Risk-Informed Decision-Making In Canadian Nuclear Regulation

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Abstract

The objective of this paper is to provide an overview of concepts pertaining to risk management and risk-informed decision-making, in order to promote the understanding of their application in the Canadian nuclear regulatory climate. As stated in the Nuclear Safety and Control Act (NSCA), the CNSC is required to protect the Canadian public against "unreasonable risk" posed by activities it regulates. Additionally, the CNSC is expected to respect findings given in reports from the Office of the Auditor General (OAG), and to follow directives issued by the Government of Canada through Cabinet, hence, the Cabinet Directive on Streamlining Regulation (CDSR). The CNSC applies an approach that strives to be easily understandable, adaptable to many situations, supported by tools to gather information, is defensible, respects stakeholder consultations and is founded on open communication.

The CNSC's conformance to the NSCA is broken into categories depending on the nature of the regulated facility: Class I power reactor facilities, non-power-reactor Class I facilities and Class II facilities.

Internationally, different countries have different perspectives on risk. The paper argues that the CNSC's approach is consistent with practices of other nuclear regulatory bodies, which factor risk into their decision-making process.

1. Introduction

This paper provides an overview of various facets of risk management and risk-informed decision-making, in order to promote an understanding of the definitions, concepts, processes and implications associated with their application in the Canadian nuclear regulatory context. The paper builds on the CNSC mandate given in the Nuclear Safety and Control Act (NSCA - [1]), on the Government of Canada's Cabinet Directive on Streamlining Regulation (CDSR - [3]), and on findings made in reports of the Office of the Auditor General (OAG - [2]). It furthermore refers to a CNSC-developed process for risk-informed decision-making, which draws on Canadian Standard "*CAN/CSA Q850 Risk Management: Guideline for Decision-Making (1997) - [6],*" and on national and international experience in risk-informed decision-making (RIDM). Finally, the paper upholds the CNSC's commitment to apply consistent risk management techniques and processes in regulating the protection of health, safety, security and the environment in the nuclear industry, and compares the CNSC approach, in this respect, with that of other nuclear regulators around the world. Specifically, this document:

- describes the basic concepts of hazards, risks and risk management;
- describes the CNSC approach, and its implications, with respect to factoring risk in decision-making;
- touches on practices by nuclear regulators in other countries;
- highlights typical decision situations in the Canadian nuclear industry; and
- outlines a decision-making process for managing risk.

2. Basic definitions and concepts

2.1. Hazard:

The terms “hazard” and “risk” are sometimes incorrectly used interchangeably. “Hazard” is defined in CSA Q850 as “a source of potential harm, or a situation with a potential for causing harm, in terms of human injury; damage to health, property, the environment, and other things of value; or some combination thereof.”

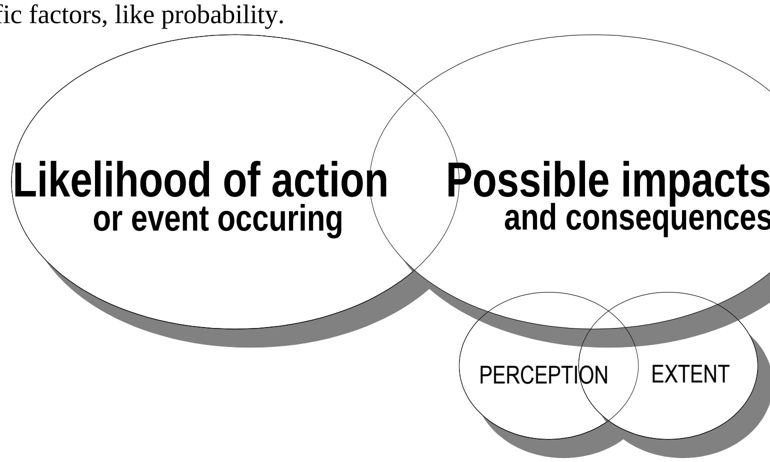
2.2. Risk:

