote (2)	1 or more events per 200 years (major release of radioactive materials – Ontario)
Improbable (1)	Less than one event in 200 years (meteorite colliding with Ontario urban centre)

- 3) **Consequence Analysis:** The *consequences* that may occur as an outcome of the *event* of each risk scenario are estimated. *Consequences* can be measured on several different scales, such as health impacts (fatalities, injuries, illness), financial *consequences* (lost productivity, equipment loss) and impacts on public image and reputation.

Dr. Hicks provided the following examples of *consequence* rating systems for public health risks and for cost evaluation:

Table 6a: Consequence Rating for Health Risk Evaluation

<b>Consequence (Risk Weight)</b>	<b>Public Health Consequences</b>
Catastrophic (100)	Multiple fatalities, and injuries
Major (60)	Single fatality, permanent total disability
Serious (25)	Major injury(s), partial injury or longer term injury
Moderate (10)	Minor injury, medical aid or low severity impairment
Minor (2)	Slight injury, illness, first aid not required

Table 6b: Consequence Rating for Cost Evaluation

<b>Consequence (Risk Weight)</b>	<b>Cost (Production, Equipment Loss)</b>
Catastrophic (100)	> \$50 M
Major (60)	\$5 - \$50 M
Serious (25)	\$500 K - \$5 M
Moderate (10)	\$50 K - \$500 K
Minor (2)	< \$50 K

- 4) **Risk Estimation:** Risk estimation involves combining the estimates of the *probability* and *consequence* analyses in a form that will demonstrate the importance of the *event* relative to others. A risk score can be calculated using the formula  $Risk = Probability \text{ (or frequency of the event)} \times Consequence$ . Risk level categories and required actions for each level of risk are defined by the organization.

Dr. Hicks provided an example to illustrate the four risk levels (Extreme risk, high risk, moderate risk and low risk) and urgency of actions associated with each level.

Table 7: Risk Score and Levels

<b>Risk Score (R)</b>	<b>Risk Level</b>	<b>Action Required</b>
>400	Extreme Risk	Cannot tolerate – Immediate action necessary to reduce risk
100 – 400	High Risk	Unacceptable for long-term, must implement risk controls
30 – 100	Moderate Risk	Undesirable, evaluate risk reduction measures in long-term
<30	Low Risk	No mitigation necessary, periodic evaluation to maintain low level

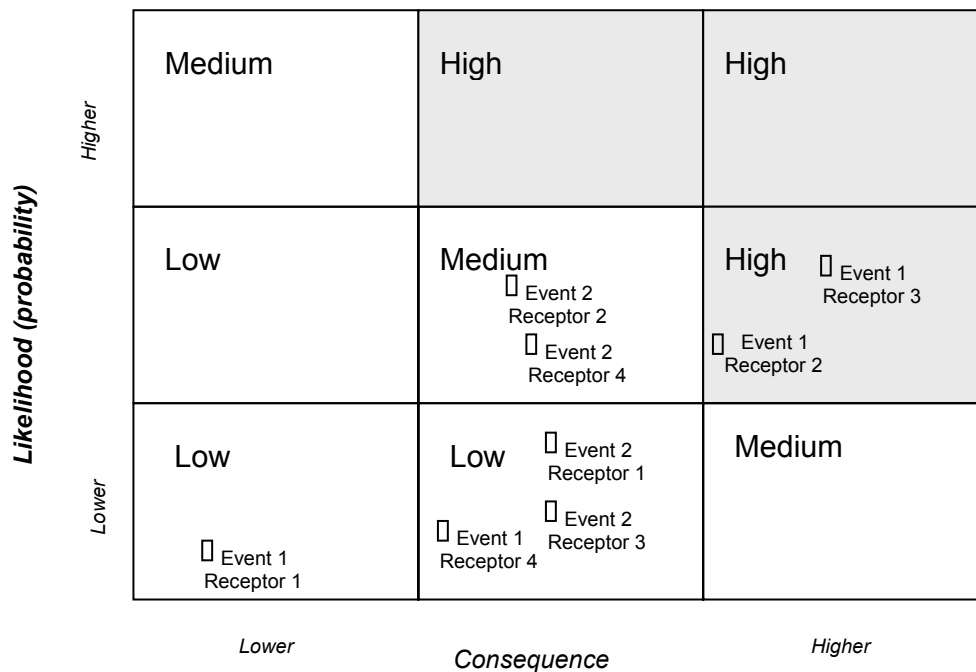
- 5) The numerical value of the calculated “risk index” determines the magnitude of the risk. Risk events with a high risk index value are given higher priority over low index events. The decision criteria may be used to establish priorities.

Ms. Tosine discussed the following examples to illustrate a typical output of a risk analysis. A risk ranking matrix summarizes the results of a risk analysis in a table format and can be used in combination with socio-economic analyses and other stakeholder considerations to identify priorities for risk management. A risk matrix summarizes the risk analysis results in a single graph to allow for a comparison of risk scenarios for each risk receptor.

Table 8: Typical Output of a Risk Analysis

Undesirable Event	Likelihood of Event	Risk Receptor 1			Risk Receptor 2			Risk Receptor 3			Risk Receptor 4		
		Consequence to Risk Receptor 1	Likelihood of Consequence	Risk	Consequence to Risk Receptor 2	Likelihood of Consequence	Risk	Consequence to Risk Receptor 3	Likelihood of Consequence	Risk	Consequence to Risk Receptor 4	Likelihood of Consequence	Risk
Event 1	3	1	1	<b>L</b>	3	2	<b>H</b>	3	2	<b>H</b>	2	1	<b>L</b>
Event 2	3	2	1	<b>L</b>	2	2	<b>M</b>	2	1	<b>L</b>	2	2	<b>M</b>
Event 3	2	1	2	<b>L</b>	1	2	<b>L</b>	2	1	<b>L</b>	1	1	<b>L</b>
Event 4	3	2	1	<b>L</b>	3	2	<b>H</b>	3	2	<b>H</b>	2	1	<b>L</b>
Event 5	1	1	1	<b>L</b>	2	1	<b>L</b>	2	1	<b>L</b>	3	1	<b>M</b>
Event 6	2	1	1	<b>L</b>	2	2	<b>M</b>	2	2	<b>M</b>	1	1	<b>L</b>
Event 7	3	1	1	<b>L</b>	2	1	<b>L</b>	3	2	<b>H</b>	1	1	<b>L</b>
Event 8	2	2	2	<b>M</b>	1	1	<b>L</b>	2	2	<b>M</b>	1	1	<b>L</b>
Event 9	3	2	3	<b>H</b>	1	1	<b>L</b>	1	1	<b>L</b>	1	1	<b>L</b>
Event 10	3	2	3	<b>H</b>	1	1	<b>L</b>	2	2	<b>M</b>	1	1	<b>L</b>

Table 9: Representation of Risk – Risk Map



Ms. Tosine presented a risk profile graph, which can be used to plot a summary of province-wide, or region-specific risks relative to predetermined cut-offs that are considered to represent acceptable, tolerable, and unacceptable levels of risks (the traditional F-N curve).

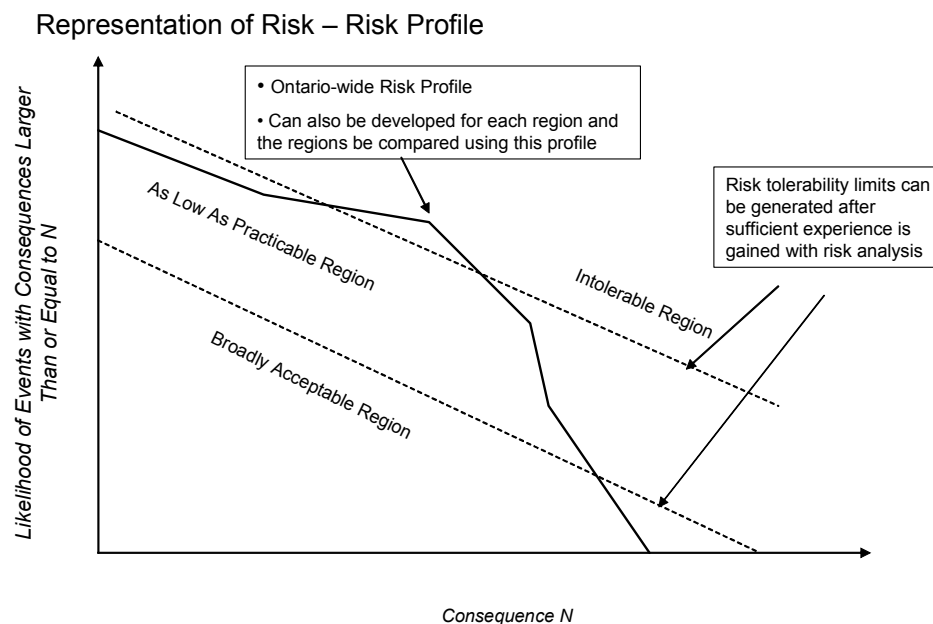


Figure 10: Representation of Risk-Risk Profile

Dr. Hicks provided a brief description of three methods of economic analysis that may be used as a criteria in risk management: cost effectiveness analysis (CEA) which identifies the least expensive way of achieving an environmental quality target; cost-benefit analysis (CBA) which estimates the costs of improved environmental controls against a project benefit (e.g. reductions in airborne sulphur oxides exposures per dollar); and socio-economic analysis (SEIA) which is very broad analysis that includes an array of non-allocative effects and costs (e.g. impacts on trade, exchange and inflation rates). The scope of the economic analysis is a critical factor in determining the utility of the risk management system. A narrow scope that evaluates only direct costs to minimize a risk may underestimate the effectiveness of some risk control options that are evaluated. On the other hand, if the scope of the economic analysis is too broad, there is a greater possibility of the risk issue being

Economic Analysis as a possible **Risk Criteria.**

depreciated in value. In response to question on the role, and form of economic models used in risk management, J. Hicks suggested that we need more dialogue between economists and risk assessors to promote the use of common terminology. There are limits to existing approaches but there are ways to improve the use of results for environmental protection. This may be the subject of another session on the discussion of specific techniques for risk evaluation.

Ms. Tosine presented a pilot project within the MOE which uses a risk based system to establish compliance inspection priorities for the Environmental SWAT inspection and enforcement team. The analysis uses the actual number of occurrences to establish a likelihood rate for various business sectors. *Consequence* categories and weights are based on known or anticipated health and environment impacts and *consequences* of non-compliance. The following example was provided to illustrate risk analysis results over all sectors:

Table 10: Risk Analysis Results

Summary Over All Sectors (Example Data Only)

Consequence Category	Number of Occurrences	Consequence Weight	Risk
9	1	1000	1000
8	416	100	41600
7	60	80	4800
6	1830	40	73200
5	4939	10	49390
4	43871	6	263226
3	33119	1	33119
2	26038	0.6	15622
1	16064	0.1	1606
0	711	0	0

To identify priority sectors for risk management the total risk score for each sector (a measure of “societal risk” for that sector in the Province) was divided by the sector “size” to provide a measure of “unit risk” for that sector (Risk per unit value generated). A higher-than-average unit risk indicates that that sector imposes a disproportionate amount of the total environmental risk in the province relative to its contribution to the economic well being of the province. Phase One of the framework pilot has identified high- risk sectors for

development of sector specific risk management strategies by the SWAT inspection and enforcement team. The pilot process has identified the importance of using both a risk assessment methodology and reliable data sources early in the process. Data and statistical analysis expertise is required as well as expertise on the subject matter to provide good judgement in addressing data gaps.

