CAN/UL 2984:2019

NATIONAL STANDARD OF CANADA

STANDARD FOR

Management of Public Risks – Principles and Guidelines

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SCC FOREWORD

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Standard for Management of Public Risks – Principles and Guidelines, CAN/UL 2984:2019

First Edition, Dated April 15, 2019

Summary of Topics

The First Edition of the CAN/UL 2984, Standard for Management of Public Risks – Principles and Guidelines, has been published.

The new requirements are substantially in accordance with Proposal(s) on this subject dated November 30, 2018.

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CAN/UL 2984:2019

Standard for Management of Public Risks – Principles and Guidelines

First Edition

April 15, 2019

This CAN/UL Standard consists of the First Edition.

This most recent edition of CAN/UL 2984 as a National Standard of Canada occurred on April 15, 2019.

This standard has been designated as a National Standard of Canada (NSC) on April 15, 2019.

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Preface

This is the First Edition of the CAN/UL 2984 Standard for Management of Public Risks – Principles and Guidelines.

UL is accredited by the Standards Council of Canada (SCC) as a Standards Development Organization (SDO).

This CAN/UL 2984 Standard is under continuous maintenance, whereby each revision is approved in compliance with the requirements of SCC for accreditation of a Standards Development Organization. In the event that no revisions are issued for a period of four years from the date of publication, action to revise, reaffirm, or withdraw the standard shall be initiated.

In Canada, there are two official languages, English and French. All safety warnings must be in French and English. Attention is drawn to the possibility that some Canadian authorities may require additional markings and/or installation instructions to be in both official languages.

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This Edition of the Standard has been formally approved by the STP on Managing Risks to the Public Interest in a Regulatory Context, STP 2984.

This Standard has been developed in compliance with the requirements of SCC for accreditation of a Standards Development Organization.

Annexes A to D, identified as informative, are for information purposes only.

This list represents the STP 2984 membership when the final text in this standard was balloted. Since that time, changes in the membership may have occurred.

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For further information on UL standards, please contact:

Underwriters Laboratories Inc.
171 Nepean Street, Suite 400
Ottawa, Ontario K2P 0B4
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This Standard is intended to be used for conformity assessment.

The intended primary application of this standard is stated in its scope. It is important to note that it remains the responsibility of the user of the standard to judge its suitability for this particular application.

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0 Introduction

Public risk, unlike other types of risk, is less organization specific and more multi-dimensional and complex. In most cases, the management of a public risk is undertaken in a multi-organizational context with many public risk stakeholders that hold different perspectives, mandates and priorities resulting in potentially conflicting mitigation strategies and requiring tradeoffs among public risks and objectives. For example, a new product could provide public health benefits but may also result in adverse outcomes for the environment.

Public risks also differ from organizational risks in that they usually involve intervention by a government or regulatory body that is responding to a market failure or a public policy objective (e. g., a government decision to reduce greenhouse gas emissions). When that government and its agencies intervene, it is to protect the public interest, rather than the interests of a single organization. However the public risks and costs of these interventions themselves are usually shared, complex and involve multiagency interactions across a variety of entities with a multitude of objectives that may impact the management of those public risks.

While all public risk stakeholders are accountable for managing risk, risk sources are different between public and private organizations, as is the management of those risks when the responsibilities are shared between them. The objectives and focus of organizations responsible for managing public risks (e. g., public sector or non-governmental organizations) also differ from organizations that manage only organizational risks (e.g., private sector organizations).

Private sector organizations are primarily focused on managing organizational risks to maintain or enhance their profitability. They are concerned with impacts to the organization itself and the perceptions of shareholders, financial markets or consumers that pertain to the organization's ability to meet its objectives. Private sector organizations that are regulated may also have a legislated responsibility for managing public risk. For example, food processing companies are required to mitigate human health risks that could result from improper food processing. Their primary objective, however, is profitability and organizational risk management while complying with their regulatory obligations.

Public sector organizations are primarily focused on managing public risks, economic, financial and supply chain risks. A public sector organization's focus is in managing risks that pose a threat to the public interest (e.g., ensuring public safety, safeguarding health, wellbeing or security) or advancing public policy objectives (such as environmental or social objectives). Those responsible for managing public risk also manage organizational risks since they may impact the organization's ability to deliver on their mandate; making public risk management even more complex.

The lack of sufficient guidance related to public risk management can result in different approaches being implemented for the management of similar public risks across multiple organizations, leading to confusion among regulated entities, a lack of consistency across jurisdictions or regulators, and conflicting requirements across regulatory bodies which may lead to increased costs and inefficiencies for the regulated entity and, ultimately, undesired consequences.

Public risk management is complex and involves the balancing of multiple, sometimes conflicting objectives; it is unique and requires specific guidance – how to apply resources, manage and maximize benefits while minimizing the harm. A consistent or commonly understood set of definitions, guiding principles and additional guidance, tools, and a common approach beyond those used to address organizational risks is necessary for the governance and management of public risk to ensure coordination and consistency, to reduce duplication of effort, to reduce possibly conflicting approaches and to address gaps that may lead to undesirable circumstances and sub-optimal outcomes. This document is intended to provide guidance to those who manage public risk or are impacted by it. It is intended to complement the existing risk management literature by providing guidance focusing specifically on the unique aspects associated with public risk management.

1 Scope

1.1 This guideline lays out the principles of and provides guidance for identification, analysis, evaluation and decision-making in the management of public risks to prevent, reduce or minimize public harm while maximizing the public good.

1.2 This guideline is written primarily for organizations responsible for the management of public risks, such as public sector organizations, government departments and agencies, regulatory agencies, crown corporations, non-profit organizations, professional licensing bodies, or regulated entities. The principles and guidance within this document may also be applicable to others who support the management of public risk.

1.3 This document provides guidance on the following key aspects:

a) Definitions for Public Risk Management;

b) Foundational Principles; and

c) Elements to be considered when undertaking Public Risk Management.

1.4 This guideline does not stipulate specific methods or techniques for risk management but identifies key elements and considerations for risk-informed decision-making essential for the management of public risk. The guideline identifies common resources, methods and techniques that may be used. Annex D provides additional resources that may provide readers additional guidance and examples.

2 Definitions

2.1 ACCEPTABLE PUBLIC RISK –
public risk deemed tolerable based on the values of society, the public good provided and the public harm being effectively managed.

2.2 EVIDENCE-BASED DECISION-MAKING –
a process for making decisions about a program, practice, or policy that is grounded in the best available data, research and experience from a variety of sources, including first hand and contextual qualitative information.

2.3 HAZARD –
A potential source of harm, injury or damage to the health of people, to property, or to the environment.

2.4 PUBLIC GOOD –
societal benefits shared amongst the public and which are provided to the community and potentially collectively regulated by the public sector. They are not divisible and cannot be appropriated individually or sold separately.