Definitions of “risk,” on the other hand, vary depending on the type of risk; this can range from the personal, everyday kind – like choosing to wear a bicycle helmet – to financial risks associated with investing, to risks related to industrial development, corporate decisions, or government policy. CSA Standard Q850 defines risk as being “the chance of injury or loss, defined as a measure of the probability and severity of an adverse effect to health, property, the environment, or other things of value.” The CNSC [5] expanded this definition slightly: *“Risk is the chance of injury or loss, defined as a measure of the probability, and severity of an adverse effect (consequences), to health, property, the environment or other things of value; mathematically, it is the probability of occurrence (likelihood) of an event multiplied by its magnitude (or severity).”*

In the definitions above, the common elements are the probability or likelihood of an occurrence and the consequence(s) thereof. It should be noted, however, that Canadian Standard CSA Q850, states that “risk” involves THREE key issues:

a) the frequency of the loss,
b) the consequences of the loss, and
c) *the perception of the loss*, i.e. how a potential risk is viewed by affected stakeholders in terms of its effect on their needs, issues and concerns.

Element (c) would likely constitute a significant consideration when attempting to formulate a risk-informed decision, as will be evident in the latter sections of this document. It is also important to bear in mind, when formulating a decision that, usually, “perception is reality;” the public will make judgments of the acceptability of a risk on the basis of the public’s perceptions of the consequences of that risk, rather than on scientific factors, like probability.



A simple illustration of the difference between “hazard” and “risk” is the presence of ice on the sidewalk. The source of harm (hazard) is the ice. The chance of injury (risk) is that incurred if I walked on that ice: I could slip and injure myself. If I walked on the other sidewalk, the hazard would remain unchanged, but the risk from that particular hazard becomes zero.

2.3. Risk management:

“Risk management” is the notion that the likelihood of an event happening can be controlled or reduced and/or its consequences minimized. Risk management reflects a strong desire to improve decision-making; it is the systematic approach to setting the best course of action under uncertainty.

Effective risk management includes determining and carrying out strategies for addressing the key aspect of adequate and timely communication with stakeholders and evaluation of results. Such consultative decision-making is fundamental to the CNSC's partnership philosophy; it benefits from collective expertise, and paves the way for ultimate acceptance of the decisions by those who will be affected by them. Communicating decisons, which could be controversial sometimes, and discussing and addressing public perceptions of risk, require particular attention and skills.

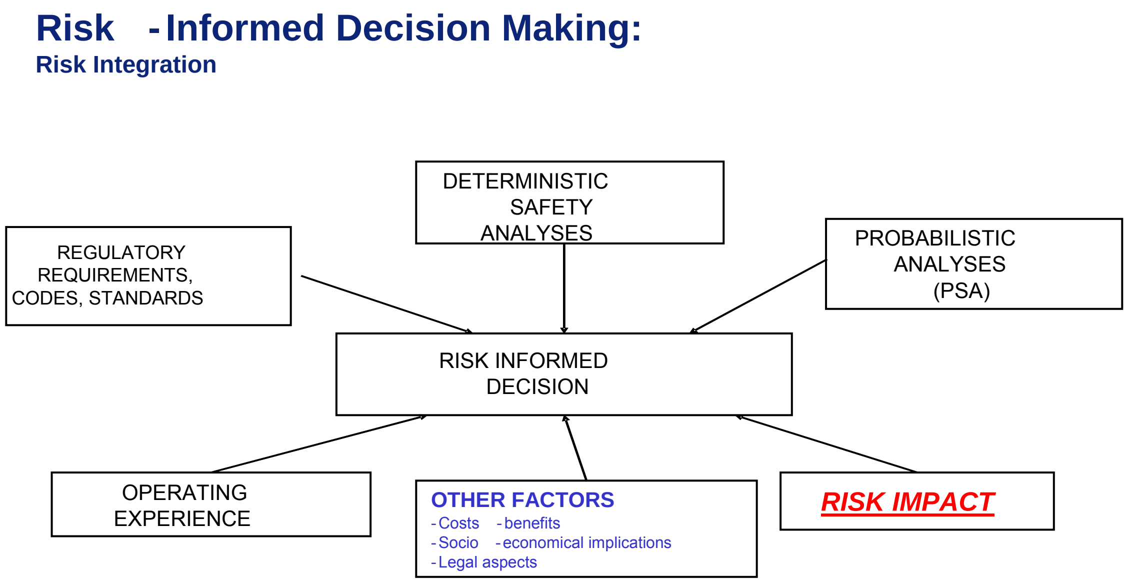
CSA Q850 defines "risk management" as being "the systematic application of management policies, procedures, and practices to the tasks of analyzing, evaluating, controlling and communicating, risk issues." The objective of risk management is to ensure that significant risks are identified, and that appropriate action is taken to minimize these risks as much as reasonably achievable. Risk management also introduces the idea that, often, there are benefits that might be derived from risk; therefore, effective risk management also seeks to maximize the benefits of a given risk while minimizing the risk itself. There are essentially four management options, or a combination thereof, with respect to dealing with risk:

a) avoid the risk (eliminate or ignore the risk),
b) tolerate the risk (accept the risk as-is),
c) transfer the risk (identify the risk as another party's responsibility), or
d) control the risk (treat the risk by reducing the frequency or consequences or both).

By taking the four options above into consideration, risk management may require decision-makers to make trade-offs between competing interests and values when deciding how potential benefits and losses should be apportioned.

2.4. Risk-informed decision-making:

RIDM starts with an issue or a situation for which a decision is required. RIDM is not an exact science; rather, it is a discipline which involves considering, appropriately-weighting, and integrating, a spectrum of often complex inputs and insights from "traditional" engineering (e.g. deterministic) analyses, probabilistic analyses, operational experience, and other considerations such as cost-benefit and time-at-risk. RIDM involves a way of thinking to integrate such inputs, insights or assessments, to result in safe, sound, and optimal management or operational actions or decisions. The "risk" component, as depicted in the figure below, thus constitutes an input among others; its significance is situation-specific.



3. Risk and the Canadian Nuclear Safety Commission

3.1. The CNSC mandate:

The CNSC must define risk as precisely as possible, because of the organization's mandate and responsibility as a regulatory authority, and because of the importance of this role to the safety of Canadians and the environment. Section 9 Paragraph (a) of the NSCA [1] defines the principal object of the CNSC as "regulating the development, production and use of nuclear energy...in order to:

"(a) *prevent unreasonable risk*, to the environment and to the health and safety of persons, associated with that development, production, possession or use,
(b) *prevent unreasonable risk* to national security associated with that development, production, possession or use, and
(c) achieve conformity with measures of control and international obligations to which Canada has agreed."

The December 2000 report of the Office of the OAG [2] observes "the overall objective of health and safety regulatory programs is to proactively protect Canadians from risks to health and safety - to catch the problem before it happens, and if it happens, to minimize the consequences."

The Government of Canada's CDSR states: "When regulating, the federal government will protect and advance the public interest in health, safety and security, the quality of the environment, and the social and economic well-being of Canadians,... and advance the efficiency and effectiveness of regulation by ascertaining that the benefits of regulation justify the costs......" The CDSR also requires regulatory authorities to ensure that the regulatory response is proportional to the degree and type of risk, and to justify proposed regulations through a Regulatory Impact Analysis Statement (RIAS): regulatory authorities must make a convincing case that the regulatory approach recommended is superior to non-regulatory alternatives, demonstrating not only that the benefits to Canadians outweigh the costs, but also that the regulatory program was structured such that the excess of benefits over costs is maximized. A corollary of the CDSR requirements is that deviations from an "optimum" set of regulations create added costs and a sub-optimal outcome.

Maximizing the overall benefit to Canadians was again echoed in a December 2007 Directive, issued by the Governor General in Council under the NSCA and addressed to the CNSC: "In regulating the production and use of nuclear substances in order to prevent unreasonable risk to the health of persons, the Canadian Nuclear Safety Commission shall take into account the health of Canadians who, for medical purposes, depend on nuclear substances produced by nuclear reactors."

