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BALANCING RISK IN REGULATORY DECISION MAKING: THE PORT GRANBY PROJECT CASE STUDY

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ABSTRACT

The purpose of this paper is to review the trade-offs that are routinely considered in regulatory decision making, and the policy basis and methods for making those trade-offs. Regulatory decisions under the *Canadian Environmental Assessment Act* (CEAA) and the *Nuclear Safety and Control Act* (NSCA) normally consider potential risks to the environment, human health and safety, if a project were to proceed. There is only limited consideration, under such circumstances, of the risks to the environment, human health and safety if the project were not to proceed. The focus is on the potential adverse effects of the project, except in the event of an emergency, where the focus shifts to the economic and other beneficial effects.

The Port Granby long-term low-level radioactive waste management project is a project to clean up and provide appropriate local, long-term management of historic low-level radioactive waste (LLRW) in the Port Granby, Ontario area. Approximately 0.4 M m^3 of LLRW, presently located at the Port Granby Waste Management Facility, is to be transported to a newly constructed long-term waste management facility ~700 m north of the bluff face where the facility is located. Accordingly, the project is subject to environmental assessment and licensing processes under the CEAA and the NSCA, respectively.

While the Port Granby Project does not represent an emergency situation, it does represent a situation that could result in a significant degree of environmental risk if the project were not to proceed. Over the course of the various studies that have been undertaken at the Waste Management Facility, it has become apparent that the facility is subject to erosion and gullying along the bluff face. The potential for the leaching of contaminants from the existing facility and the erosion of the Lake Ontario bluffs are recognized as ongoing risks that will continue and potentially worsen if the project does not proceed.

The economic and other considerations that could influence regulatory decision making are particularly apparent in the case of the Port Granby Project. Achieving the necessary balance between costs and benefits is not straightforward, however. In recent years there has been a growing trend towards increasingly quantitative approaches to regulatory decision making, including cost-benefit analysis, but cost-benefit analysis is recognized as having both advantages and disadvantages. When recent approaches to cost-benefit analysis are applied to the Port Granby Project, the advantages are clear, as are the potential benefits of proceeding with the project.

1. INTRODUCTION

The purpose of this paper is to review the trade-offs that are routinely considered in regulatory decision making and the policy basis and methods for making those trade-offs. The policy direction on which regulatory decisions are based is primarily concerned with potential risks to health, safety, security and the environment. The methods for weighing or trading off those risks range from qualitative assessments and judgments to more quantitative assessments involving mathematical models.

The trade-offs are particularly apparent in the case of clean-up projects like the Port Granby long-term low-level radioactive waste management Project (the Port Granby Project). The Port Granby Project is a project for the establishment of a safe, local, long-term management solution for the historic low-level radioactive waste (LLRW) that is situated in the Port Granby Waste Management Facility. Because the Waste Management Facility is located on the Lake Ontario shoreline, there are risks associated with not proceeding with the project, as well as with proceeding with the project.

1.1 Background

The Port Granby Project was initiated by the federal government in 2001, as one of two historic LLRW clean-up projects under the Port Hope Area Initiative (PHAI). The Port Hope and Port Granby projects were initiated based on *An Agreement for the Cleanup and Long-term Safe Management of Low-level Radioactive Waste Situate in the Town of Port Hope, the Township of Hope and the Municipality of Clarington* [1.]. The Agreement was established between the affected municipalities and the Minister of Natural Resources in 2001 June. Atomic Energy of Canada Limited was later designated the proponent of the project, on behalf of the Government of Canada.

In 1955 a dedicated waste management facility (WMF) was established on the Lake Ontario shoreline near the hamlet of Port Granby in the Municipality of Clarington. Approximately 0.4 M m^3 of LLRW was placed in a series of ravines (East and West Gorges) and trenches along the shoreline (Figure 1). The waste consisted of radium waste, neutralized raffinate, calcium fluoride, metal slag, chemical waste and industrial refuse. Industrial refuse, such as scrap equipment, rubble and drums, were specifically placed in the East Gorge.