2.5 PUBLIC HARM –
adverse consequences (such as death, injury, loss, environmental damage) from which the public expects protection.

2.6 PUBLIC RISK –
combination of the likelihood of occurrence of a public harm and/or a public good and the impact of these public harms and/or public goods on societal objectives.

2.7 PUBLIC RISK ASSESSMENT –
a systematic process of identifying, analyzing and evaluating public risk from public risk sources.

2.8 PUBLIC RISK MANAGEMENT –
an iterative process of managing public risk, whereby public harm is minimized and public good is maximized.

2.9 PUBLIC RISK PERCEPTION –
the subjective judgement (or belief) (whether rational or irrational) held by the public about the occurrence of a public risk, its characteristics, or about the extent, magnitude, and timing of its effect(s).

2.10 PUBLIC RISK SOURCE –
things (e.g., technologies, products etc.), processes (e.g., financial transactions, airport security etc.), or behaviors (e.g., individual or collective actions) that have the potential to increase or impose public risks.

2.11 PUBLIC RISK STAKEHOLDERS –
those directly or indirectly responsible for, or who may be impacted by, a public risk.

2.12 PUBLIC RISK TREATMENT (PUBLIC RISK MITIGATION) –
processes to modify public risk.

Note 1: Public risk treatments whose objectives are to counter the negative consequences are sometimes referred to as “public risk mitigation”, “public risk elimination”, “public risk prevention” and “public risk reduction”.

Note 2: For the purposes of this Guideline, the terms “public risk treatment”, “public risk mitigation”, “public risk prevention”, and “public risk reduction” are considered to be synonymous. [SOURCE: ISO Guide 73:2009, modified]

3 Foundational Principles

Organizations directly or indirectly responsible for the management of public risk should demonstrate adherence to the following principles. Knowing that trade-offs may be required, each organization will need to determine how and when to apply the principles and should document how each was considered and applied. In all cases, maximization of public good and minimization of public risk should be sought.

3.1 Consistency

3.1.1 All aspects of public risk management (such as risk analysis, or risk-informed decision-making, etc.) should be undertaken in a consistent manner while recognizing not all public risk stakeholders may necessarily be satisfied with decisions all the time. Organizations should take measures to demonstrate consistency in their decision-making (e. g., develop policies and procedures) and could make their decision-making process available upon request.

3.2 Adequate Communication and Consultation

3.2.1 Organizations should establish an agreed approach to communication and consultation to support risk-informed decision-making and facilitate the effective application of public risk treatments. Adequate communication should involve sharing information with targeted audiences (e.g., those directly affected by a public risk treatment). Consultation should involve participants providing meaningful feedback to the decision-makers with the expectation that the feedback will contribute to and shape decisions or other activities.

3.2.2 Stakeholders affected by public risk management decisions should be consulted to understand the impact of decisions. For an example of the types of consultations that can be undertaken with public risk stakeholders, see Annex B.

3.2.3 Concepts such as ALARP (as low as reasonably practicable) and reasonable implementation schedules should be used to facilitate compliance when decisions affect public risk stakeholder

obligations. For an example of an ALARP approach, see Annex C. Members of the public and others impacted should be provided a reasonable opportunity to provide their views, concerns and expectations on acceptable or tolerable levels of public risk.

3.2.4 Communication and consultation methods and content should reflect the expectations of public risk stakeholders, where relevant. Communication and consultation should be timely and ensure that relevant information is captured, consolidated and shared, as appropriate, and that feedback is provided and improvements are made.

3.2.5 The purpose of communication and consultation is to assist relevant stakeholders in understanding the public risk, the basis on which public risk decisions are made and the reasons why particular actions are required. Communication seeks to promote awareness and understanding of public risk and how to deal with it, whereas consultation involves obtaining feedback and information to support public risk decision-making. Close coordination between the two should facilitate factual, timely, relevant, accurate and understandable exchanges of information, taking into account the confidentiality and integrity of information as well as the privacy rights of individuals.

3.2.6 Communication and consultation with appropriate external and internal stakeholders should take place within and throughout all steps of the public risk management process. Communication and consultation should aim to:

– bring different areas of expertise together for each step of the public risk management process;

– ensure that different views are appropriately considered when defining public risk criteria and when evaluating public risks;

– provide sufficient information to facilitate public risk treatments and public risk decision-making; and

– build a sense of inclusiveness and ownership among those affected by public risk.

3.3 Evidence-Based Decision-Making

3.3.1 Structured risk assessment processes should be used when making public risk management decisions. Decisions should be made on the basis of best available information and analysis (e. g., economic, legal, ethical, jurisdictional, international, security, etc.). Where evidence is available, it should be an important consideration and should take precedence over other factors (such as perception) in decision-making. In the absence of a formal scientific process or peer reviewed data, best available and relevant evidence should be used.

3.3.2 Oversimplification of available information and exclusion of available data should be avoided in order to maintain objectivity and robustness in evidence-based decision-making. Dissenting or contradictory evidence should be considered and rationales for excluding certain evidence should be documented and made available to stakeholders if possible, subject to legal or legislative restrictions.

3.4 Fairness

3.4.1 Public risk management decisions should be implemented in an objective, transparent, consistent and impartial manner.

3.4.2 Precedence and conflict resolution processes should be defined to address potential conflicts and to ensure procedural fairness and fair application of public risk treatments and public risk decision-making.

3.4.3 Public risk treatments should consider grandfathering, transitionary periods, phased implementation or other mechanisms if appropriate to mitigate significant adverse impacts on affected public risk stakeholders where possible.

3.4.4 Precedence and conflict resolution paths should be proactively defined to address potential conflicts and to provide redress to public risk stakeholders that may not agree with decisions.

3.5 Independence

3.5.1 It is possible for an organization's public risk management objectives to be in conflict with the organizational risk management objectives. The potential for this conflict should be acknowledged and anticipated. To mitigate this possibility, public risk management decision-making should be undertaken independently from organizational risk management decision-making within organizations. Where possible, separation in decision-making between organizational risk management and public risk management should be incorporated throughout organizations whose primary purpose is public risk management to avoid potential conflicts of interest. Measures should also be taken to prevent, reduce or minimize influences that could affect the independence and objectivity of public risk management decision-making, including excessive stakeholder or political influence.

3.5.2 Where separation is not possible or practical or excessive influence cannot be avoided, the impact on decision-making should be clearly documented and should be made available to stakeholders where possible, with executive level decision makers being accountable for ensuring public risk is managed as the top priority within the context of the overall strategic decision-making.