The CNSC has endorsed the definitions of risk and risk management given in Sections 2.2 and 2.3; this endorsement constitutes an initial and necessary step towards meeting the mandated responsibility of protecting the CNSC's client, the Canadian public, against any "unreasonable risks" posed by the activities which the CNSC regulates. It is worth noting, however, that the word "unreasonable" often results in qualitative and sometimes opposing interpretations, government policies and regulatory practices, which influence stakeholders' understanding of the mandate.

3.2. Summary of CNSC obligations:

To re-cap, in order for the CNSC to discharge its mandate given in the NSCA, to respect the CDSR, and to disposition the OAG findings, we can infer that the CNSC is required to:
(a) *prevent unreasonable risk*, to the environment, to the health and safety of persons, and to national security, as a result of regulating the development, production and use of nuclear energy,
(b) *proactively protect Canadians from risks to health and safety* - to catch the problem before it happens and if it happens to minimize the consequences,
(c) *protect and advance the public interest* in health, safety and security, the quality of the environment, and Canadians' social, economic well-being,
(d) *advance the efficiency and effectiveness of regulation* by ascertaining that the benefits of regulation justify the costs,
(e) *ensure that the regulatory response is proportional to the degree and type of risk,*

(f) *make a convincing case that the regulatory approach recommended is superior to non-regulatory alternatives*, and
(g) *demonstrate that the regulatory program is structured such that the excess of benefits over costs is maximized.*

3.3. The CNSC approach - the extent to which the CNSC's programs are risk-informed:

Several initiatives (elaborated below) at the CNSC were undertaken, and continue to advance, in order to satisfy the directives mentioned above. In carrying out these initiatives, the CNSC is implicitly recognizing that effective risk management, based on a sound, well-reasoned process, improves:

decision-making,
delivery, and its effectiveness, of the organization's legislated mandate,
credibility with stakeholders, and
confidence of the Canadian public in general (recognizing that the Canadian public is not only part of the "stakeholders," but also the CNSC's client).

The CNSC's approach to risk management is thus based on applying a process which:

* is easily understandable,
* is adaptable to different decision-making situations,
* is supported by tools to gather information affecting the risk,
* is defensible,
* respects stakeholder consultation, and
* is founded on open communication.

It should be noted at this point, though, that risk management at the CNSC is not an alternative to delegated authority. Where a contravention of regulations is noted, inspectors *must* exercise their delegated authorities in a risk-informed manner, in accordance with principles laid out, inter alia, in CNSC documents such as "P-299: Regulatory Fundamentals" and "P-211: Compliance."

Risk management permeates all CNSC's activities from policy development and planning to day-to-day decision-making. The NSCA is the foundation of a regulatory framework that, at a policy level, is intended to maximize the overall benefits for Canadians.

3.4. Preventing "unreasonable risk:"

Analyzing the CDSR leads to interpreting "regulate to prevent unreasonable risk" as regulation that:

- permits nuclear activities to take place where the risks are justified by the benefits,
- optimizes protection without unduly curtailing the economic benefits,
- ensures that no single individual bears an unacceptable risk of harm, and
- ensures that regulatory response is proportional to the degree and type of risk.

On the other hand, "regulate to prevent unreasonable risk" does not mean:

- "no risk", nor
- regulation without regard to cost or consequence for the benefits to Canadians.

The question of "how risk-informed is the CNSC" thus translates into:
"To what extent does the CNSC program conform to the mandate given in the NSCA, respect the CDSR, and disposition the findings of the OAG?"

This issue is a question of degree which requires evaluation; examples are given in the Sections below.