The LLRW originated from Eldorado Gold Mines Limited's (Eldorado[1]) uranium processing activities in the neighboring Town of Port Hope. Radium and uranium were processed in the town since the 1930s, producing uranium oxide and uranium hexafluoride for nuclear power generating stations across Canada and around the world. Waste placement at the Port Granby WMF was, however, discontinued in the 1980's when the Atomic Energy Control Board (now the Canadian Nuclear Safety Commission) issued a decommissioning order for the site.

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[1] A federal crown corporation also named Eldorado Mining and Refining Limited and later, Eldorado Nuclear Limited.

Figure 1. View of bluff face slightly to the east of the Waste Management Facility [2.].

The Port Granby WMF was still active when the decommissioning order was issued. The LLRW was considered to be in a safe and stable condition in the short-term, but considerable oversight and administration was required to maintain it in that condition. As mentioned, the shoreline in the vicinity of the WMF is primarily bluffs, which are eroding at a rate of approximately 0.3 m per year. There is also evidence that the contaminants are leaching into the native soils around the waste. While the Port Granby Project represents a safe, stable condition in the short-term, it does not represent an acceptable condition in the long-term. There is an acknowledged need for in-place stabilization of the waste and, or the relocation of the waste to a long-term waste management facility further inland.

1.2 Organizational structure

This paper is comprised of five sections. Section 2 provides an overview of the regulatory framework through which risks to health and safety, security and the environment are considered. Section 3 describes the policy direction that is the basis for the consideration of such risks. Section 4 reviews the findings of the Port Granby Project from the perspective of the various risks that are considered during the environmental assessment (EA) and licensing processes. Finally, Section 5 outlines the conclusions that are reached when current approaches to risk analysis are applied to the Port Granby Project.

2. REGULATORY PROCESS

The Port Granby Project was subject to an EA under the *Canadian Environmental Assessment Act* (CEAA), because it is federally funded and could involve shoreline works that would result in the harmful alteration, disruption, or destruction (HADD) of fish habitat. The Project also requires a licence for the possession, management and storage of a waste nuclear substance under subsection 24(2) of the *Nuclear Safety and Control Act* (NSCA), which is also an EA trigger.

2.1 *Canadian Environmental Assessment Act*

The CEAA, which came into force in January 1995, and its regulations are the legislative basis for federal EAs in Canada. Many assessments are conducted jointly with the provinces, but the CEAA sets out the responsibilities and procedures for the EA of projects involving the federal government. The Act applies to projects for which the federal government holds decision making authority, whether as proponent, land administrator, source of funding, or licensing authority.

Where the need for a licence triggers the CEAA, the Canadian Nuclear Safety Commission (CNSC) is normally the Responsible Authority and must therefore determine whether an EA is required. If an EA is required, the CNSC is responsible for ensuring that the EA is performed, that other federal and provincial authorities with an interest in the project are involved, and that the required public consultation is carried out. The licensing process cannot be launched and a licence cannot be issued until an EA has been completed, as the EA decision determines whether or not to proceed to licensing.

The purpose of the EA process is to minimize or avoid adverse environmental effects before they occur and to incorporate environmental factors into decision making. The focus is necessarily on the potential for adverse environmental effects as the intent is to render a decision on whether a project will result in significant adverse environmental effects. There are exceptions to this process, however, which allow a project to be exempted from an EA if it: i) is to be carried out in response to a national emergency for which temporary special measures are being taken under the *Emergencies Act*, or ii) is to be carried out in response to an emergency and the project is in the interest of preventing damage to property or the environment, or is in the interest of public health or safety.

2.2 *Nuclear Safety and Control Act*

The NSCA came into force on 2000 May 31, thereby establishing the Canadian Nuclear Safety Commission. The CNSC consists of the Commission, an administrative tribunal that takes licensing decisions, and employees who review applications for licenses, prepare recommendations to the Commission, exercise delegated licensing and authorization powers and enforce compliance with the Act, regulations, and any licence conditions imposed by the Commission. The Act requires organizations that possess, use, transport or store nuclear substances to be licensed by the CNSC, unless otherwise exempted.