3.5.3 Whether separate, or undertaken by a single office or an individual, executive level accountability should be established, and information regarding public risk should flow independently and unfiltered up to top management for decision-making, separate from and independent of operational or other internal data used to manage organizational risk.

3.5.4 All efforts should be made to avoid conflicts of interest. Where conflicts cannot be avoided, these should be discussed and made transparent so that they are clearly understood.

3.6 Integrated Approaches

3.6.1 Where a public risk is managed by multiple organizations (multi-organizational context), organizations should coordinate to the greatest extent possible. Integrated approaches are preferable to address potential gaps, prevent conflicts and avoid duplication.

3.7 Continuous Improvement

3.7.1 Ongoing monitoring of public risk decisions and public risk treatment should be implemented as a basis from which to determine effectiveness of public risk decisions and to identify improvements in public risk treatment methods.

3.7.2 Evidence-based processes should be used as the basis for assessing outcomes and impacts of public risk management decisions and public risk treatments. Assessments should include a mechanism to monitor decision-making processes and outcomes, performance metrics to assess ongoing impacts, and a mechanism for continuous improvement. Assessments should ensure an appropriate level of quality assurance, which may include technical verification and validation of the analyses undertaken to ensure that they are correct.

3.7.3 Changes to governance and public risk treatment methods used to manage public risk may be necessary to address gaps and allow for continuous improvement. Continuous improvement should not only comprise mechanisms to continually lower public risk, but may include such things as greater

transparency, better public risk treatments and public risk management processes, less costly approaches, etc.

3.7.4 Organizations responsible for the management of public risks should consider implementing reporting structures, so that ongoing monitoring can be undertaken efficiently. Reports should be made available to stakeholders where possible.

3.8 Prioritization of Public Risk Management

3.8.1 All organizations, regardless of their primary focus, should consider public risk within their decision-making processes.

3.8.2 Organizations whose primary responsibility is public risk management should demonstrate that their resources are focused on addressing identified public risks for which they are responsible. Public risk management should be a priority at all levels of decision-making, including the setting of strategic and operational objectives, performance metrics, and budgetary considerations.

3.8.3 Organizations that have responsibility for the management of multiple public risks (e.g., energy efficiency and low cost access to electricity) and/or have varied accountabilities (e.g., safety and economic development) should prioritize their public risk management activities so as to maximize the public good and prevent, reduce or minimize public harm.

3.8.4 Risk assessments should be prioritized based on the severity of the risk.

3.9 Proportionality

3.9.1 Risk-informed decision-making should be used to focus attention and resources in proportion to the magnitude of identified public risks, so as to maximize the public good. The rigor of the process should be proportional to the potential impact of the decision.

3.9.2 Public risks should be clearly identified and characterized. The level of impact should be assessed based on a variety of factors, including the severity of the public harm, the vulnerability of affected populations, estimates of costs associated with the available decision options, and other societal or public policy considerations.

3.10 Transparency

3.10.1 Public risk decisions should be communicated in an understandable way to affected public risk stakeholders while respecting privacy and confidentiality requirements.

3.10.2 Key documents in the decision-making process should be made available to public risk stakeholders. These documents may include policies, procedures, processes, data, results from investigations, and risk assessments.

3.10.3 Public risk stakeholders should be made aware that trade-offs may be necessary among public goods when public-risk management decisions are being made.

4 Elements of Public Risk Management

The following key elements should be considered essential for the management of public risk:

– Defining and monitoring the public risk context;

– Understanding the governance environment;

– Assessing the public risk and decision-making; and

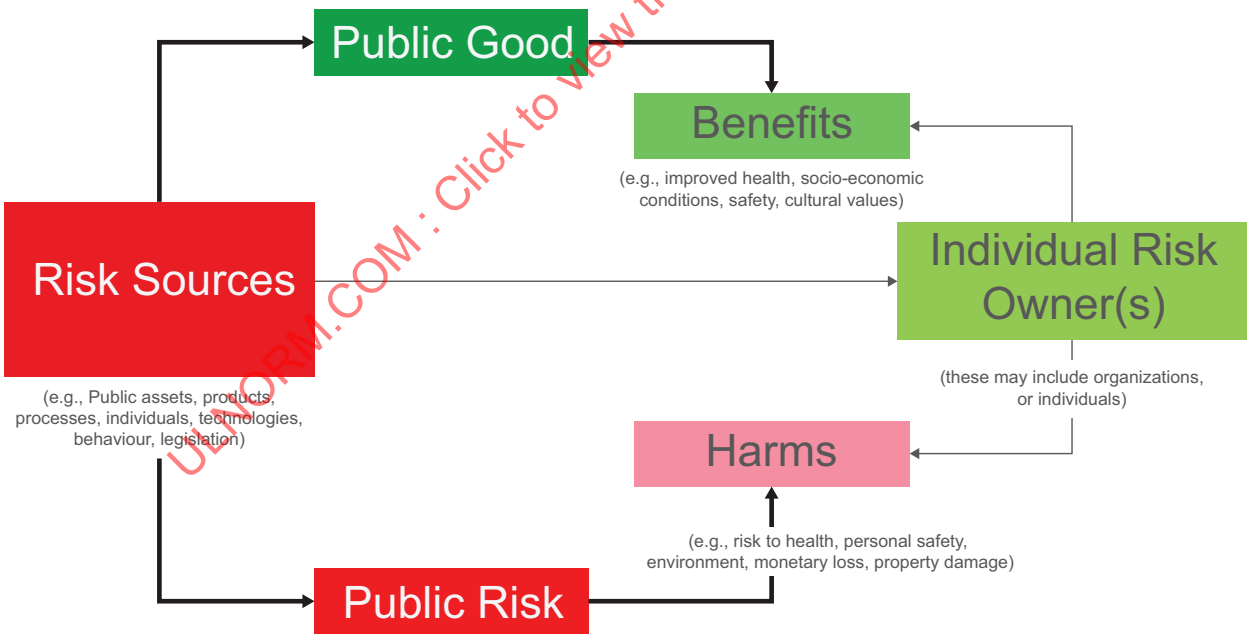
– managing the public risk.

4.1 Defining and Monitoring the Public Risk Context

4.1.1 Private and public assets and/or services (public risk sources) create public good intended to provide benefits. However, they may also pose a risk of causing harm (s) to the public and/or other impacted public risk stakeholders. Public goods provide benefits that are either shared by some or many members of the public or individual organizations. Public risks pose harms to individuals or organizations who may not be the same organizations or individuals who receive the public good. Society acknowledges acceptable public risks and tolerable public risks, based on perceived or actual benefits, while fully knowing that all activities carry some risk. A level of public risk associated with a public harm may be tolerable to society in one context or circumstance, but intolerable in another context or circumstance. There is an inherent assumption that proper public risk management will result in the avoidance of unacceptable public risks with only tolerable or accepted public risks being allowed.