### Sources of Evidence in Health Risk Assessment

Lorraine Craig discussed sources of evidence in evaluating a suspected environmental health hazard. The primary sources of evidence are i) epidemiological studies of human populations which measure the occurrence of disease patterns in human populations that have been unintentionally exposed to an environmental contaminant and ii) toxicological studies which measure the production of harmful effects in laboratory animals exposed to predetermined levels of an environmental contaminant. In addition to the principal findings of long term toxicity studies and epidemiological findings, several types of supporting evidence may also be considered. These secondary sources include i) physico-chemical property studies to examine the molecular structure of a chemical in an attempt to reveal clues about possible biological activities in cells and tissues and ii) pharmacokinetic property studies which determine how a substance will be absorbed into the body, distributed to different body tissues, biotransformed by various enzymes and finally excreted. A variety of short term tests can be used for screening purposes using mammalian cells, cells of plants and insects or bacteria. Finally PBT tests evaluate the persistence, bioaccumulation and toxicity factors for an environmental contaminant. The weight of evidence approach attempts to balance positive and negative evidence of harmful effects, principally using toxicological and epidemiological data, with the other data playing a supporting role. NERAM's Environmental Health Risk Primer (McColl et al., 2000, [www.neram.ca](http://www.neram.ca)) provides further information on the weight of evidence approach including criteria for assessing weight of evidence.

#### **Risk Estimation**

Weight of Evidence for a risk is determined principally by the epidemiological and toxicological findings, with supporting evidence playing a contributing role. Both the existence of a risk and the dose-response curve are estimated.

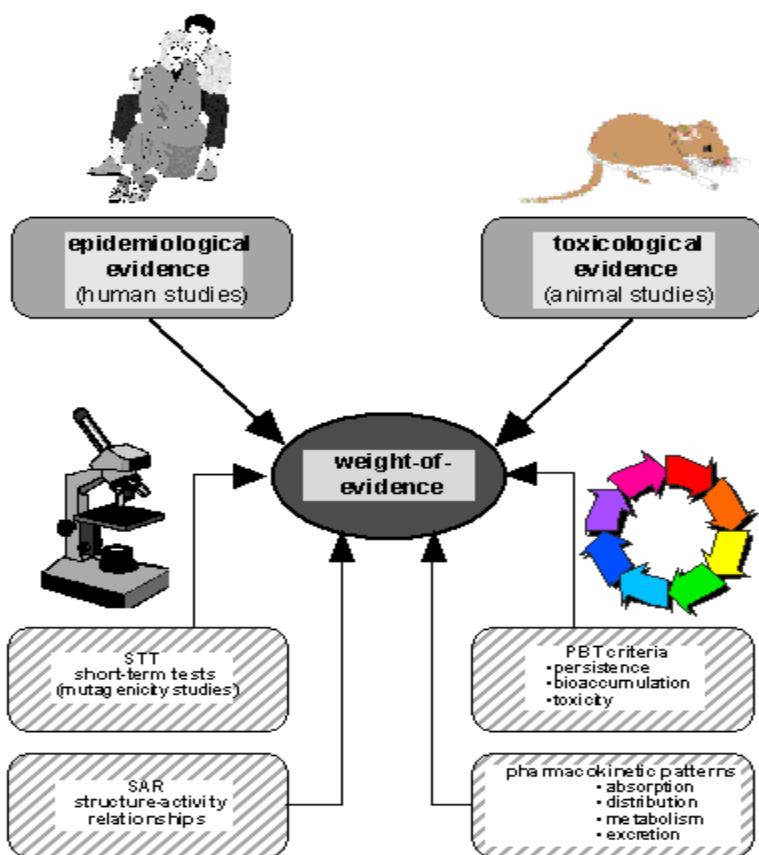


Figure 11: Sources of Evidence in Risk Identification.  
Combined weight-of-evidence (e.g. weigh human and animal studies more, weigh supporting studies less)

### Risk Assessment and Air Quality

Dr. Daniel Krewski, Director of the R. Samuel McLaughlin Centre for Population Health Risk Assessment within the Institute of Population Health at the University of Ottawa, reviewed two major US cohort studies which assessed the association between mortality and long term exposure to air pollution and presented results of a reanalysis of the two studies. His presentation illustrated the value of epidemiological methods as a tool for estimating population health risks. Dr. Krewski also presented the regulatory process for the development of Canadian sulphur in gas regulations as an example of the integration between scientific evidence and air quality policy.

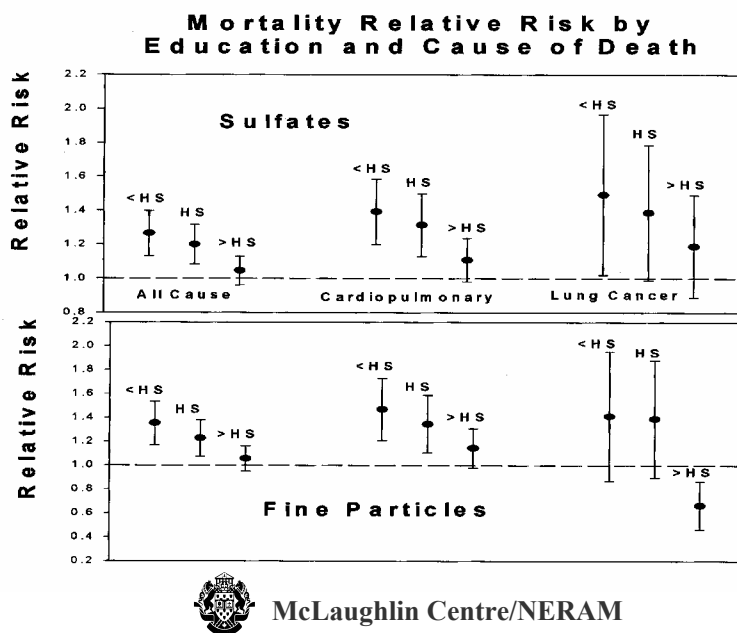


Dr. Krewski provided a historical overview of the scientific evidence for air pollution health effects beginning with the December 1952 London smog episode which was followed by a sudden rise in daily mortality. Similar associations have been found in Canada, for example, in Toronto ambient levels of particulate matter (PM) and ozone are associated with increases in daily mortality rates (Ozkaynak et al. 1995; Burnett et al. 1998) and ozone episodes are associated with increased hospital admissions for respiratory and cardiac conditions (Burnett et al., 1997) and poorer pulmonary function in children (Kinney et al., 1996).

**Risk Estimation** (part of **Risk Analysis**) use of epidemiological evidence to estimate the population health risks associated with long term exposure to urban air pollution

Two US prospective cohort studies of the association between air pollution and mortality have played a key role in setting national ambient air quality standards for PM in North America. The Harvard Six Cities Study (Dockery et al. 1993) and the American Cancer Society (ACS) Study (Pope et al. 1995) followed large numbers of individuals over multiyear periods and observed their rates of mortality. Dockery et al. in the Six Cities study followed a cohort of 8,000 adults in northeast and midwest United States from the mid 1970s to 1989. The results showed that higher ambient levels of fine particles and sulfate were associated with a 26% increase in mortality from all causes and an increase in fine particles was associated with increased mortality from cardiopulmonary disease. In the larger ACS study, Pope et al. followed a cohort of 550,000 adults in 154 cities between 1982 and 1989. Higher ambient levels of fine particles were associated with increased mortality from all causes and from cardiopulmonary disease in the 50 cities for which fine particle data were available. Higher ambient sulfate levels were associated with increased mortality from all causes, cardiopulmonary disease and lung cancer in the 151 cities for which sulfate data was available. The difference between all-cause mortality in the most polluted city and the least-polluted city was 17% and 15% for fine particulates sulfate, respectively. Following intense scrutiny of the studies' methods and results by Congress, industry and scientific community, the HEI commissioned the Institute for Population Health to conduct an independent reanalysis of the data and results. Overall, the reanalysis confirmed the quality of the original data and replicated the mortality risk estimates in both cohort studies (Krewski et al., 2000). The reanalysis team tested various models and variables to determine whether the original results

would remain robust to different analytic assumptions. One of the most significant findings was the modifying effect of educational attainment on risk. Figure 12 below illustrates the significantly higher mortality risk among the subgroups with less than a high school education.



**Risk Estimation**

The relative risk (for a 10 mg/m<sup>3</sup> change) gives an estimate that can be used with various risk factors to estimate population health effects.

Figure 12: Relative Risks of mortality by cause of death and educational attainment associated with sulfate or fine particles in the reanalysis of the ACS study. HS= high school. Error bars represent ±2SE

Spatial analysis showed that when the analyses controlled for correlations among cities located near one another, the associations between mortality and fine particles or sulfate remained but were diminished. Spatial analysis of the ACS study found that the association between sulfur dioxide and mortality persisted when other possible confounding variables were included in the model. When sulfur dioxide was included in the models with fine particles or sulfate, the associations between PM and mortality were reduced.

Dr. Krewski indicated that the next steps in the Reanalysis Study are to update the analysis with the extended time period follow up of the ACS and possibly the Harvard six cities cohorts, and continue the development of new spatial analytic methods.

Prior to the late 1990s, Canada did not have legislation to regulate the sulphur content in gasoline. Dr. Krewski discussed the role of scientific evidence in the standard setting process. Policy development began by initiating a multistakeholder study to provide scientific evidence of i) atmospheric modeling to estimate air quality improvements associated with various reductions in sulfur in gas ii) the health and environmental benefits associated with these reductions and iii) the economic costs to Canada’s fuel industry associated with various sulphur in gas scenarios in a process illustrated below.

**Risk Estimation**

Large scale epidemiological studies showing a significant and consistent association between ambient PM and mortality played a key role in the decision to adopt a stringent regulatory standard for sulfur in fuels.

### Evidence to Policy: Sulfur in Gasoline

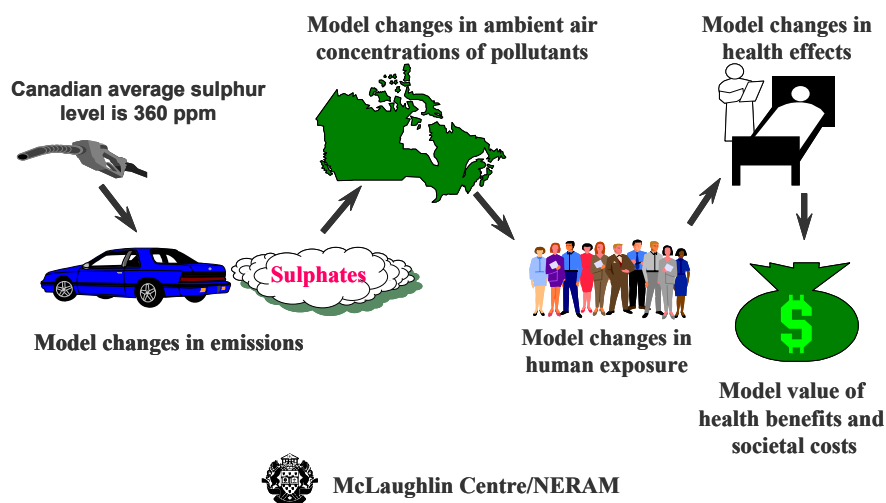


Figure 13: Evidence to Policy: Sulfur in Gasoline

A monetary valuation of avoided health effects (including premature mortality, hospital admissions, emergency room visits, new cases of chronic bronchitis, new cases of chronic bronchitis in children, restricted activity days, asthma symptom days, acute respiratory symptoms) based on epidemiological studies and health economics literature was conducted for six options for sulphur in gas ranging from 350 to 30 parts per million (ppm). The costs of retrofitting refineries to meet the various standards and the impacts of the standards on industry competitiveness were also estimated. The most stringent standard of 30 ppm, to be achieved by January 2005, was selected as this option resulted in the greatest difference between benefits and costs and brought Canadian sulphur levels into line with current California standards as well as with proposed US and European standards.