The CNSC's mission is to protect health, safety, security and the environment and to respect Canada's international commitments on the peaceful use of nuclear energy. To this end, the CNSC regulates the development, production and use of nuclear energy, and the production, possession, use and transport of nuclear substances, prescribed equipment and information. Proponents are required to submit descriptions of the project, emergency preparedness and other plans, in support of their licence applications, but a licensing submission is treated as a risk-informed business decision. It is the Commission's prerogative to determine whether the evidence presented during the licensing hearing is sufficient.

Nuclear emergencies are managed in accordance with Section 9 of the NSCA. The CNSC's policy statement on nuclear emergency management similarly indicates that "health, safety, security and the environment are the top priorities in dealing with a nuclear emergency" [3.]. In this sense, the CNSC's approach is a risk-informed one, or commensurate with the risk.

2.3 The Port Granby Process

The Port Granby Project EA process was initiated with the submission of the project description to the Responsible Authorities in 2001. A series of biophysical studies were subsequently undertaken between 2002 and 2004, including studies to assess the potential atmospheric, aquatic, terrestrial, socio-economic, health and geologic effects of the Project. The study results were compiled in an EA Study Report that was submitted to the Responsible Authorities in 2006 [4.]. In 2007, the authorities rendered a favorable EA decision, accepting that no significant adverse effects would result from the Project. The Project has proceeded to licensing and a licensing decision will likely be rendered in the fall of 2011.

3. CONSIDERATION OF RISK

One of the more difficult aspects of regulatory decision making is evaluating, or achieving the appropriate balance of identified risks. EA and licensing decisions require multi-disciplinary knowledge, because the decision to minimize risk in one area could lead to increased risk in another. This difficulty has been alleviated to some degree through the establishment of policy direction, which outlines the specific priorities of the various regulatory agencies. Agencies like the CNSC have documented principles that support regulatory decision making in a risk-informed manner, or "in a manner that is consistent with the risk posed by the regulated activity" [5.].

3.1 Canadian Environmental Assessment Agency

The Canadian Environmental Assessment Agency works to integrate Canada's environmental goals with its economic, social and cultural values. The Agency's role is to ensure that EAs are completed to a high level of quality and that they contribute to informed decision making and decision making that supports sustainable development. The agency's policy direction on sustainable development comes from the federal sustainable development strategy and goals, which include addressing climate change, air quality, water quality, protecting the natural environment and reducing the environmental footprint [6.].

Environmental, economic and technical benefits and costs are balanced during the consideration of the need for, purpose of, alternatives to, and alternative means of carrying out the project, that are technically and economically feasible. The Agency recently clarified its policy direction on the provisions for the consideration of the need for a project - *Addressing "Need for", "Purpose of", "Alternatives to" and "Alternative Means" under the Canadian Environmental Assessment Act* - when concerns arose about the inconsistent application of this provision [7.]. As indicated in the policy direction, the consideration of need helps to establish the conditions under which significant adverse environmental effects may or may not be justified, should such a determination be required.

3.2 Canadian Nuclear Safety Commission

In addition to the various regulations issued pursuant to the NSCA, the CNSC issues regulatory documents such as policies, standards, guides, notices and procedures for licensees and the public. The regulatory policy documents describe the regulatory philosophies, principles and fundamental factors on which the regulatory decisions associated with a project are based. At a fundamental level, the regulatory policy documents describe why a regulatory decision is warranted and promote consistency in the interpretation of regulatory requirements.

CNSC policy direction is consistent with its mission to regulate the use of nuclear energy and materials to protect the health, safety and security of Canadians and the environment and to implement Canada's international commitments on the peaceful use of nuclear energy. CNSC compliance policy aims to "design and carry out implementation measures to maximize compliance for each type of regulated activity while giving consideration to: the risk to the health and safety of persons; the risk to the environment; the risk to national security; the effective implementation of measures of control and international obligations to which Canada has agreed; and the past compliance record of the regulated person" [8.].