4.1.2 As a consequence, those who either receive the public good benefit or may be harmed by the public risk created are known as the individual risk owners. Since the public risk and public goods are external to the public risk sources, the specific public risk context could require different public risk treatments and could involve multiple public risk stakeholders and organizations responsible for managing public risk. This concept is illustrated in Figure 1.0 below.

Figure 1.0
Public Risk Contexts



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4.1.3 Sources, other than public assets and/or services, may also pose a risk of harm to the public while creating public good.

4.1.4 Understanding the public risk context and the changing environment is important prior to undertaking effective public risk management. The following should be identified when considering the public risk context:

– All public risk stakeholders directly responsible for the management of one or more types of public risk;

– All relevant public risk sources;

– All associated benefits and harms of these public risk sources;

– Tolerable public risk levels;

– Public risk perceptions; and

– Public risk stakeholder expectations.

4.1.5 Should a risk assessment be undertaken, once completed, it may inform the development of a public risk management approach. In a regulatory context, it should be clearly established and clearly stated at this stage if an analysis is meant:

a) For the development of public policies (e.g., laws and regulations);

b) For the purposes of policy administration (e.g., enforcement); or

c) To shape behaviour or voluntary actions of those who may have an impact on the effects of the public risk.

4.1.6 The scope and magnitude of a proposed public risk management approach may be influenced entirely or in part by the mandate(s) of those directly responsible, or may influence the mandate of others who are either directly or indirectly responsible, for the actions of those impacted. Determining what type of management strategy should be followed should be part of the decision-making process (described under Section 4.4.2).

4.1.7 The management of public risk also involves a number of trade-offs, including:

– The risks posed to the public by risk sources in relation to the public good they offer to the public (e.g., appliances, power, transportations, utilities, farms, etc.);

– The risks posed to the public in relation to the risks that would result from the non-availability of the source (e.g., removing treatment options); and

– The level of public risk relative to the ability to supply and maintain the public risk source to an acceptable level to the public.

4.1.8 To understand the public risk context, organizations should consult public risk stakeholders when establishing tolerable levels of risk for making public risk management decisions.

4.2 Understanding the Public Risk Governance Context

Public risk management requires an understanding of the public risk governance context, which includes:

– the public risk stakeholders who may impact or be impacted by the decisions being contemplated;

– the actors who may make decisions;

– the regulatory context, if any, within which the public risk is to be managed; and

– the mandate, jurisdiction, or other constraints that may impact decisions.

Any public risk governance structure should, at a minimum, identify all relevant stakeholders; their mandates, responsibilities, relationships, and conflict resolution mechanisms. Engagement of relevant stakeholders may vary from one entity to another and may be affected by either mandates, operational considerations or other constraints.

4.2.1 Identification of relevant public risk stakeholders

4.2.1.1 Unique to the management of public risk is the multi-organizational and multi-stakeholder context (depicted in Figure 2.0). While all public risk stakeholders are accountable for managing risk, not all stakeholders are equal partners in managing risk. Risk sources are different for regulators and industry, as is the management of those risks when those risks are shared between them. For example, industry bears a distinctly different set of responsibilities, management and accountability of ensuring they have sufficient plans and controls in place to eliminate or effectively control the risks associated with their business /operational activities, while government is responsible for putting controls or frameworks in place that support and/or mandate appropriate behaviours intended to mitigate or manage the entire public risk.

4.2.1.2 When defining the public risk governance context, all relevant public risk stakeholders and their inter-relationships should be identified and understood. Public risk stakeholders may include those:

a) directly responsible for the assessment and management of public risks (Direct Stakeholders);

b) indirectly responsible for the assessment and management of public risks (Indirect Stakeholders); and

c) impacted by the risk including those potentially harmed by or benefiting from the risk sources (Impacted Stakeholders).

4.2.1.3 Although the various public risk stakeholders may operate independently, they should seek to develop integrated approaches when there are overlapping responsibilities or their actions may impact the responsibilities of others. This level of influence over the management of the risk may vary across the different public risk stakeholders as depicted by the arrows in Figure 2.0, below. And depending on the specific circumstances, the identified public risk stakeholders may shift from being directly responsible and accountable to being indirectly responsible and accountable.

a) Directly Responsible Public Risk Stakeholders

Responsible based on their operational context and the regulatory framework within which they operate, for managing or creating public risk sources on their own or through interactions with others (Figure 2.0, dark blue); may include:

– **Industry and supply chain** – Are providers of goods and services that may result in public risk, and are responsible for directly managing the public risk they create or impact;

– **Government(s)** – may manage public risk directly or give authority to others, set rules and requirements on industry and the supply chain for managing public risk, may influence the balance between benefits and harms, and may create public risk; and

– **Regulatory and oversight agencies** (e.g., independent boards, delegated authorities, government appointees, others who are mandated to manage public risks) – may or may not be an extension/arm of government (s), manage public risk, administer rules, requirements and undertake compliance, and may create public risk.