## Stakeholder Perspectives on Issues in Risk Management

The Workshop concluded with a panel discussion on issues related to the value of risk management in government decision-making. The five panelists represented the following perspectives: academic (Dr. John Shortreed, Professor Emeritus, NERAM); scientist in private consulting (Dr. Robert Willes, Cantox Environmental Inc.), environmental non-government organization (Mr. Ken Ogilvie, Pollution Probe), industry (Mr. Howard Carter, Imperial Oil), and provincial government (Ms. Cathy Grant, Ontario Ministry of the Environment). The Panel discussion was moderated by Dr. John Hicks of Ryerson University.

### **Engaging Stakeholders in the Risk Management Process**

The Panel was asked the question “Who are stakeholders and what is their role? Two diverse perspectives on the definition of stakeholders were offered. Mr. Ogilvie defined stakeholders as anyone who can inform or influence a decision and noted the limited capacity in which stakeholders are currently allowed to be involved in decision-making. Dr. Shortreed defined stakeholder as anyone who is affected by a decision or “interested and affected parties” who should be engaged early and often. Dr. Shortreed disagreed with the view that stakeholders are decision-makers, noting that decisions should ultimately be made by elected officials, and stakeholders should be consulted in the process as often as deemed appropriate by the decision-maker. The public consultation process for Xenotransplantation was identified as an example of an effective, but expensive, approach to engaging the public in risk management issues.

Grant and Carter commented that often stakeholders get involved at the end of the decision-making process and noted that it is a challenge to engage stakeholders from the outset. They noted that successes have been achieved in engaging stakeholders at the community level, however it is much more difficult to engage stakeholders in broader issues such as global climate change. Willes agreed that early involvement of stakeholders is an essential part of the decision-making process, particularly at the local level. He estimated that 99% of issues are due to misunderstandings or mistrust because of inadequate stakeholder involvement. He commented that including stakeholders is easy to do, but the difficulty is in sharing control to allow the process to take place. He also noted that in some cases stakeholders have been paid to participate because often there is a large time commitment required. Willes identified the need to move from stakeholder consultation towards stakeholder participation through a process that is integral to the risk management framework. He commented on the lack of clarity in the federal government definition of public participation.

Stakeholder participation also leads to the question of funding. Grant noted that stakeholders have various interests and that efforts are being made to improve in this area. There is always a challenge in fairly determining which stakeholders could be compensated for their involvement. Ogilvie commented that stakeholders would not compromise their positions by being paid to participate. He identified the need for more debate on how to deal with people's values in risk assessment and risk management decision-making and how to let people express their values. He noted that a proper public consultation process and consistent terminology can make the decision process effective. Grant emphasized the importance of transparency in decision-making and the essential role that effective consultation plays in facilitating this transparency.

### **Risk-Based Approaches to Public Policy and Public Demands for Zero Risk**

Several delegates identified the challenge of making cost-effective risk management decisions in the face of increasing public demands for zero risk. Willes stated that there is no such thing as zero risk. Ogilvie indicated that politicians are coalition builders and it is important to involve coalitions in the risk management process by giving them the scientific risk information and a fair decision-making process. Shortreed noted the duality of the risk management decision-making process in which science is on one side and stakeholders' views are on the other. Achieving a balance between this duality is the essence of risk management. It is an iterative process in which additional information is collected if not enough is known about either dimension of the risk to make an informed decision. Grant suggested that decision-makers should create and promote a system to obtain the most value per dollar spent in terms of risk reduction and positive improvements for health and the environment. She noted that decision-makers cannot make decisions in a void. Science is knowledge and that has to be put on the table. The Standards Development Branch is continuing to develop a clear, transparent, decision-making process for air standard setting to bring the right information in at the right time to make informed decisions.

### **How Far Will the Risk Management Framework Approach Go?**

Shortreed noted that the business community is farther along than government in embracing a risk management approach. Most firms now have a Chief Risk Officer position. Our global economy and the increasing complexity of problems call for a structured risk management process. Grant indicated that there are a variety of activities within government that consider promoting tools for effective risk management. The Risk Management Framework for Setting Priorities for Compliance (Tosine) in combination with the Framework for Air Standards are some examples which will have a variety of applications. The tools have great potential and will hopefully evolve over time. Willes observed that the workshop presentations indicate that there is general agreement on the overall components of a risk management framework. He indicated that there is continuing confusion on terminology, which may contribute to misunderstandings and failures to resolve risk management issues. He identified the need to improve the consistency of risk terminology at the international level.

## **Chapter 4 Design and Assessment of Risk Management Frameworks**

The design of an organization's risk management framework takes place functionally within the risk management system of the organization. As emphasized by the Japanese risk management standard and the NERAM benchmark framework, the risk management system is not only charged with the design of the risk management framework, but also with the implementation and operation of the framework in organizations with the necessary capacity requirements. This chapter does not deal with the implementation of the risk management framework including the resourcing of skills, data, and methods for that framework, however, it is clearly an important aspect and worthy of considerable attention. The Japanese standard is perhaps the best check list for this task. Here it is sufficient to note that in the early stages of the introduction of a risk management framework, much of the effort and activity will be concerned with the framework itself and not using the framework for risk management.

There are many other framework issues in addition to the implementation issues for frameworks discussed above. For example, the whole issue of iteration within a framework - for the risk management of a contaminated site, risk management frameworks typically have three iterations for risk assessment. These include the usual first iteration of the benchmark framework "preliminary analysis," a sort of screening analysis of the site, followed by the second iteration or the "risk analysis" of the benchmark framework which in the case of a site remediation is the application of sampling by drill holes at selected locations, with analysis of the pollution being compared to standard "acceptable" concentrations. The third iteration is reserved for special situations that do not meet the standards, perhaps for good reasons - for example the background levels of arsenic may exceed the standard. In this third iteration there is detailed examination of the risks, usually from first principles and including estimates of exposure of population etc. These interesting and important issues are many in number and must be left to other more detailed documents.

Each organization must design its own risk management framework using the basic elements identified in Chapter 2. In general, each framework will contain, implicitly or explicitly, most of the basic elements, however the individual elements may be emphasized differently, use different methods and tools, or occur in a different sequence. There may be several different frameworks within an organization for different tasks, but ideally the frameworks will be integrated into a comprehensive overall framework and will be united through the use of common terminology.

This chapter will outline the basic criteria that can be used to evaluate a risk management framework in an organization. The actual design of a framework will use these criteria for testing alternative designs and also for identifying effective design elements. The chapter will identify ten guidelines for designing a risk management framework. Detailed discussion of risk management framework design methods is outside of the scope of this document.

An organization's risk management framework must reflect three basic considerations:

1. the organization's culture and inherent *risk criteria*,
2. the nature of the risk and the organization's stakeholders, and
3. the resources, both human and other, that are available to the organization.

### Culture and risk criteria in frameworks

*Risk criteria* are defined by ISO as “*terms of reference by which the significance of the risk is assessed.*” By definition, risk criteria are an input to risk management frameworks from outside the framework. Nevertheless they are key elements in the design of a framework. One example to illustrate the importance of risk criteria is by comparison of the truck and rail industries. Consider that one industry takes an open and transparent approach to risk management and publishes all accident and incident data in a timely, comprehensive, and accurate way while their competitor adopts the “fortress” approach which says “tell me, regulator, what I need to do to comply with the regulations and I will do it, but other data on accidents and incidents is private and will not be released.”

In this example, experience indicates that media attention will focus on the available data and the open industry will be perceived as the more dangerous mode of transportation due to the reports of their accidents, while their competitors will appear to be safer. There is the possibility that after a particular accident the media and public will criticize the “fortress” industry for not being more open in disclosing information that might have prevented the accident or exposure of the public to *consequences*.

Clearly, each organization must decide what its approach to safety and risk management will be. It is expected that the risk criteria will incorporate as a minimum all legal regulations as well as health, safety and environmental issues and will in some way address the criteria listed in the benchmark framework. However, it is their choice as to the risk criteria that are selected. Consider the criteria identified in Table 1 of Chapter 2:

- **Agency objectives:** These should be reflected in the risk criteria, but they may wish to go well beyond regulatory requirements or just meet them. They may wish to use industry performance standards, and so forth.
- **Capacity:** How many people will be assigned to risk management activities? Will these be staff or line positions? Will every manager be expected to do risk management as an integral part of their job?
- **Trust of Stakeholders:** Does the organization consider this to be a priority or not?
- **Transparency:** See example above of the two extreme choices of “open” versus “fortress” approach described above.
- **Flexible-Consistent:** Does the organization wish to commit, as proposed by Willes in Chapter 3, that stakeholders be given decision authority or do they wish to retain all authority within the organization? In the case of the precautionary principle, does the organization wish to commit to a specific definition of the principle and allow this to dictate their choice of *risk treatments*? Does a regulator wish to judge on a case by case basis or follow an explicit

standard for action? This clearly is a key choice to make and one that will dictate the level of expenditures on *risk communication*, *risk estimation*, etc.

- **Budget:** Will available resources allow for extensive risk communication, which can double the costs of risk management? Does the budget preclude the development of new approaches and only allow for borrowing methods of risk estimation and evaluation from other jurisdictions?
- **Cost-Effective:** Should risk treatment stop at the point where the marginal costs exceed the marginal risk reductions or should risk reduction continue to the point of a “gross disproportion” of costs to risk reduction as specified by the ALARA (As Low As Reasonably Achievable) principle<sup>7</sup>?
- **Stakeholder Acceptance:** Organizations must judge the importance of this criteria. Do they believe that they can stonewall against all opposition or is it necessary to have the maximum acceptance of decisions by stakeholders? Who are the key stakeholders (financial partners, regulators, media with leverage over the organization, etc.) and what are their views and requirements?
- **Uncertainty Explicit:** Will the organization use average estimates, or in addition, communicate the range of possibilities, including the worst case scenario? Should the board and other stakeholders be informed of low *probability*, unlikely, and very negative outcomes.
- **Reasonable Relationship:** The Conference Board of Canada argues that there should be a reasonable relationship between expenditures on risk reduction and the risks (Howatson, 1998). On the other hand, since the Krever Inquiry, the Canadian blood system has not followed this approach but has, as argued by Krever, spent large amounts of money to reduce risks to the blood system to the lowest achievable levels. This may be a trade-off between an unreasonable expenditure in terms of other available life-saving investments in the health care system and the need to restore public trust in the blood system. Making trade-offs between choices of risk criteria is common practice within organizations.
- **Precautionary Principle:** There is a trend to incorporate this principle into risk criteria of organizations. It is not yet a normal requirement of common law, but is being accepted by some organizations as a statement of principle, even though the particular details of its implementation are not yet defined.
- **Comprehensive:** This criteria concerns the degree to which all factors impacting a risk should be considered, even if methods of analysis, measurement tools, etc. are not available. Some organizations prefer to deal only with risk factors that can be measured and quantified and set aside all other factors.
- **Achieve Operational Plan:** For instance, some have argued that the Canadian adaptation of the Kyoto Protocol is done in the expectation that there is a significant *probability* that this plan will not be achieved, while others argue that the plan is achievable and point to specific

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<sup>7</sup> ALARA stands for “As Low As Reasonably Achievable” – a concept which asserts that environmental exposure to toxic substances should be kept as low as is reasonably achievable, using pollution control equipment and industrial processes that can be installed and operated at reasonable cost. See McColl et al. (2000) p. 1-16 <http://www.neram.ca/Pages/research/primer/hazard.pdf> and CSA (1997) p. 25 for further information.



firms that have already met the 2012 requirements. Normally an organization has a goal of achieving the risk reduction plan.