Policy direction is also provided on health and safety, security and the environment. The policy direction on regulatory fundamentals reinforces that persons subject to the NSCA are "responsible for managing regulated activities in a manner that protects health, safety, security and the environment, while respecting Canada's international obligations" [9.]. CNSC policy direction on the protection of the environment goes a step further in ensuring that the activities that they regulate do not result in an unreasonable risk to the environment; in keeping with Canadian environmental policies, acts, regulations and international obligations [10.].

Also of note is the CNSC policy direction on the consideration of cost-benefit information [11.]. This policy acknowledges that federal regulation-making authorities must adhere to related policies and processes, including weighing the benefits and costs of proposed regulations, and applying government resources where they can do the most good. This policy also recognizes that cost-benefit information may have relevance to activities other than the development of regulations and expresses an openness to the receipt of such information during hearing proceedings and other regulatory review processes.

The CNSC principle of ALARA (as low as is reasonably achievable social and economic factors being taken into account) was traditionally associated with cost-benefit analysis, but no formal process was established for determining, or calculating what is ALARA from a cost-benefit perspective.

3.3 Assessment of the Port Granby Project Risks

The Port Granby Project EA scope [12.] required the assessment of potential effects on the atmospheric, aquatic, terrestrial and geophysical environments. Socio-economic and health (radiation) aspects were also to be assessed. "Alternatives to" the project were not considered, however, because the Project was based on a conceptual design put forward by the Municipality of Clarington. Also of note were the low-probability failure scenarios that were assessed to explore the upper bound of potential environmental effects, such as those that would occur in the event of containment failure.

The scope of the EA did require the consideration of "alternative means of carrying out the project that are technically and economically feasible and the environmental effects of any such alternative means," such as varying transportation routes, locations and designs for the facility [12.]. The following three alternatives were specifically considered: i) the onsite management of the LLRW; ii) the relocation of the LLRW to the Cameco property north of the existing WMF; and iii) the relocation of the LLRW to the Welcome Waste Management facility in the neigbouring town of Port Hope.

A weighted summation method, typical of EA processes, was used to evaluate the alternatives. The various alternative means through which the above alternatives could be achieved were identified and then reviewed with the local community. Community members were also consulted in the development of the criteria that were the basis for comparing the alternative means. The criteria included technical (20%), human health and safety (27.5%), community (18.75%), economic (11.25%) and environmental (22.5%) considerations, each of which was assigned a weighting (values in brackets). With the application of these criteria, and a qualitative analysis of the results, it became apparent that the preferred approach was to relocate the waste to a long-term waste management facility that would be constructed north of the Port Granby WMF.

Also a consideration during the EA was the assessment of malfunctions and accidents with a reasonable probability of occurrence, but also a couple of low-probability (i.e., less than 1:1

million) failure scenarios to identify the upper bound exposures associated with the loss of institutional control. The scenarios specifically included the natural degradation of the engineered barrier features resulting from the complete loss of waste containment. Through this assessment it was determined that the groundwater down gradient of the facility would be impacted by contaminated leachate, the groundwater would in turn impact Port Granby Creek, the aquatic and terrestrial communities would also be affected, and that the human health risks would exceed regulatory dose limits. The economic implications of these effects, were not, however, assessed.

4. ACHIEVING BALANCE

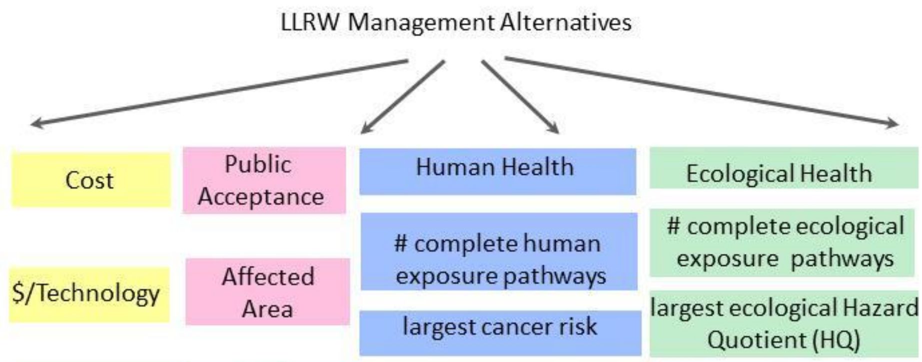
Recent literature on regulatory decision making states that "numerous statutory provisions establishing technology-based criteria for setting standards require agencies to consider cost, but they do not require agencies to weigh those costs against value of avoided harms, or benefits." [13.]. It has also been widely observed that "the setting of environmental standards is still determined by considerations unrelated to benefit estimates" [14.]. In recognition of the inherent difficulty in achieving the necessary balance between costs and benefits, approaches are being developed, which go beyond the typical qualitative type of assessment to a more quantitative type of cost-benefit analysis.