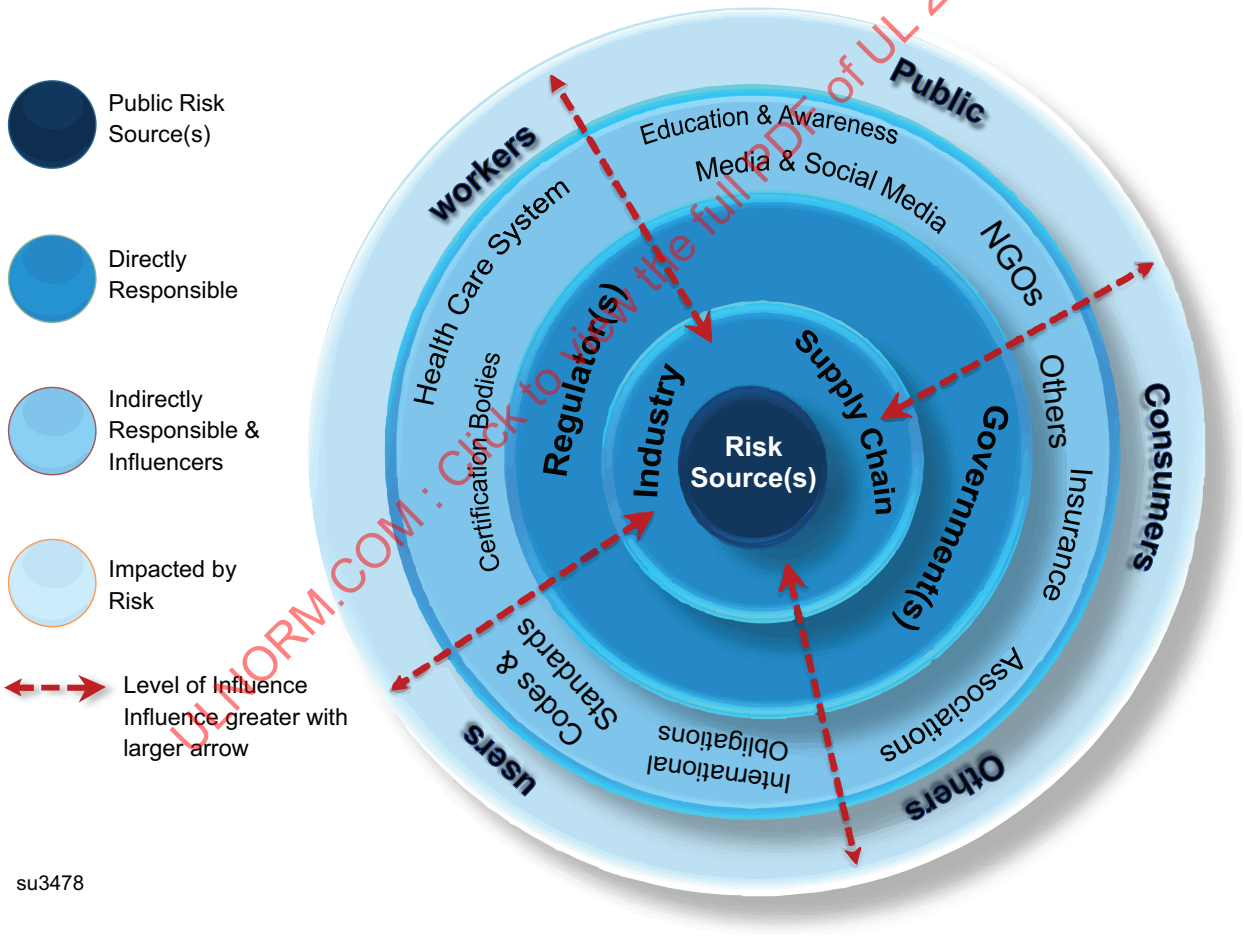
b) Indirectly Responsible Public Risk Stakeholders

Indirectly responsible for managing or creating public risk sources, may also be directly responsible in certain limited circumstances (Figure 2.0, mid blue). These may include: standards development organizations; industry associations; insurance companies; non-governmental organizations; media/social media; testing, certification and inspection organizations; health care providers; academic/educational institutions; and special interest groups.

c) Impacted Public Risk Stakeholders

Beneficiaries of, or those subject to potential harms from, public risk sources may directly or indirectly contribute to public risk (Figure 2.0, light blue); may include: consumers; workers; end users; the public (either as individuals or as communities); and particular groups in society (such as those with disabilities).

Figure 2.0
Public Risk Management – Multi-Stakeholder Context



NGOs = Nongovernment Organizations

4.2.2 Governance and Accountabilities

4.2.2.1 Given the multi-stakeholder nature and complexity of managing public risk, mandates, responsibilities, and relationships across all relevant public risk stakeholders should be clearly articulated and made transparent.

4.2.2.2 If more than one organization is directly responsible for managing the risk or if one organization is assessing the risk while another is managing the risk, a single organization to coordinate actions across organizations or integrated approaches should be sought and a governance structure should be developed.

4.2.2.3 The governance structure should:

– Be designed to be as simple as possible;

– Be proportionate to the public risk being considered;

– Be clearly articulated and shared with affected public risk stakeholders;

– Explain how decision-making will be undertaken; and

– Explain how activities will be coordinated across organization(s).

4.2.2.4 The governance structure should include a clear decision-making process that:

– Is transparent and well understood by all;

– May not be unanimous but should be based on a consensus process where possible;

– Is based on science, logic, and data where possible including consideration of the weight of evidence;

– Is preferably separate and autonomous from each organization's internal enterprise risk management framework; and

– Includes an ultimate decision maker or process for making decisions, recognizing that not all public risk stakeholders may agree to the final decision.

4.2.2.5 If the public risk is regulated, a governance structure should be established to identify:

– The mandate of all regulators involved;

– Their roles and responsibilities;

– The role of public risk stakeholders within each organization's decision-making process;

– Appropriate and independent oversight based on best practices;

– Results oriented performance management; and

– Other aspects of public governance.

4.2.2.6 Roles, responsibilities and accountabilities within and across organizations should be mapped where possible and clearly articulated, even if not all are participating in decision-making processes, so as to understand who is best positioned to manage the public risk. This process should explain the role of each organization, the interaction among public risk stakeholders (e. g., the lead organization can set timelines for updates and/or decisions and the means of communicating that information so that all public

risk stakeholders know how to receive updates), and the nature of relationships (an example is the accountability shared among organizations). Affected organizations should confirm their understanding of their role in managing the identified public risk.

4.2.2.7 The roles of regulatory agencies or oversight bodies should be clearly established either in legislation or other mechanisms (such as memoranda of understanding, contractual agreements etc.) and should be available to all stakeholders. Expectations, mandates, accountabilities, performance reporting etc. should be clearly established.

4.2.2.8 Regulatory bodies should seek integrated approaches, with one body taking the lead so that individual mandates and responsibilities do not conflict, overlap, duplicate, or create gaps and the overall risk is managed effectively. If an integrated approach is not possible, all overlapping regulatory bodies and jurisdictions should be documented and a communications plan should be developed.

4.2.2.9 Mandates should not override each other to the detriment of managing the risk and should safeguard objective regulatory oversight.

4.2.2.10 The independence of individual statutory officials with public risk decision-making authority from the individuals with organizational risk management authority should be maintained and demonstrable and should be developed on the basis of sound scientific principles and use evidence, as available. Where there are uncertainties, they should be clearly identified and communicated.

4.2.2.11 Once roles, responsibilities and decision-making processes have been established, a Terms of Reference document should be developed and made available to stakeholders, so as to ensure transparency and clarity.

4.2.2.12 Organization(s) undertaking risk assessments should engage with those responsible for the risk management to: define responsibilities; seek information and clarifications; understand the actions being contemplated that may affect options or mitigation strategies being considered; and understand the decision-making process, or the risk assessment, being undertaken.

4.2.2.13 When selecting who should take the lead on the management of a public risk (i.e., the lead organization(s)), the following criteria may be considered:

– Which organization has an explicit mandate to address the public risk;

– Which organization has the closest responsibility/accountability;

– Which organization has the technical and scientific knowledge and the capacity (i.e., resources) to lead;

– Which organization is best positioned to lead;

– Which organization has the willingness to lead; and

– Which organization will be best accepted by affected public risk stakeholders (i.e., legitimacy).