There are clearly normative and moral expectations for risk criteria. These considerations are not a formal part of the risk management framework, but are determined by the organization and its decision maker(s) as a precursor to the design of a framework.

The criteria selected for comprehensiveness will determine the resources for i) risk assessment (only preliminary analysis or also detailed analysis and evaluation), ii) risk communication (full consultation and communication at all stages in the framework, or only at the implementation step), and iii) flexible-constrained (decision-makers decide standards and process only, or make decisions at each step shown in Figure 4.). In terms of this design framework, the most significant impact will be on the organization's views of stakeholders and the degree to which they should be informed and consulted.

Design Guide 1 - The framework must reflect the *risk criteria* and other aspects of the context that are selected by the organization.

If for reasons of flexibility-consistency and budget, an organization uses standards as an expression of their risk criteria and as an administrative and enforcement necessity of their operations, then this must be reflected in the framework. This will usually be in terms of a separate, but linked, sub-framework for establishing or reviewing standards (i.e. MOE Proposed Risk Management Framework for Air Standards as discussed in Chapter 5 (MOE, 2001)). There will also be criteria related to the periodic review and monitoring of standards in achieving the risk reduction objectives.

Design Guide 2 - The framework should reflect the use of standards and other a priori risk evaluation determinants.

#### Nature of the risk and stakeholders

The characteristics of risk, mainly the degree of uncertainty and confidence in risk estimates, are an important input into the design of a framework. If the risk is well known with lots of historical data, such as falls from construction sites due to the lack of a safety perimeter fence, then there is little need for more than a cursory risk assessment process. If on the other hand, the risk is uncertain, such as the contribution of NO<sub>x</sub> to air pollution health effects<sup>8</sup>, then a major research effort could be initiated to estimate the risks prior to establishing standards. Similarly for some air pollutants, the distribution from the *source*, combined with the exposure from other sources may be critical for health effects and it may be necessary to have an extensive investigation of population exposure.

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<sup>8</sup> While positive associations have been found between nitrogen oxides and daily mortality (Anderson et al., 1996), a meta-analysis of the European APHEA study of 10 European cities showed positive associations with mortality and sulphur dioxide and ozone, but not with nitrogen oxides (Zmirou et al., 1998). On the other hand, some policy officials and current regulations identify NO<sub>x</sub> as an important risk factor that acts to wash metals from particles and the metals are of concern (Maynard, Robert. UK Dept of Health, personal communication).

Design Guide 3 – Risk estimation is proportional to the uncertainty of the risk estimation and the importance of the risk estimate in the risk evaluation and selection of risk treatment options.

If the concerns of stakeholders are uncertain, then the risk evaluation and stakeholder acceptance processes will have to be extensive. For example, Health Canada recently spent about \$1 million to measure the acceptability of xenotransplantation clinical trials. This was considered necessary for many reasons including: most Canadians are not well informed about xenotransplantation risks; uncertainty in the effectiveness of safeguards against the spread of diseases, such as mad cow, from animals to humans; and significant ethical issues. In other situations stakeholders are well informed about risks, such as the health impacts of summer smog, and therefore less expenditure on risk communication and consultation are required.

Design Guide 4 – Risk evaluation and stakeholder acceptance are proportional to the uncertainty associated with stakeholders' level of understanding of the risk.

Risk perception is defined as “set of values or concerns with which a stakeholder views a particular risk”. Risk perception is associated with a number of factors such as: familiarity, voluntary or involuntary, effects on children, timing of effects, knowledge about the mechanism, multiple deaths, and so forth. For example, rare *events* such as nuclear accidents are viewed by the public as far riskier than more common risks such as traffic accidents which cause about 3,000 deaths per year in Canada. Risk communication efforts must consider these psychological, social and cultural factors that influence public judgments of risk.

Design Guide 5 – Risk communication needs increase with increasing scores on risk perception factors.

For many risks, public acceptance of *risk treatments* are based more on trust in organizations than on a detailed evaluation of individual policies. If this trust is lost, then there is a tendency to reject many of the risk treatments that are proposed. Alternatively, if during the public debate on an issue it is suggested that decisions are being made to favour one group for reasons other than risk, there may be a sudden shift in the risk communication required to evaluate a particular risk treatment. Similarly, if opponents of a risk decision, for example, the decision to approve the Kyoto Protocol, mount a vigorous campaign and introduce new issues, such as the economic impact, then the risk communication efforts may need to be expanded.

A good example of the need to revise a risk management framework is the Royal Society of Canada Expert Panel review (RSC, 2001) of the socio-economic analysis conducted for the PM and Ozone Canada Wide standards-setting process. The panel recommended that the analysis be redone and adequately funded to attain a level of credibility consistent with the implementation costs of proposed standards for Particulate Matter and Ozone.

Design Guide 6 – The framework should be flexible to allow for modification of elements and to go back to previously completed steps if there is a change in the trust of stakeholders, if new issues are raised in the debate or if the character of the risk or risk decision changes.

Many risk treatments, once implemented as *risk controls*, do not fully achieve the estimated risk reductions. This is due to i) a lack of compliance (for example with speed limits), ii) changes in behaviour (some traffic safety measures result in modified driving behaviour with little overall improvement in safety, the so called “risk homeostasis” concept), or other reasons (changes in economic activity may negate levels of pollution that were predicted). It is essential to have a monitoring process that uses well-defined, easily understood, and efficiently estimated performance measures.

Design Guide 7 – Monitoring of implemented risk controls is proportional to uncertainty in the compliance with, effectiveness of, and the realization of risk reduction benefits.

#### Human and other resources

The benchmark framework uses the term “Best ‘Practical’ Practice” to convey the limitations placed on risk management by both resources and by available technology. There are many concepts such as “Best Available Technology” (BAT) and ALARA which describe a sort of negotiating approach to the determination of what is practical or not. Similarly, the size of an organization will limit the resources that can be allocated for risk management. In some cases, this size issue is resolved by the development of an industry-wide set of guidelines for risk management that even small firms can follow. In other cases, the enforcement of risk controls is done through the courts and results in the elimination of many small firms. For example, in the state of New Jersey the introduction of regulations for storage of dangerous goods resulted in elimination of 80% of the firms (who only did about 20% of the volume), mainly by merging with larger firms.

Many firms, after assessing the level of risk and the associated benefits, have opted to get out of the business. The risks are often controlled by *risk transfers* in the form of insurance and the unavailability of insurance is a major factor. In other cases, the risks are associated with legal actions for negligence, lack of due diligence, etc. In some cases industries such as the international shipping industry limit their risks through having a numbered company for each ship – an approach which clearly may act to the detriment of the environment.

Design Guide 8 – The resources of the organization are reflected in the risk management framework. In particular there needs to be an explicit opportunity to “end” an activity.

The assignment of roles and responsibilities for risk management and the processes in the risk management framework will follow the general organizational structure. The two classical forms of “centralized” or “dispersed” organizational structures will have similar arrangements for the risk management framework. For dispersed organizations, there will need to be signals between the small central function and the dispersed elements of the organization to try to integrate policies such as the level of risk taking and the stopping criteria for risk reduction between the

various self-contained business components. This is similar to signals for revenue targets, ratios of debt, use of part time labour, profitability, and so forth.

As noted in Chapter 1, the organization can assign the roles and responsibilities outside of the risk management framework, however, these roles and responsibilities should reflect the general structure of an organization.

Design Guide 9 – The risk management framework should reflect the organizational and hierarchical structure of the organization.

The benchmark framework as well as other frameworks such as the Australian Framework for Management of Drinking Water Quality (National Health and Medical Research Council, 2001) have associated with the framework a number of capacities that the firms must create through hiring, training, succession planning, and so forth. These capacities are directly related to the organization's risk management framework and address capacities in:

- Risk communication,
- Documentation,
- Methods used, and
- Staffing

In addition, staff will need to have a network of partners mainly because risk issues are rapidly growing in number and complexity, and the associated uncertainty creates the need to have considerable expert opinion consensus.

Design Guide 10 – The risk management framework must be supported by a formal plan to achieve adequate capacity in risk communication, documentation, tools and techniques, and staff.

Summary

The design of risk management frameworks and allocation of capacity requirements for their implementation are required for each application of risk management in an organization. Inevitably the frameworks will reflect all the elements in the Benchmark framework, but the degree of effort and time required will vary dramatically depending on three critical factors:

1. The *risk criteria* selected by the organization,
2. The uncertainty in the risk and the *stakeholders'* perception of the risk, and
3. The resources available to the organization for risk management.

These vary considerably to the point where it is likely that each risk management framework will be unique, but will have common terminology and will use standard functional elements. In general the design of the risk management framework should be proportional to the above three characteristics.

## Chapter 5 Review of the Ministry of Environment Proposed Risk Management Framework for Air Standards Setting Process in Ontario

This chapter will review Ontario’s proposed Risk Management Framework for Air Standards as presented by Jim Smith, Director of the Standards Development Branch, Ministry of Environment at the Dec. 6, 2001 Seminar on Basic Frameworks for Risk Management. The framework is outlined in the Discussion Paper “A Proposed Risk Management Framework for the Air Standards Setting Process in Ontario” (MOE, 2001). The Framework will be reviewed within the context of:

- i) the NERAM Benchmark Framework for Risk Management, and
- ii) the design principles developed in Chapter 4.

The chapter will provide recommendations and future directions to further improve the proposed Ministry framework.

### Ontario’s Proposed Risk Management Framework for Air Standards

Jim Smith, the Director of the Standards Development Branch presented the Ministry of Environment’s proposed policy and mechanism for the development of a risk management system to set air quality standards. There are existing standards that were developed about 20 years ago and these are being reviewed and modified if appropriate.

Mr. Smith discussed the need to continuously improve local air quality with a focus on managing emissions from industrial and commercial sources.

The MOE is in the process of reviewing 70 high priority air standards to develop appropriate air quality limits through consultation. There are a number of implementation issues such as:

- i) the time needed for industry to comply with the standards,
- ii) the access to best available technology to comply with the standards, and
- iii) the cost of compliance with the standards by stakeholders.

#### **Context**

The risk management task and the decision-making environment.

Implement Possible guidelines *for Risk Treatment* Options to respond to stakeholder concerns.

Commitment to openness and transparency in *Stakeholder* Relations and improved *Risk Analysis* methods

Mr. Smith noted that the operative risk management process should be transparent. In addition, the Ministry has proposed to update the existing air dispersion models used to assess the concentration of contaminants. Mr. Smith's presentation emphasized the transparent and consultative approach to all these initiatives including the risk management framework development. Specifically, the Ministry's actions have included considerable stakeholder involvement and a transparent formulation phase including the following.

- A discussion paper "A Proposed Risk Management Framework for the Air Standards Setting Process in Ontario" (March, 2001)
- A generous period for open public consultation on the issue,
- Meetings around the province with industry representatives, environmental groups, environment industry practitioners, and the public,
- A stakeholder questionnaire, and
- The December 6, 2001 seminar to review risk management frameworks.

All of these steps are consistent with the best practice components identified in the Benchmark document.