There is a growing trend towards the requirement for some form of regulatory cost-benefit analysis in regulatory decision making. More cost-benefit type of analyses are being used in the United Kingdom than ever before [14.]. The United States requires that a cost-benefit analysis be completed for all new major regulations, regulatory objectives be chosen to maximize the net benefits to society, and alternatives involving the least net cost to society be chosen [14.]. In fact, quantitative methods, including risk assessment and cost-benefit analysis, are the predominant decision making approach in the European Union and the United States. Canada similarly requires that a regulatory impact analysis be conducted, but mainly for new regulations [15.].

Recent trends in the use of cost-benefit analysis are at the forefront of discussions on the clean-up of contaminated sites. The uncertainty associated with the legal framework that governs regulatory decisions on contaminated sites, such as the Port Granby WMF, can "create an adversarial atmosphere, leading to unnecessarily long site investigations and overly conservative remediation designs" [16.]. Some would argue that this uncertainty could be alleviated through a transparent cost-benefit type of analysis and that it would particularly effective in selecting alternative approaches to radioactive and, or hazardous waste management [16.].

4.1 Cost-Benefit Analysis of the Port Granby Project

There are both advantages and disadvantages to cost-benefit analysis, as becomes apparent when three different approaches are applied to the Port Granby Project. The approach outlined in Figure 2 below is the typical outcome of Superfund feasibility studies undertaken to determine the feasibility of cleaning up abandoned hazardous waste sites in the United States. Alternative remediation approaches are evaluated based on factors such as: cost, stakeholder acceptance, health risks (maximum cancer risk) and ecological risks (number of exposure pathways and hazard quotients). The analysis would not normally include alternatives to the project proceeding, or the costs that would be incurred in the event of an emergency (i.e., containment failure).



Approach	Cost ($M)	Public Acceptance	Human Health		Ecological Health	
		Hectares	Pathways	Max. Cancer Risk	Pathways	Max. HQ
IA Onsite Management, Excavation	79.99-584.98	32	3	2.5E-04	3	0.90
IB Onsite Management, No Excavation	50.04-278.15	29	3	1.2E-04	3	0.90
II Relocation to New WMF	57.73-159.16	22	3	2.5E-04	3	0.18
III Relocation to Existing WMF	52.93-956.61	12	-	-	-	-

Figure 2. A common decision criteria and matrix, as applied to the Port Granby Project [17.].

There are acknowledged difficulties in making choices in a complex decision making environment, involving trade-offs and uncertainty [14.]. For example, while relocating the waste to the existing Welcome WMF would minimize both the costs and risks associated with the Port Granby Project (Figure 2), this option was removed from consideration, because the neighbouring Municipality was against the cross-boundary movement of the LLRW. In the case of the Port Granby Project, minimizing the area required to manage the waste would not maximize public acceptance. Similarly, the failure to consider "not proceeding with the Project," and the potential containment failure that could result, removes what may be the most costly alternative and valuable context.

James et al. [16.] used a Bayesian decision analysis type of cost-benefit analysis to evaluate whether: i) to provide interim containment of radioactive waste buried in trenches at the Oak Ridge National Laboratory in Tennessee until a permanent solution is identified; or to select the less expensive option, ii) to simply monitor the waste and associated leaching, leading to potentially greater clean-up costs if the waste were to spread. The formula (1), in its simplest form, considers both the known costs and the costs associated with project failure. The formula when applied to alternative approaches to the clean-up of the Port Granby WMF and to the option of not proceeding with the project, clearly shows that the cost of not proceeding is greatly in excess of proceeding (see Table 1 below).

$$\textbf{\textit{CT (Total Cost) = C (Known Cost) + }}\underbrace{\textbf{\textit{Pf (Probability of Failure)*Cf (Cost of Failure)}}}_{\textbf{\textit{Risk}}} \qquad \textbf{(1)}$$

Table 1. Cost-Benefit Analysis of the Port Granby Project Alternatives.