4.2.2.14 Where there are conflicting objectives across organizations, (e.g., public security and privacy of personal information) the decision-making process should maximize the net benefit to society by using a consistent approach across organizations.

4.2.2.15 If sufficient information is not available, public risk stakeholders should be made aware and appropriate mechanisms be instituted by the organization best positioned to obtain the information to mitigate or manage the lack of information and data. For example, a weight of evidence approach could be considered where information from a single piece of evidence is insufficient for arriving at a decision.

4.2.2.16 If quantitative data is not available, anecdotal evidence or qualitative information may be used when interim or quick decisions are necessary. Any uncertainties should be explicitly stated and plans for gathering additional data should be articulated.

4.2.3 International Cooperation

4.2.3.1 Public risk, as it relates to human health, security, environment, and information can transcend borders. New risk pathways can emerge as more frequent and efficient means to convey people, goods, services and information become available and the operating environment becomes more integrated through globalization. Domestic efforts to manage public risks increasingly need to be conducted in tandem with other key international public and private stakeholders.

4.2.3.2 Opportunities for international cooperation should be sought in supporting domestic efforts where public risks are either common or can be introduced through trade.

4.2.3.3 Efforts should be taken by organizations to work with their respective foreign/regulatory counterparts where feasible and appropriate to explore cooperation when it comes to risk treatments to mitigate common risks. Exploring opportunities to share information, co-develop new policies, or create greater alignment of systems or approaches to controlling risk can lead to:

– Better decision-making;

– Facilitation of trade by reducing duplicative requirements and activities;

– More effective execution of regulatory mandates through access to expertise and facilities; and

– More efficient use of resources by work sharing and avoiding duplication of activities.

4.2.3.4 The following should also be developed:

– A process to manage disagreements, disputes, complaints among organization (s) (e. g., ombudsman) and a conflict resolution mechanism;

– A process to share information and data;

– A process to ensure full engagement and communication among public risk stakeholders;

– A process to make quick decisions, should an emergency or unforeseen issue arise that requires a short-term decision; and

– A public risk stakeholder engagement strategy and consultation process.

4.2.3.5 Due process should be afforded to all public risk stakeholders with a robust dispute settlement and appeal mechanism available.

4.3 Assessing the Public Risk and Decision-making

Once the contexts and public risk issues have been identified, an assessment of the risk should be undertaken to allow decisions to be made. A list of informative resources is included in Annex D for consideration by users. A risk assessment may be undertaken by any of the public risk stakeholders in a multi-organizational/multi-stakeholder context.

The most important aspect of the risk assessment process is to provide stakeholders with the opportunity to review the risk assessment and provide input so as to ensure that no gaps, overlaps or inconsistencies exist that could result in undesired, or less than optimal, outcomes.

In a regulatory context, the following aspects should be considered:

a) Application of the foundational principles (Section 3);

b) Purpose of risk assessment (Section 4.2);

c) Selection of a Risk-Informed Decision-Making Approach;

d) Establishing appropriate procedures and risk measures; and

e) Demonstrable commitment to reducing uncertainty in risk measurement.

The risk assessment should include all potential public goods and harms (Section 4.1) for each option being considered. This analysis should be undertaken without focussing on one option of managing public risk at the expense of other options.

4.3.1 Selection of a Risk-Informed Decision-Making Approach

4.3.1.1 The approach that is best suited to a particular risk-based decision is dependent on the foundational principles, the decision being undertaken, and the context. Appropriate scientific and technical procedures must be used to prepare a sound risk assessment. Where available, data regarding likelihoods, expected outcomes, and causality should always be used. Where such key information and knowledge are lacking, it is important to obtain a high level of assurance that the assessment is robust and based on using the best available information gathering and analytical methods.

4.3.1.2 Once the available science and data have been identified, the decision-making contexts and foundational principles can be used to define a risk-informed decision-making approach. This may range from a qualitative balance of outcomes using a risk matrix or similar tool to a rigorous, fully-quantified risk assessment with numerical limits on outcomes. For public risk stakeholders new to such processes, a selection of guidance documents that may provide a starting point are provided in Annex D.

4.3.2 Public Risk Decision-Making Process

4.3.2.1 Public risk management is primarily a decision-making process. The most significant types of decisions include:

– Whether to set rules and expectations (e.g., laws and regulations);

– If a decision is made to set rules and expectations, determining the degree and level of regulation; also incorporating the views of the public expressed through comments, which form part of the regulatory process in North America;

– Priority setting (e.g., identifying government priorities/policies);

– Resource allocation (e.g., inspections, audits);

– Oversight and enforcement (e.g., compliance management);

– Prosecutions;

– Public reporting (e.g., independent audits, third-party reviews, public interest watchdogs); and

– Whether Performance Management is undertaken (e. g., reporting tools, outcome measures, program review).

Some of the decisions may require changes to regulatory or legislative authority, which would require a legislative or regulatory amendment and political consultation.

4.3.2.2 In all such cases, the following attributes, at a minimum, should be considered and integrated into a formal decision-making process:

– Results and limitations of supporting risk assessments;

– Identification and assessment of options;

– Application of best available risk-benefit analysis tools;

– Public risk stakeholder engagement;

– Public and public risk stakeholder perception of risks and associated decisions; and

– Identification of appropriate methods and indicators for measuring effectiveness of decisions.

4.3.2.3 Once a decision to mitigate a risk is taken, the most important element of public risk management is the process and timeliness of measuring, reporting and communicating the risks to the public. The following should be considered, as a minimum, when measuring, reporting and communicating public risk:

– Decisions and associated impacts and effects;

– Direct benefits to the public from risk reduction actions, and possible risks if no action is taken;

– Ongoing measurement on the state of the public risk, decisions taken and the impacts (e.g., time-based uncertainties of historical conditions, future conditions and values) and ability to detect emerging risks;

– Indicators that demonstrate the state of the identified public risk, its sources and its effects;

– Indicators that are easily understandable and are evidence or science based;

– Transparent depiction of all the sources and effects of uncertainties on the reported indicators;

– Indicators that describe historical trends and future projections; and

– Process for peer reviews, public comments, and continuous improvement.

4.3.3 Establishing Procedures for Conducting Risk Assessments

4.3.3.1 Formal processes should be established, documented, and maintained to ensure that risk assessments provide the appropriate inputs into decision-making. These processes apply to both the overall management of the risk assessment and to the conduct of the risk assessments.