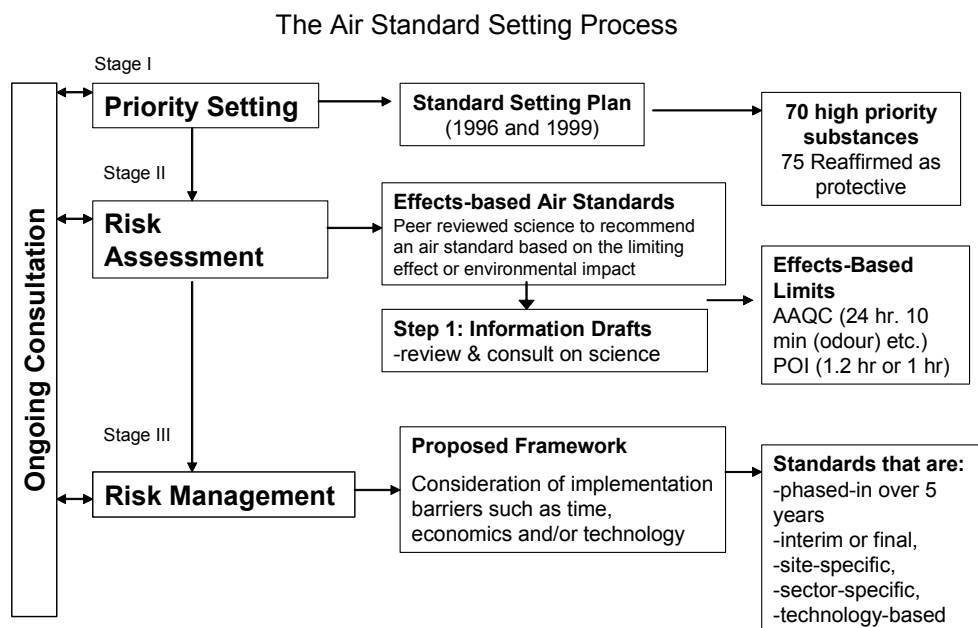
The air quality standard setting process was outlined as illustrated in Figure 14.

***Risk Communication*** and Consultation elements.

NOTE: *Risk Communication* and Consultation are tools for possible use at every function of the Benchmark Risk Management Framework.

Note: Risk Management Approach is the use of standards and this is a process to revise standards based on a review of the health and environmental effects literature.

Risk Management here is Risk Treatment in ISO Terminology.



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Figure 14: The Ministry of Environment Air Standard Setting Process

**Stage 1 - Priority Setting:** In the air standards formulation process, the first stage is necessary to determine priorities amongst the extensive list of air contaminants to a shorter list of those that will require more study. The MOE 1999 Standards Plan [http://www.ene.gov.on.ca/envision/env\\_reg/er/documents/2000/pa9e0004.pdf](http://www.ene.gov.on.ca/envision/env_reg/er/documents/2000/pa9e0004.pdf) identified 70 “high priority” contaminants needing further assessment. An additional 75 existing standards had been reaffirmed as “protective.” Priorities have been set primarily based on the toxicology of the contaminants and the quantity of the release.

**Stage 2 – Risk Assessment:** In risk assessment the science to specify numerical values of “Ambient Air Quality Criteria (AAQC)” or “Point of Impingement (POI)” standards is identified and evaluated. MOE sets effects-based air quality standards based on peer reviewed science and known ambient air concentrations to protect human health, prevent environmental damage and minimize offensive odours.

**Preliminary Analysis**

The risk scenarios are individual toxic air pollutants. This analysis divides pollutants into those with an “acceptable” existing standard and those that require more detailed study.

**Risk Assessment** which is *Risk Analysis* and *Evaluate Risk*.

**Risk Treatment Options** according to ISO definitions, but the traditional usage has been to call this Risk Management.

**Stage 3 – Risk Management Framework:** In this stage, implementation issues are proposed to be addressed through a RM Framework, where decisions will be transparent and implementation considerations are identified. The MOE proposal of March 2001 identified the following considerations to provide flexibility, fairness, economic efficiency and effectiveness in meeting environmental protection goals:

- The timing for new air standards implementation,
- The identification of economics as a consideration in the setting of standards, and
- Technical/technology considerations of new standard implementation.

The Risk Management Implementation framework proposed in March 2001 began once a new or revised air quality standard has been set by MOE. The new or revised air quality standard would be the effects-based standard developed under the Risk Assessment stage of the air standard setting process. The goal of the proposed Risk Management framework is “*to implement, where possible, the effects-based air quality standard and develop a process to deal with those exceptional cases where time, technology and/or economic issues need to be considered*”. The proposed four steps of the RM Implementation framework are outlined in Figure 15.

**Step 1** focuses on gathering the necessary background material to determine who may be potentially impacted by the introduction of a new or revised air quality standard. Scientific information is gathered and reviewed to develop the proposed effects-based air quality standards including identifying and reviewing information from North American and other jurisdictions as appropriate. Standard setting involves two stages of public consultation: 1) an Air Standard Information Draft which summarizes the science and, 2) a Rationale Document which proposes a standard. Information is also sought from stakeholders to assess issues regarding implementation decisions including possible issues of timing, economic and/or technology considerations. If no implementation issues are identified by the industry, MOE may finalize the standard and it will come into effect 6 months following the posting of the decision on the Environmental Registry.

In **Step 2 (Implementation)** industrial facility owners are responsible for completing a site-wide assessment of emissions and predicted impacts relative to the proposed new or revised air standard(s). If the emission summary and dispersion modelling report showed compliance with the proposed new or revised air quality standards, then a facility would be eligible for an incentive (in March 2001 the proposed incentive was the Comprehensive Site-Wide Certificate of Approval that provided operational flexibility). If there was non-compliance and the facility was experiencing implementation difficulties related to time, technology and cost, then they proceeded to Steps 3 or 4.



**Proposed Risk Management Implementation Framework for Air Standards**

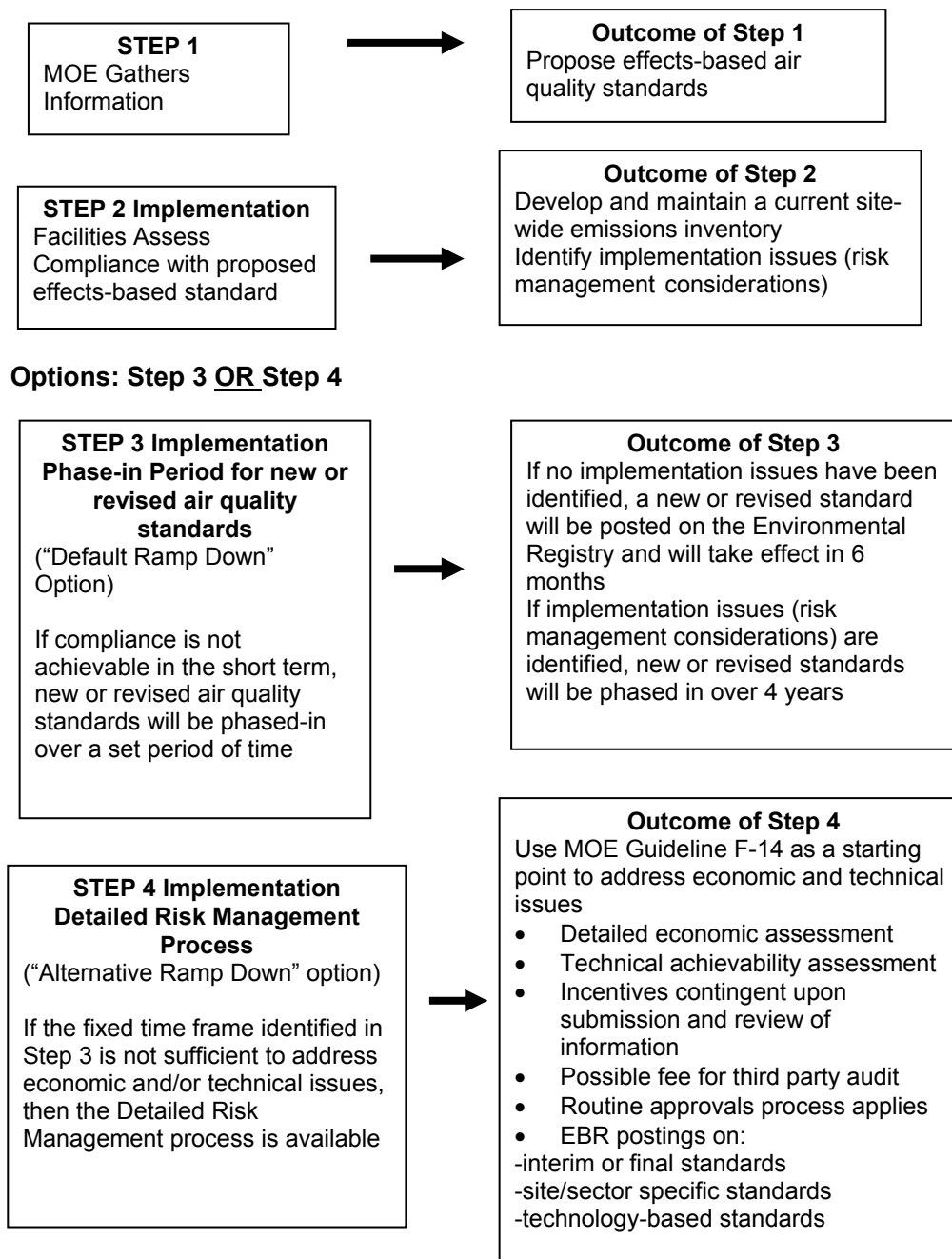


Figure 15: Proposed Risk Management Framework for Air Standards (MOE, March 2001)

**Step 3 (Implementation)** was a “Default Ramp Down” option for those facilities who do not comply with the proposed new or revised air quality standard(s) but make a commitment to comply with a set period of time (i.e. 4 years was proposed). This phase-in period will allow stakeholders time to develop plans for achieving compliance with the new or revised air quality standards. Facilities that made this commitment would be eligible for the incentive.

**Step 4 (Implementation)** was an “Alternate Ramp Down” option for those industrial stakeholders who could not make a commitment to meet a new or revised air quality standard within the four-year phase-in period due to site specific technical and/or economic issues. MOE proposed that in order to be eligible for the incentive a proponent or sector must demonstrate that economic and/or technology barriers would make it unduly difficult for their facility to comply within the four year timeframe. MOE provided a summary of the factors that could be considered in a detailed economic assessment and references MOE Guideline F-14 “Economic Analysis of Control Documents in Private Sector Enterprises and Municipal Projects” to define information requirements and a protocol for a detailed economic analysis. In order to promote transparency in decision making, the economic and/or technical information submitted for MOE review would be posted on the Environmental Registry for public review and comments.

A companion discussion paper entitled “Updating Ontario’s Air Dispersion Models” is related to the proposed standard setting process. The past regulations dating back to the late 1960’s the Ministry of Environment had structured local air quality decisions on the projections of comparatively simple air dispersion models. These models estimate concentrations of contaminants at the Point of Impingement. However, several new model algorithms have significantly improved the simulation capabilities of atmospheric models and it is apparent that many local air quality issues can be more accurately identified with these models. The Risk Management Framework discussion paper suggests that the proposed new dispersion models may predict higher maximum ground level concentrations, and therefore could affect the implementation of air standards . Hence the need to link the introduction of new models to the risk management process.

***Risk Analysis***  
improvements to support estimates of the impacts of ***Risk Treatment*** Options.

Models are an analysis tool for ***Risk Assessment/ Risk Estimation***

Mr. Smith identified the following key issues raised by stakeholders regarding the proposed Risk Management Implementation Framework:

- **Phase-In Period For New Air Standards:** The proposal suggested a four year period for phasing-in new standards if there are economic or technical considerations identified that may affect compliance with the standard. If there are no implementation issues, the proposal suggested a six-month implementation period. Some stakeholders have suggested that a term of five years should be used rather than the four year period.
- **Financial Effects Analysis:** If a facility cannot comply with the requirements of the new standard within the proposed time frame a “financial effects analysis” was proposed to support an extension of the term. Stakeholders have responded that the terms of the economic analysis will need to be clarified. For example, the specific scope can be limited to a fairly narrow cost-effectiveness analysis, or expanded to a much broader socio-economic analysis. The potential costs, and resource utilization to complete these analyses are very different. Some stakeholders also had significant concerns about the disclosure of financial information.
- **Continuous compliance, and approvals-related issues:** The introduction of a risk management decision-making framework must coincide with several other processes that regulate emissions to the environment. Existing practices of regulating industrial emitters must be taken into account in these new initiatives.