	C (Known Cost $M)	P_f (Probability of Failure)	C_f (Cost of Containment Failure $M)	Total ($M)
IA On-site Management, Excavation	78.99-584.98	$<10^{-6}$	173.19-477.48	78.99-584.98
IB On-site Management, No Excavation	50.04-278.15	$<10^{-6}$	173.19-477.48	50.04-278.15
II Relocation to New WMF	57.73-159.16	$<10^{-6}$	173.19-477.48	57.73-159.16
III Relocation to Existing WMF	52.93-956.61	$<10^{-6}$	173.19-477.48	52.93-956.61
Port Granby Project does not Proceed[1]	500 (1/year)	1	173.19-477.48	673.19-977.48

1. It is assumed that the maintenance costs of the Port Granby WMF are $1M/year and that emergency remedial action will cost three times that of the planned remedial costs of approach II. It is also assumed that some form of bluff failure would occur within the 500 year period that the long-term waste management facility would have been in operation, given that the bluff is eroding at ~0.3 m/year.

The approach offered by James et al. provides for a more balanced approach to decision making in that it acknowledges the consequences, and costs, of any associated failure. It shows which alternatives would be the least costly, but also what the failure of the Port Granby Waste Management Facility would cost, if the Project were not to proceed. As such, it represents a potentially valuable tool for communicating trade-offs to stakeholders and documenting the reasoning behind the decision to proceed. However, it also causes one to question whether the health and environmental risks are captured in the costs.

Katherine Kiel and Jeffrey Zabel propose using the hedonic method to ensure that the benefits from clean-up projects are appropriately considered during decision making. They used the hedonic method, a housing price model that estimates the individual willingness to pay, to estimate the economic benefits of cleaning up the Woburn Massachusetts Superfund Sites [18.]. The proposed approach is appealing in that it recognizes the effects of the site on the immediate community and that the effects and therefore cost will vary with distance from the site. However, the population in the vicinity of the Port Granby WMF would not support this type of regression analysis, as it is located in a rural community with approximately 48 residences are within view of the facility.

5. CONCLUSIONS

There is the view, according to risk management specialists, that one cannot conduct an objective analysis of risk. There are people who tend to support the objective view of risk, and people who tend to argue that all views of risk are socially constructed and that risk cannot be measured objectively. The distinction between 'perceived' and 'objective' risk is challenged by those who hold that all calculations of risk reflect our world views. Monetary valuation has, however, been effectively used for many years to assess damages, or to conduct liability assessments of projects, including projects for the clean-up of hazardous and other waste.

One of the common criticisms of the cost-benefit analysis approach is that it does not allow for 'multi-goal' objectives and therefore fails as a comprehensive decision making tool [17.]. While it may be argued that cost-benefit analysis cannot assign a cost to everything and therefore does not represent a comprehensive assessment of cost, it could be similarly argued that cost-benefit analysis brings to our attention a number of benefits that would be otherwise excluded from consideration, due to political and other reasons. In the case of the Port Granby Project, alternatives to the project proceeding were not considered, because the decision to proceed had already been made by the Municipality. However, the consideration of not proceeding with the project and, or the potential for containment failure, could have provided valuable context.

A more quantitative, cost-benefit type of analysis would enable decision-makers to see a more complete picture of the project by integrating economic and other considerations into decision making [16]. Failing to consider the possibility that "not proceeding with the Port Granby Project" could lead to greater contamination related costs in the future, provides for an incomplete picture of the Port Granby Project. Upon considering the complete picture, the results clearly show that the greatest costs, environmental and health risks are associated with the current condition, or not proceeding with the Project.

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