4.3.3.2 Examples of processes that apply to the management of the risk assessment function are as follows:

a) Setting priorities for risk assessments where multiple risk sources and pathways are to be considered (Example Section 4.1);

b) Establishing frequently applied technical assumptions to be applied across multiple risk assessments;

c) Establishing quality control and quality assurance procedures;

d) Establishing criteria for determining whether a qualitative or quantitative risk assessment is preferred;

e) Establishing standard peer consultation and review processes and criteria for triggering various levels of the intensity of peer review;

f) Establishing public risk communication guidelines to be followed; and

g) Establishing acceptance criteria or overall measures by which the results can be reviewed and accepted. For non-quantitative assessments of public risk, the public risk evaluator must be provided with sets of qualitative criteria by which to gauge the importance of the public risk results.

4.3.3.3 Examples of processes that may apply within the conduct of individual public risk assessments are as follows:

a) Using formal methods to review evidence to ensure that all the relevant information has been captured in a defensible and reproducible manner;

b) Applying weight-of-evidence methods in drawing conclusions on the causal relationship between a potential hazard and an adverse outcome;

c) Using approaches and methods for the propagation of uncertainty in inputs to estimate the level of uncertainty in the level of public risk; and

d) Applying multiple measures of public risk to describe different dimensions and possible interpretations of the public risk situation.

4.3.4 General Principles for Public Risk Assessment

4.3.4.1 Quantitative assessments are preferred, where feasible. It is recognized that semi-quantitative or qualitative assessments may be the only options for some decisions and that these may be appropriate in some contexts.

4.3.4.2 The public risk assessment should include all potential outcomes in the scope of the decision, without focussing on one at the expense of other outcomes. The public risk assessment of all such outcomes should be conducted concurrently and consistently.

4.3.4.3 The public risk assessment process should include the input of key public risk stakeholders to ensure that there are no gaps, overlaps or inconsistencies that could result in undesired or less optimal outcomes.

4.3.4.4 Any public risk assessment should clearly articulate all assumptions upon which decisions are made. It should not be assumed that a public risk response is produced by a single relationship nor should it be assumed that the relationship between a hazard and a specific public risk treatment is necessarily affected by the public risk assessment methodology chosen.

4.3.4.5 The appropriate measures (or set of measures) of public risk should be selected considering scientific factors, integration with economic analysis, and other key elements of the public risk management process, such as cost-effectiveness. This is important because a public risk or hazard can be explained in terms of specific characteristics, such as potential to cause cancer, or in terms of policy objectives, such as reducing the public risk of lung cancer. Understanding the desired outcomes at the outset of the public risk assessment process will help ensure that decision makers have the best available information to facilitate selecting appropriate public risk treatments.

4.3.5 The Public Risk Assessment Process

4.3.5.1 There are several examples of frameworks that describe the steps in a public risk assessment irrespective of whether they are quantitative or qualitative. Annex A provides two such examples typically

used in the environmental, public/worker safety, and food safety sectors. The general activities and aspects involved in public risk assessment are described below:

4.3.5.2 Problem formulation, sometimes referred to as “defining the public risk context”, involves characterizing the hazard or public risk in a broader context of social, economic, political or other factors relevant to the public risk management decision-making process. This context should be described along with the elements that are determined to be within and outside the scope of the public risk assessment. In some instances, this exercise may also involve pre-identification of public risk sources and hazards, public assets requiring protection, identification of key public risk stakeholders, available data and data needs, the routes and pathways via which the public may be exposed, and public risk management options. At this stage, many methods require the determination of public risk acceptability criteria such as ALARP for public risk evaluation purposes.

4.3.5.3 All public risk assessments identify and characterize the ways in which adverse events can arise (also known as hazard identification) involving the recognition that a hazard can cause a specific adverse outcome.

4.3.5.4 As part of hazard identification, conclusions are limited to describing the possibility of adverse outcomes, including the evidence that a causal relationship exists between a specific source of harm (i.e., a hazard) and the observable adverse outcomes.

4.3.5.5 Where the underlying causal relationship is in question, close attention should be paid to the process for inclusion, exclusion and weighing of evidence. The determination of causality should be transparent, including what evidence is or is not included and how it was weighed. Formal methods of systematic review should be used to ensure transparency and reproducibility among different hazard identification processes.

4.3.5.6 Where complexity exists when attempting to identify all the ways public risk can be generated, established techniques should be applied wherever possible to analyze the issue from a systems level. It should be noted that some systems may be too complex to proportionally identify all the ways a public risk can be generated, however best efforts should be made to identify those that pose the greatest public risk.

4.3.5.7 Exposure assessment consists of converting the possibility of harm associated with a hazard into estimates of the frequency and extent of the interaction between the hazard and specific public risk treatments. Given the breadth of public risks, assessments may require consideration of a wide range of public harms. For example, exposures to physical, chemical, biological and radiological agents present in the human environment (air, soil, water, the built environment and ecosystems) may need to be assessed with respect to their potential impact on the well-being of humans, animals, plants and ecosystem health.

4.3.5.8 All potential hazards should be considered however, the scope of a public risk assessment will often be significantly reduced as a result of the following:

a) Organizational or jurisdictional context;

b) Decisions made in the problem formulation to limit scope; or

c) Scientific and technical arguments that determine the most important public risk sources to be considered.

4.3.5.9 To ensure transparency, a clear statement explaining why a particular scope was chosen, including associated limitations, should be provided. Where the scope has been determined by scientific or technical arguments, these arguments should be provided in the exposure assessment stage. If the scope is largely determined by various public risk management considerations (e. g., legal, economic, political, etc.), they should be described in the problem formulation stage.

4.3.5.10 The estimate of probability (i.e., that the effects of concern will occur) can be assessed and reported using qualitative and/or quantitative methods. The choice of method is generally determined by the type of assessment and the way in which the assessment results will be used, or it may be a function of the amount of data available. Greater amounts of data and resources are required for the assessment of public risks:

a) That arise from highly non-linear phenomena;

b) That arise from the combination of a set of events leading of exposure;

c) Where there are high degrees of variability in the level of public risk; and

d) Where there is a need for decision makers to make trade-offs between one level of public risk and another (discussed in Section 4.1).

4.3.5.11 It is important to describe the most important sources of variability that influence estimates of public risk and the resulting variability in the level of public risk assessed for the public risk stakeholders.

4.3.5.12 Qualitative methods and measures are often used in conjunction with or when quantitative methods are unavailable. Expressions of probability (e.g., “unlikely,” “remote,” “often,” “rare”) are not considered to be appropriate, except when insufficient data exists to undertake a quantitative interpretation. Where used, these terms should be used consistently within and among organizations and should be transparently described.

4.3.5.13 Consequence Analysis involves the outcomes described and expressed for the hazard based on the evidence available to estimate public risk. In many cases, the consequences may need to be estimated in several stages, where the result is best described as having several cascading steps. For example, the presence of viruses in the environment may contaminate crops potentially affecting food products which when consumed, may cause gastro-intestinal illnesses.