#### Discussion of Ontario’s Air Standard Setting Framework

The Ontario Ministry of the Environment is currently engaged in a review of Point of Impingement air standards within an existing regulatory framework for all the individual substances considered to significantly impact health and the environment. Before commenting on the risk management frameworks used and comparing them to the NERAM Benchmark framework it is necessary to define the general context for the decisions being examined and in particular decisions which are not being considered. Some of the comments relate to powers and mandates that are exclusive to the Ministry and any comments are intended to be descriptive in nature and not to address in any way the correctness or appropriateness of the choices made, which would clearly be inappropriate in this document as these considerations are outside of a risk management framework and are part of the organizations decision-making.

The Ministry has existing regulations that consider a specified list of individual chemical substances and the allowable concentrations (the standards) at a point of impingement, where people would have the maximum exposure to the chemical emissions. The concentration of chemical emissions is assessed at the source and dispersion models are used to calculate the concentration at the maximum point of impingement. The current review of regulations has three elements:

1. A review of the standards to determine if the standard accepted has acceptable impacts on human health and the environment,
2. A review of the dispersion models used to calculate the change in concentration from the emission source to the point of impingement, and
3. Design of implementation criteria for the time period for the regulated firms to meet the revised point of impingement air standards.

In our view the risk communication and stakeholder relationships fostered by the Ministry of the Environment are exemplary. They consider the high level of stakeholder concern both for those who emit the chemicals and those who are exposed. Risk communication and consultation with stakeholders is done at each step in the process and is well documented. The process for revising standards, the methods for stakeholders to provide input and reaction, and so forth are well documented and widely available.

Given the decisions made by the Ministry to use a literature review method of risk analysis and assessment, clearly made on the basis of the resources available and timing considerations, the framework elements for risk analysis are appropriate in scale and again have a state-of-the-art risk communication and consultation component.

The Ontario Ministry of the Environment's process for setting air standards, the first of the three tasks in their review, is consistent with the NERAM benchmark risk management framework as illustrated in Figure 16. The functional activities and their arrangement in the framework are standard. The MOE framework deals with many pollutants and the process is iterative with several different levels of risk assessment efforts depending on the available knowledge, the amount of uncertainty, and so forth, again this reflects the concept of "preliminary analysis" in the benchmark framework.

The framework consults with stakeholders at virtually every step, documents the stakeholder concerns and considers these in the development of standards all within a reasonable time schedule. As noted above the risk analysis is based on a literature review of peer reviewed scientific information as well as other standard setting documents and the recommendations from these reviews are subject to risk communication and consultation with stakeholders.

The third item in the overall MOE review – consideration of implementation of the standards that are selected is a combination of risk treatment and implementation. The MOE framework uses the terminology "risk management" whereas the ISO terminology for this activity would be risk treatment. This has been reflected by inserting the word "implementation" in the Figures reproduced from MOE documents. This task follows from the use of the existing Point of Impingement regulatory approach and the need to consider the phase in of the new standards. This is also consistent with the NERAM benchmark risk management framework as illustrated in Figure 17. Given the new standard, the "implementation" risk management framework applies mainly to the implementation of the standards and the design of ramp down risk treatment options for implementation which may vary by economic impacts on firms.

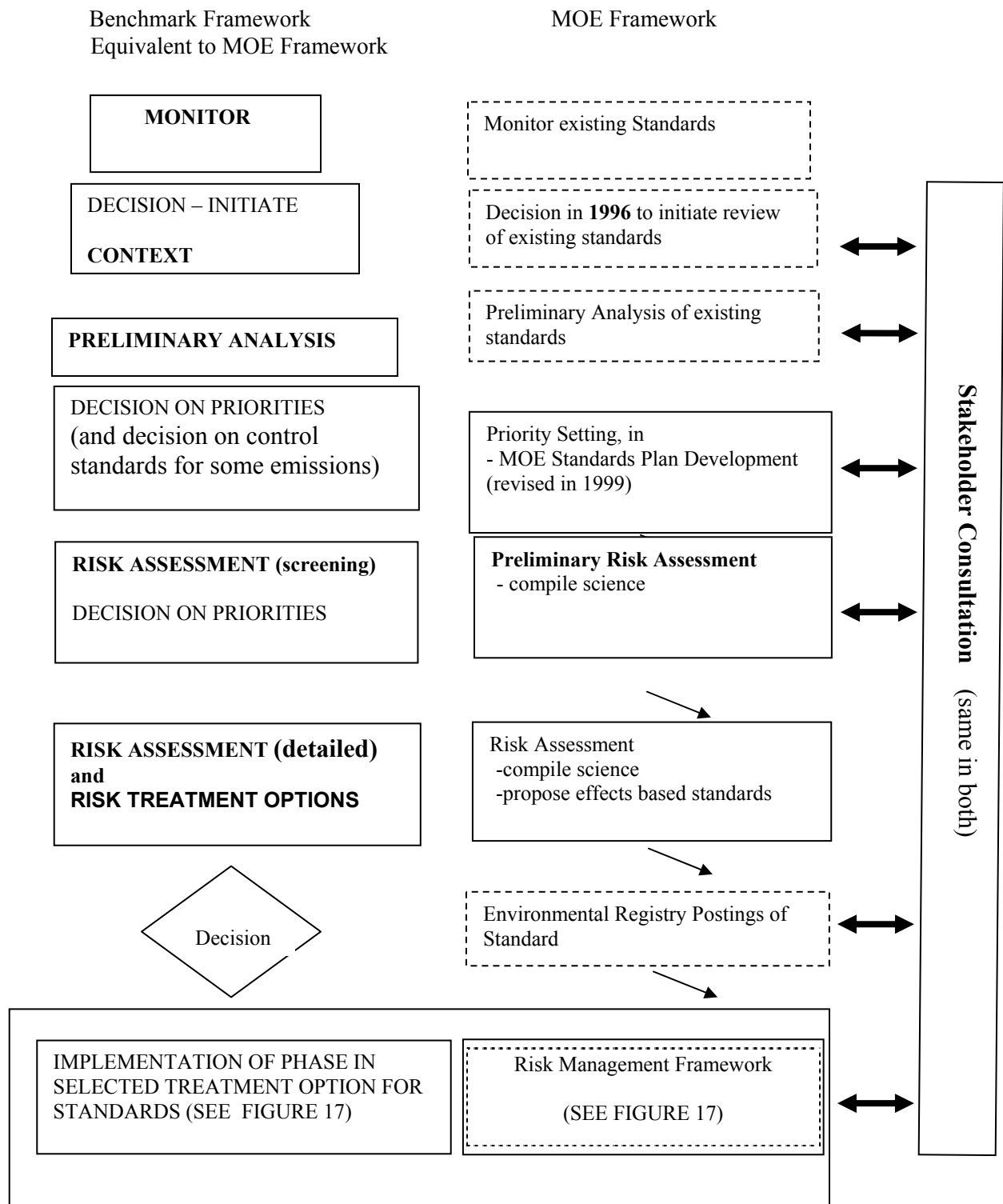
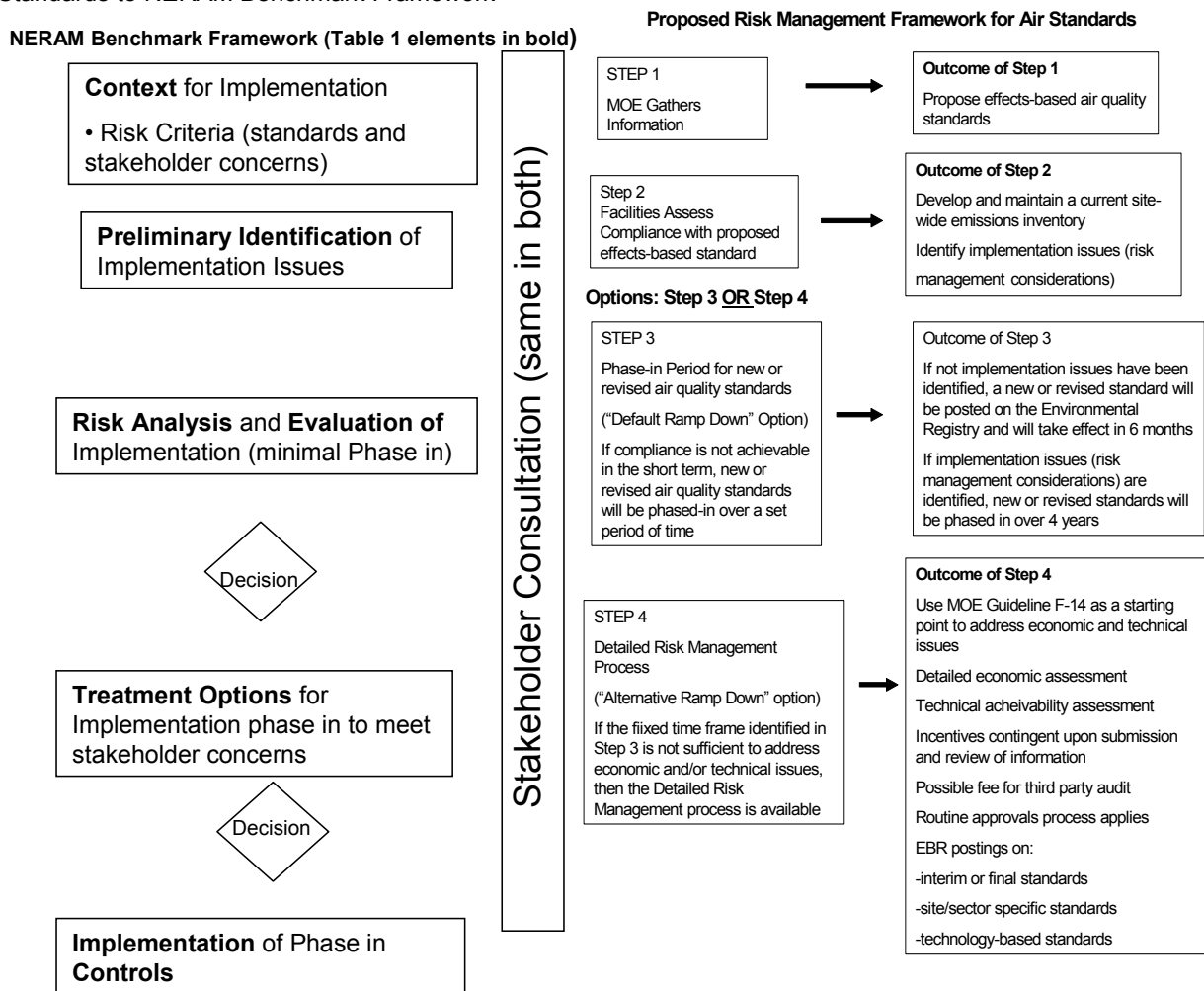


Figure 16: Comparison of MOE Risk Management Framework for Standard Setting and NERAM Benchmark Framework

Figure 17. Comparison of Figure 15 - MOE Risk Management Framework for Implementation of Revised Standards to NERAM Benchmark Framework



The implementation approach for the new standards responds to stakeholders concerns and is based primarily on the economic consequences and how these change with a longer phase in period. The proposed implementation criteria include an iterative series of steps that progress from basic screening methods to methods that require detailed studies from individual firms. The parameters and approach are subject to communication and consultation with stakeholders. From a framework perspective the approach is well done and consistent with the design guidelines for risk management frameworks.

No comments are made about item 2 above – the review of air pollution dispersion modeling from the point of emission to the point of maximum impingement on people. It is outside the scope of this document. It is obvious that the accuracy of those methods have considerable impact on the achievement of health and environment objectives.

The following comments are included for completeness and are intended not to be judgmental but to be descriptive in nature. They are clearly outside the scope of risk management frameworks as defined here, but they are of interest in terms of the overall risk management of air pollution and the concerns of stakeholders. They are included for completeness and should not be taken as critiques of the MOE approach but rather as possible direction for consideration once the existing regulations have been updated. Given the existence of existing regulations in the format of point of impingement standards the approach taken could be considered efficient and effective.

1. For convenience in the permitting processes, the point of impingement approach tends to focus on emissions from single facilities only, as opposed to impacts of multiple emission sources, although this is possible. Many risk criteria based on health and environmental impacts of pollution have been modified to include the total impact of all emission sources on air quality. The result of using multiple emission sources is that the regulation of emissions is more restrictive in areas with a high density of emission sources.
2. Similarly, the current point of impingement approach does not account for background air quality due to regional and long distance transport of pollutants, in some cases from outside the province. However, background levels could be added to point of impingement concentrations.
3. As indicated by some stakeholders' presentations there is a desire to have the precautionary principle included in the selection of standards. This principle is still under development and while the European Union (EU) have proposed some methods to operationalize the precautionary principle, these are still in the research stage. It is unlikely that this principle could be implemented as one of the risk criteria at this time.
4. In doing this project the NERAM team had some initial difficulty in understanding the context for risk management and the relationship of the decision-making activities to the three review items listed above. The risk criteria were implicit and they might have been made explicit. There was also some confusion due to the terminology differences between

the NERAM benchmark framework and that used by the MOE (note that theirs is in fact more traditional from an historical perspective). In some respects this comment is not unusual given the rapid development and evolving nature of risk management in government regulatory activities.

### Summary

The review of the MOE risk management framework in terms of comparison to the NERAM benchmark framework led to the following conclusions

1. The risk communication and consultation in the MOE framework is exemplary
2. There are two related frameworks, one for a review of air quality standards and one for the establishment of implementation criteria for the new air standards within the existing regulatory framework. These frameworks are inextricably linked together in a larger policy framework.
3. The MOE frameworks are standard and in terms of the design guidelines are well done.
4. It would be desirable to develop an overall, higher level, risk management approach, that incorporates both risk management frameworks used.



## Chapter 6 Conclusions

The main findings of the review of basic frameworks for risk management include the following observations:

- standard risk management framework elements are emerging as mature set of functional components at the International level including ISO terminology
- for any organization these standard elements must be designed into an organization-specific framework which will be unique in some aspects but will be constructed from standard components
- the proposed MOE framework is generally compatible with existing frameworks for environmental risk management and is exemplary for risk communication considerations
- the standard risk management framework has a number of components that have reached mature status such as the health risk as outlined in the NERAM primer. Another example is the method of assessment and evaluation used for screening or preliminary analysis purposes
- a set of risk management framework design guidelines is proposed

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## **APPENDIX A**

### List of Participants

Sat P. Anand  
Chief Chemist/Tech. Ser. Mgr.  
Anco Chemicals Inc.  
85 Malmo Court, Maple ON L6A 1R4  
sanand@ancochemicals.com

Ed Arnold  
Vice President, Risk Management  
Jacques Whitford Environment Ltd.  
1200 Denison St., Markham ON L3R 8G6  
earnold@jacqueswhitford.com

Louise Aubin  
Environmental Health Research and Policy Analyst  
Public Health, Region of Peel  
44 Peel Centre Drive, Brampton ON L6T 4B5  
louise.aubin@region.peel.on.ca

Asra Aziz  
Toxicologist, Standards Development Branch  
Ministry of the Environment  
40 St. Clair Ave W, Toronto ON M4V1M2  
asra.aziz@ene.gov.on.ca

Lou Bacs  
Woodbridge Foam Co.  
4240 Sherwood Town, Mississauga ON L4Z 2G6  
lou\_bacs@woodbridgegroup.com

Stephane Baffier  
Manager, Composites and Construction  
Canadian Plastics Industry Association  
5925 Airport Rd., Mississauga ON L4V 1W1  
sbaffier@cpia.ca

Robert B. Barlow Cash  
Corporate Compliance & Regulatory Affairs  
ADM Agri-Industries Ltd  
24 Ontario St, Georgetown ON L7G 3K6  
r\_barlowcash@admworld.com

Tom Barnett  
Learning and Development Consultant  
Ministry of the Environment  
40 St. Clair Ave. W 5th Floor  
Toronto ON M4V 1M2  
tom.barnett@ene.gov.on.ca

Ron Bell  
Air Policy and Climate Change Branch  
Ministry of the Environment  
135 St Clair Ave W, Toronto ON M4V 1P5  
bellro@ene.gov.on.ca

Robert Bloxam

Environmental Modelling and Emissions Inventory  
Ministry of the Environment  
125 Resources Road, Toronto ON M9P 3V6  
bloxamro@ene.gov.on.ca

Lucette Bouchard  
Manager, Environment Health & Safety  
Aventis Pharma Inc.  
2150 St Elzear Blvd W., Laval PQ H7L 4A8  
lucette.bouchard@aventis.com

Bob Breeze  
Associate Deputy Minister  
Implementation and Transition Secretariat  
Ministry of the Environment  
135 St. Clair Ave. W., Toronto ON M4V 1P5  
bob.breeze@ene.gov.on.ca

Tom Broen  
Senior Policy Advisor  
Bus. & Ec. Development Custer Policy Secretariat  
Ministry of Economic Development and Trade  
900 Bay St., Toronto ON M7A 2E1  
tom.broen@edt.gov.on.ca

Teri Bulman  
Senior Advisor, Brownfield Regulation  
Standards Development Branch  
Ministry of the Environment  
40 St. Clair Ave. West, Toronto ON M4V 1M2  
terri.bulman@ene.gov.on.ca

Sheila Burke  
Manager, Regulatory Affairs & External Relations  
Safety & Environment  
Sterling Pulp Chemicals Ltd.  
302 The East Mall, Etobicoke ON M9B 6C7  
sburke@sterlingpulp.com

George Cadete  
Senior Advisor, Sector Competitiveness Branch  
Ministry of Economic Development and Trade  
900 Bay St, Toronto ON M7A2E1  
george.cadete@edt.gov.on.ca

Paul Callanan  
Environment Health Research and Policy Analyst  
Public Health, Region of Peel  
44 Peel Centre Dr., Brampton ON L6T 4B5  
paul.callanan@region.peel.on.ca

## Basic Frameworks for Risk Management

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Sean Capstick  
Engineer, EAAB  
Ministry of the Environment  
2 St. Clair Avenue, Toronto ON M4V 1L5  
capstise@ene.gov.on.ca

Howard Carter  
Senior Advisor, Environment and Safety  
Imperial Oil Ltd.  
111 St. Clair Ave. W., Toronto ON M5W 1K3  
howard.carter@esso.com

Paula Carty  
McLaughlin Centre, Institute of Population Health  
University of Ottawa  
1 Stewart St., Ottawa ON K1N 6N5  
pcarty@uottawa.ca

Mike Cassidy  
Coordinator, Food Safety Science Unit  
Ontario Ministry of Agriculture, Food & Rural  
Affairs  
Guelph ON N1G 4Y2  
mike.cassidy@omafra.gov.on.ca

Robert Chapman  
Air Standards Development Officer  
Standards Development Branch  
Ministry of the Environment  
40 St. Clair Ave. W., Toronto ON M4V1M2  
chapmaro@ene.gov.on.ca

Mark J. Chappel  
Senior Regulatory Toxicologist  
Human Toxicology/Air Standards  
Ministry of the Environment  
40 St. Clair Ave. W., Toronto ON M4V 1M2  
mark.chappel@ene.gov.on.ca

Andrew Chiu  
Air Standards Coordinator  
Human Toxicology & Air Standards  
Ministry of the Environment  
40 St Clair Ave. W, Toronto ON M4V 1M2  
andrew.chiu@ene.gov.on.ca

Francis Chua  
Assistant Technical Engineer  
Environment Management

Bruce Power  
P.O. Box 300 B06, Tiverton ON N0G 2T0  
francis.chua@brucepower.com

Mary-Anne Ciampini

Manager, Policy Development  
Canadian Vehicle Manufacturers Association  
170 Attwell Dr Suite 400, Toronto ON M9W 5Z5  
mciampini@cvma.ca

Melody Collis  
Environmental Specialist, Engineering  
Toyota Motor Manufacturing Canada  
1055 Fountain St N, Cambridge ON N3H 5K2  
mcollis@tmmc.ca

Paul Complin  
Principal-Environmental Compliance  
Canadian ORTECH Environmental  
2395 Speakman Dr., Mississauga ON L5K 1B3  
pcomplin@ortech.ca

Jeremy Cornish  
International Centre for Aviation and the  
Environment  
33 Upland Dr., Whitby ON L1N 8H9  
jlcorni@attglobal.net

Lorraine Craig  
Institute for Risk Research, University of Waterloo  
Waterloo ON N2L 3G1  
lcraig@rogers.com

Satish Deshpande  
Sr. Regulatory Toxicologist  
Standards Development Branch  
Ministry of the Environment  
40 St. Clair Ave. W., Toronto ON M4V 1M2  
satish.deshpande@ene.gov.on.ca

Joanne Di Caro  
Air Resource/Enforcement Specialist  
Investigations and Enforcement Branch  
Ministry of the Environment  
5775 Yonge Street, Toronto ON M2M 4J1  
Joanne.Dicaro@ene.gov.on.ca

Jack A. Donnan  
Team Leader  
Economic Services Branch  
Ministry of the Energy Science and Technology  
135 St. Clair Ave. W., Toronto ON M4V 1P5  
jack.donnan@est.gov.on.ca

Chris Drope  
Supervisor HES, Safety & Hygiene  
Bayer Inc. Rubber Division  
1265 Vidal St. South, Sarnia ON N7T 7M2  
chris.drope.b@bayer.com

## Basic Frameworks for Risk Management

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Michelle Duncan  
Environmental Engineer  
Environmental Activities - Technical Services  
General Motors of Canada Ltd.  
1908 Colonel Sam Drive, Oshawa ON L1H 8P7  
michelle.duncan@gm.com

Steve Elliott  
Senior Environmental Officer  
Air Quality Management Group  
Ministry of the Environment  
133 Dalton Ave., Kingston ON K7K 6C2  
Steve.Elliott@ene.gov.o.ca

Angela Fong  
Health & Safety Specialist  
Environment Health & Safety  
Acsys Technologies  
155 Division St., Oshawa ON L1G7Z6  
afong@acsys-tech.com

Diane Freeman  
Project Manager, Air Quality  
Conestoga-Rovers & Associates Ltd.  
651 Colby Dr., Waterloo ON N2V 1C2  
dfreeman@craworld.com

Christina Fung  
Manager, Environmental Quality  
Environment Energy & Vehicle Safety  
Ford Motor Co. of Canada Limited  
The Canadian Road, Oakville ON L6J5E4  
cfung@ford.com

Arnold Fung  
Facilities Manager  
Eli Lilly Canada Inc.  
3650 Danforth Ave., Scarborough ON M1N 2E8  
arnold\_fung@lilly.com

Andy Gemza  
Program Analyst  
Environmental SWAT Team  
Ministry of the Environment  
305 Milner Ave, Toronto ON M1P 3V4  
andy.gemza@ene.gov.on.ca