4.3.5.14 Different levels of susceptibility as well as simultaneous exposures to the same or related hazards may lead to variations in the probability or the severity of consequences among individuals or groups for a variety of reasons.

4.3.5.15 In addition, there may be temporal components, where outcomes may change at differing times. Where distinct populations are expected to incur greater or less severe consequences than the general population, these should be calculated and described separately. The specific differences in vulnerability, given the same degree of exposure, may be driven by a variety of public risk factors, including age, gender, socio-economic status, nutritional status, genetic differences, region, cultural practices, climate and occupation, and many others.

4.3.5.16 The public risk estimation process or public risk characterization includes calculations, description of the level of public risk, and the uncertainty associated with the estimate. Various methods are available to combine estimates of the frequency and extent of exposure with the relationship between exposure and consequences to yield estimates of public risk.

4.3.5.17 Public risk estimation or characterization integrates the information generated from the public risk assessment into a summary conclusion describing the public risk in a way that aids public risk management decision makers. The information provided should be used in combination with other assessments (i.e., legal, technological, economic, environmental, social and political) to inform the process for selecting the public risk treatment option(s).

4.3.5.18 Where there is uncertainty in the data or analysis, the source, type and significance of uncertainty should be specified. Detailed estimation or characterization methods should be applied when

significant uncertainty can affect critical public risk calculations (i. e., when it leads to uncertainty with regard to determining the preferred public risk treatment option).

4.3.5.19 There are different methods for assessing and expressing uncertainty, such as bounding values, interval analysis, sensitivity analysis and importance analysis. The rationale for employing these techniques, and the processes, data sets or inferences used, should be described.

4.3.5.20 As part of public risk evaluation and subsequently assessing the public risk reduction impacts of public risk management options, the estimated or characterized public risk are typically compared against the public risk acceptability criteria such as ALARP. In most practical scenarios, existing public risk management (public risk treatment) options and a new range of public risk management (public risk treatment) options (if necessary) should be selected for evaluation and should be compared against each other and to the status quo. The evaluation and comparison should include the effectiveness of public risk treatment options, the possible creation of new public risks through measures to control the baseline public risk, and any other known side effects of each option. The effectiveness of each public risk management option in reducing the severity of the public risk, or the probability that it will occur, should be estimated.

4.3.5.21 A public risk assessment report should characterize the change in levels of public risk estimates associated with each option while avoiding value statements. The determination that a specific option, such as regulatory intervention, is preferred is a product of public risk management and should not be characterized or implied by the public risk assessment.

4.4 Managing Public Risk

4.4.1 Public Risk-Cost-Benefit: Decision on Need for Intervention

4.4.1.1 The decision on the need for intervention should, at a minimum, account for:

– Magnitude of the public risk;

– Costs borne by public risk stakeholders including society;

– Benefits of the public risk source to society; and

– Other temporal considerations.

4.4.1.2 Regulatory oversight should consider all available tools within the regulatory structure and those outside the structure. The process should safeguard the independence of the oversight function. Risk-informed and evidence-based approaches should be used to determine the type, scope, extent, magnitude and frequency of regulatory oversight tools (such as inspections, audits, licensing, etc.). Voluntary approaches should be considered as an option in addition to, or as an alternative to, regulation.

4.4.1.3 Regulatory oversight should only be considered when necessary and if other voluntary approaches either fail to adequately address the public risk or cannot be effectively implemented. A range of options from building awareness, influencing behaviors, and enhancing compliance, should be considered before enforcement tools are used. The pre-determined balance between benefits and harms (such as the use of tools like ALARP) should be the basis for the design and implementation of regulatory oversight tools.

4.4.1.4 Types of regulatory tools implemented should be considered in conjunction with other regulatory tools that may impact the public risk. Where possible, regulatory tools should be complimentary across regulators and never conflict. If an oversight tool is already implemented by others, that tool should be shared amongst regulators so as to eliminate burden, overlap, confusion or gaps.

4.4.1.5 Selected option (s) should achieve sufficient public risk reduction to reduce the public risk to acceptable or tolerable/ALARP level. The need for intervention should consider opinions of subject matter experts who may be internal or external to an organization and affected public risk stakeholders. Strategies for engaging public risk stakeholders should be developed. Strategies for public risk communication balancing real public risk and perceived public risk should be developed.

4.4.2 Identification of Options

4.4.2.1 Identification of different options is relevant when the objective is for identification of options that can reduce public risk to acceptable/tolerable levels. Public risk reduction options should be sufficient to reduce public risk to acceptable /tolerable levels. Tolerability may be justified by being ALARP. Justification for ALARP will need to be defined. Organizations must ensure that option selection is not unduly influenced by cost. Options selection may involve different technologies that will likely involve different organizations. The lead organization should be cognizant of this. Public risk stakeholders may include many organizations and the interaction of their positions, concerns and viewpoints are required.

4.4.2.2 Identification of public risk control options should consider recognized and generally accepted good practices. Examples may be found in leading organizations both nationally and internationally. Selection of options should be fair to all public risk stakeholders, but this may not be possible every time. Options identified for public risk reduction assessment should be communicated to public risk stakeholders unless there are valid reasons not to do so. Organizations should seek out new/recently available options and should have a structured process for doing so.

4.4.2.3 Public risk reductions options should recognize grandfathering and should provide compensatory measures if “cease and desist” is needed.

4.4.3 Selecting Options: Assessing Pre-Established or Given/Available Options

4.4.3.1 Assessment of options should consider net public risk reduction, practicality to implement and cost. This will include reiteration of the public risk analysis to incorporate an identified option to determine the net public risk reduction. Organizations should ensure that assessment of options is independent of those controlling expenditures. Public risk assessment should be executed by technically competent individuals. Best available methods and data should be used. Adequate verification and validation methods to check assessments should be employed.

4.4.4 Performance

4.4.4.1 Monitoring ensures that the public risk has not increased due to a deterioration of the system and that the identified interventions continue to remain effective. Periodic review also ensures that there is continued review and improvement of the interventions, including incorporation of latest data and public risk analysis methods, and innovations in public risk management solutions. Organizations should establish metrics for measuring effectiveness of public risk control that also accounts for preventative measures (e.g., events that did not happen).

4.4.4.2 Organizations need to understand that public risk assessment and public risk management is an ongoing process and need to make available adequate resources to ensure that monitoring and review are maintained. The monitoring should ensure that the public risk has not increased, the public good has not decreased, and/or the system has not deteriorated. At the same time, opportunities to introduce innovation by those directly responsible for the public risk should be encouraged, as long as the public harm is not increased.

4.4.4.3 Engagement of independent third parties for reviews and audits may be considered. Relevant causative indicators should be identified and measured periodically to evaluate the effectiveness of the interventions and public risk responses. The indicators should be identified on the basis of appropriate