April Gowing  
Environmental Engineer  
Conestoga-Rovers & Associates  
651 Colby Dr., Waterloo ON N2V 1C2  
agowing@craworld.com

Cathy Grant  
Engineering Specialist - Air Pollution  
Standards Development Branch  
Ministry of the Environment  
40 St. Clair Ave. West, Toronto ON M4V 1M2  
cathy.grant@ene.gov.on.ca

Scott Grant  
Engineering Specialist - Air Pollution  
West Central Region  
Ministry of the Environment  
40 St. Clair Ave. West, Toronto ON M4V 1M2  
scott.grant@ene.gov.on.ca

Madeleine Hart  
Ontario Power Generation Inc  
700 University Ave., Toronto ON M5G 1X6

Dale Henry  
Manager, Standards Development Branch  
Ministry of the Environment  
40 St. Clair Ave. West, Toronto ON M4V 1M2  
dale.henry@ene.gov.on.ca

John F. Hicks  
Applied Chemistry and Biology  
Ryerson Polytechnic University  
350 Victoria Street, Toronto ON M5B 2K3  
jhicks@acs.ryerson.ca

Robert Holland  
Hydrogeologist, Eastern Region  
Ministry of the Environment  
133 Dalton Ave., Kingston ON K7L 4X6  
robert.holland@ene.gov.on.ca

Christian Horbasz  
Policy Advisor, Red Tape Secretariat  
Ministry of Economic Development and Trade  
99 Wellesley St. W., Toronto ON M7A 1A1  
christian.horbasz@cab.gov.on.ca

Greg Jenish  
Policy & Decision Analyst  
Environmental Commissioner of Ontario  
Suite 605, 1075 Bay St., Toronto ON M5S 2B1  
greg.jenish@eco.on.ca

Barbara Johnston  
Assistant Director  
Environmental Partnerships Branch  
Ministry of the Environment  
40 St. Clair Ave. W., Toronto ON M4V 1M2  
johnstba@ene.gov.on.ca

## Basic Frameworks for Risk Management

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Roger T. Keefe  
Toxicologist, Occupational Health  
Imperial Oil Ltd.  
111 St. Clair Ave. W., Toronto ON M5W 1K3  
roger.keefe@esso.com

Mohamud Khalif  
Economist, Economic Analysis Section  
Ministry of Energy Science and Technology  
880 Bay St, Toronto ON  
Mohamud.khalif@est.gov.on.ca

Kapil Khatter  
Executive Director  
Canadian Assoc. of Physicians for the Environment  
314 Logan Ave., Toronto ON M4M 2N7  
kap@yorku.ca

J. Craig Kinch  
Senior Advisor - Brownfields  
Standards Development Branch  
Ministry of the Environment  
40 St. Clair Ave., Toronto ON M4V 1M4  
craig.kinch@ene.gov.on.ca

Alan Kirschbaum  
Policy Advisor, Red Tape Secretariat  
Ministry of Economic Development and Trade  
99 Wellesley St. W., Toronto ON M7A 1A1  
alan.kirschbaum@cab.gov.on.ca

Steve Klose  
Manager, Certificate of Approval Review Section  
Environmental and Approvals Branch  
Ministry of the Environment  
2 St. Clair Ave West, Toronto ON M4V 1L5  
steve.klose@ene.gov.on.ca

Graham Knowles  
Environment Management Program  
Vinyl Council of Canada  
Canadian Plastics Industry Association  
5925 Airport Rd., Mississauga ON L4V 1W1  
grahamknowles@msn.com

Dan Krewski  
Centre for Population Health  
University of Ottawa  
451 Smyth Road, Ottawa ON K1H 8M5  
dkrewski@uottawa.ca

Michael Ladouceur  
Air Scientist  
Eastern Region Air Quality Management Group  
Ministry of the Environment  
133 Dalton Ave., Kingston ON K7L 4X6  
michael.ladouceur@ene.gov.on.ca

Kevin Laframboise  
Hydro One Networks Inc.  
North Tower TCT 15 A5  
483 Bay St., Toronto ON M5G 2P5  
kevin.laframboise@hydroone.com

Angela Li-Muller  
Research Consultant  
Toronto Public Health  
277 Victoria St., Toronto ON M5B1W2  
alimulle@city.toronto.on.ca

Carol Lonero  
Policy Advisor, Red Tape Secretariat  
Ministry of Economic Development and Trade  
99 Wellesley St. W., Toronto ON M7A 1A1  
carol.lonero@cab.gov.on.ca

Lynn Lovell  
Senior Analyst, Project Management Office I.T.S.  
Ministry of the Environment  
135 St. Clair West 8/F, Toronto ON M2M 4B5  
lynn.lovell@ene.gov.on.ca

Srikanth Mangalam  
Senior Engineer, Risk Management  
Jacques Whitford Environment Ltd.  
1200 Denison St., Markham ON L3R 8G6  
smangala@jacqueswhitford.com

Sheila McAllister  
Air Standards Development Officer  
Standards Development Branch  
Ministry of the Environment  
40 St. Clair Ave West, Toronto ON M4V 1M2  
sheila.mcallister@ene.gov.on.ca

Stephanie McCallum  
Air Quality Technologist, Ventilation Department  
Kuntz Electroplating Inc  
851 Wilson Ave., Kitchener ON N2C 1J1  
stephaniem@kuntz.com

Joanne McGovern  
Director, Taxation & Ontario Environmental Policy  
Canadian Manufacturers & Exporters  
5995 Avebury Rd., Mississauga ON L5R 3P9  
joanne.mcgovern@cme-mec.ca



## Basic Frameworks for Risk Management

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Andrew Morley  
Program Coordinator, Assistant Director's Office  
Ministry of the Environment  
133 Dalton Ave., Kingston ON K7L 4X6  
andrew.morley@ene.gov.on.ca

Scott Munro  
General Manager  
Sarnia-Lambton Environmental Association  
265 Front St. N., Sarnia ON N7T 7X1  
scottmunro@sarniaenvironment.com

Stephen Neville  
Senior Advisor, New Program Development Group  
Ministry of the Environment  
40 St. Clair Avenue West, Toronto ON M4V 1M2  
steve.neville@ene.gov.on.ca

Ken Ogilvie  
Executive Director  
Pollution Probe  
625 Church St. Suite 402, Toronto ON M4Y 2G1  
kogilvie@pollutionprobe.org

Mike Pawlicki  
Director Environmental Affairs, Cement Dept.  
Lafarge Canada Inc  
10655 Southport Rd SW, Calgary AB T2W4Y1  
mike.pawlicki@lafarge.ca

Allan Prits  
Manager, Engineering Services  
Santec Consulting Ltd.  
7070 Mississauga Rd., Mississauga ON L5N 7G2  
aprits@stantec.com

Karen Prokopec  
Senior Policy Analyst  
Project Management Office I.T.S.  
Ministry of the Environment  
135 St. Clair West 6/F, Toronto ON M2M 4B5  
karen.prokopec@ene.gov.on.ca

Ronald Pushchak  
School of Occupational & Public Health  
Ryerson Polytechnic University  
350 Victoria St., Toronto ON M5B 2K3  
pushchak@acs.ryerson.ca

David Putnam  
Director, Engineering and Audit Services  
Altech Environmental Consulting Ltd  
12 Banigan Drive, East York ON M4H 1E9  
dputnam@altech-group.com

Gloria Rachamin

Toxicologist, Public Health Branch  
Ministry of Health  
5700 Yonge St. 8th Floor, Toronto ON M2M 4K5  
gloria.rachamin@moh.gov.on.ca

Michael C. Rogers  
Engineering  
ICI Canada Inc.  
1120 Finch Ave. West, North York ON M3J 3H7  
michael\_cf\_rogers@ici.com

Jean Saun  
Manager, Internal Audit Division  
Ministry of the Environment  
40 St. Clair Avenue West, Toronto ON M4V 1M2  
saunja@ene.gov.on.ca

Michael Shackleton  
Program Analyst, Environmental SWAT Team  
Ministry of the Environment  
Suite 1003, 305 Milner Ave., Toronto ON M1P 3V4  
michael.shackleton@ene.gov.on.ca

John H. Shortreed  
Director, Institute for Risk Research  
University of Waterloo  
200 University Ave., Waterloo ON N2L 3G1  
shortree@uwaterloo.ca

Adolfo Silva  
Director, Environmental Affairs  
Canadian Petroleum Products Institute (CPPI)  
510-235 Yorkland Blvd., North York ON M2J 4Y8  
adolfofilva@cppi.ca

Jim Smith  
Acting Director, Standards Development Branch  
Ministry of the Environment  
135 St. Clair Ave. W., Toronto ON M4V 1P5  
smithji@ene.gov.on.ca

John Stager  
Director, Environmental SWAT Team  
Ministry of the Environment  
305 Milner Ave., Toronto ON M1P 3V4  
john.stager@ene.gov.on.ca

Brian Sulley  
Chemical Process Coordinator  
Industrial Services Group  
Rowan Williams Davies & Irwin Inc  
650 Woodlawn Road West  
Guelph ON N1K 1B8  
bgs@rwdi.com

## Basic Frameworks for Risk Management

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Wally Szumylo  
Environment and Health Co-ordinator  
Safety Health and Environment  
Inco  
Copper Cliff ON P0M 1N0  
wszumylo@inco.com

Helle Tosine  
Director, Inspections  
Investigation & Enforcement Secretariat  
Ministry of Labour  
14-655 Bay St., Toronto ON M7A 1T7  
helle.tosine@mol.gov.on.ca

Jean-Yves Urbain  
Chair  
Air & Waste Management Association  
105 Commerce Valley Dr. W.  
Markham ON L3T 7W3  
jyurbain@earthtech.ca

Tony van der Vooren  
Manager Air Process  
AMEC Inc.  
885 Don Mills Rd., Toronto ON M3C 1V9  
tony.vandervooren@amec.com

James Virtue  
Program Support Coordinator  
Environmental Assessment and Approvals Branch  
Ministry of the Environment  
2 St. Clair Ave. West, Toronto ON M4V 1L5  
virtueja@ene.gov.on.ca

Michael Wagle  
Engineer  
Enbridge Consumers Gas  
PO Box 650, North York ON M1K 5E3  
michael.wagle@cgc.enbridge.com

Chris Walton  
Environmental Technologist, Environmental Affairs  
Bowater Pulp and Paper  
2001 Neebing Ave., Thunder Bay ON P7E 6S3  
waltonc@bowater.com

Melanie Ward  
Toxicologist, Standards Development Branch  
Ministry of the Environment  
40 St. Clair Ave West, Toronto ON M4V1M2  
wardme@ene.gov.on.ca

Robert F. Willes  
Chairman  
CanTox Environmental Inc.  
1900 Minnesota Court, Mississauga ON L5N 3C9  
rwilles@cantoxenvironmental.com

Kyle Wivcharuk  
Environmental Health Research and Policy Analyst  
Region of Peel  
44 Peel Centre Drive, Brampton ON L6T 4B5  
kyle.wivcharuk@region.peel.on.ca

Darren Wolek  
Graduate Student  
School of Public and Occupational Health & Safety  
Ryerson University  
350 Victoria St., Toronto ON M5B 2K3  
dwolek@hotmail.com

Wendy Wong  
Environmental Engineer, Environment Health & Safety  
Acsys Technologies Inc  
155 Division St., Oshawa ON L1G7Z6  
wwong@acsys-tech.com

Jen Wynne  
Environmental Coordinator  
St. Lawrence Cement Inc.  
2391 Lakeshore Rd. W., Mississauga ON L5J 1K1  
jwynne@stlawrencecement.com