3.4.1. Regulatory programs for Class I power reactor facilities:

The CNSC regulatory programs for Class I facilities comprise the main elements of siting, licensing, compliance and reporting, with the integral components of environmental assessment, document development, planning and resource allocation. In each of those elements, the associated regulatory sub-activities include and largely satisfy the intent of points 3.2 (a), (b) and (c), sometimes without explicit reference to "risk" or to "risk management":

- environmental assessments, identify possible (the probability of) environmental effects (consequences) and propose mitigating measures;
- a siting, construction or operating licence, for a given facility, is only issued after CNSC staff has diligently ascertained the proponent's qualifications (to minimize the risk of error) and the facility's design, operation and maintenance program adequacy (to minimize the risk due to equipment malfunction);
- the frequency and composition of audits and routine compliance inspections and enforcement measures implicitly consider the consequences of errors and/or failures, the necessary corrective and mitigating actions, and the means to prevent recurrence (to reduce error/failure frequency and consequences);
- planning and resource allocation are done on the basis of utilizing resources where they do the most good (to prevent unreasonable risks to the public and/or the environment); and
- regulatory requirements, given in regulations, regulatory documents, licence conditions and standards which licensees are required to apply, implicitly take into consideration "acceptable time at risk" for certain activities and equipment unavailabilities (such as impairments of safety systems).

In the area of "compliance," performance of each licensee is assessed, rated, and reported annually to the Commission, using the CNSC's risk-informed decision-making process, which first determines the licensee's "score" in each of a number of safety and control areas (analogous to the ones given below for Class II facilities) then, using the same process, determines the overall score for each licensed facility. Compliance inspections comprise three subtypes: Type I detailed audit, Type II inspection report of operations, and the Annual Compliance Report, as described briefly above, that covers the activities of the previous year for the facility. The process used yields a rating of "Fully Satisfactory," "Satisfactory," "Below Expectations," or "Unacceptable" for each of the safety areas as well as for the overall facility performance (see also Secion 3.3.2).

3.4.2. Regulatory programs for Class I non-power reactor facilities:

In addition to applying, and adherring to, several regulatory documents, the regulatory program for non-power reactor Class I facilities applies the expert judgment approach based in CSA Q850-97. A risk ranking system is used and this ranking system is supplemented by performance ratings that are used to evaluate each risk area on a regular basis. A score of low, moderate or high is assigned to each risk area for each facility, with three possible sub-levels (eg. L1, L2, L3) for each value. The risk areas examined are chosen to satisfy the key points of the CNSC's mandate as outlined in Section 3.3. Risk factors and performance indicators are defined in each risk area based on judgment from both technical and facility experts. Similarly, the ranking activity is conducted by subject matter experts, as well as the corresponding CNSC licensing division. Using these combined scores and past performance records, a risk profile is developed to create annual work plans for each facility. As a result, the baseline for each facility becomes risk-informed and the oversight for the facility is performance-based. This creates a system where compliance verification frequency and depth are commensurate with the risk profile for each facility.

3.4.3. Regulatory programs for Class II facilities:

Most of the points made in 3.4.1 above are valid for Class II facilities. For those facilities, however, the CNSC systematically applies a risk-informed decision-making process, which first determines the applicable requirements for the facility from the NSCA, regulations and licence conditions. For each of the requirements, the impact of non-compliance is then ranked by risk level. A high level of risk indicates an immediate or serious health, safety or security issue; a medium risk indicates that there is a health, safety or security issue, but not an immediate one; finally a low risk level shows that there is no health, safety or security issue - generally, administrative problems fall into this category. In the case of radiation protection, the radiological risk is also ranked: "low" being a dose of less than 1 mSv per year, "medium" between 1 and 5 mSv per year and "high" being a dose greater than 5 mSv per year. Areas of high risk become areas of high regulatory priority and effectively, areas of high regulatory effort. This may then translate to more frequent inspections, audits and evaluations and more frequent or detailed reporting requirements. The verification portion of the program comprises three subtypes: Type I detailed audit, Type II inspection report of operations, and the Annual Compliance Report that covers the activities of previous years for the facility. These three report types rate the following safety and control areas:

- radiation protection
- emergencies and unplanned events
- environmental protection
- fire protection
- training and qualification
- operational procedure
- transportation
- quality management
- organization and management
- non-radiological health and safety
- public information programs
- security
- international obligations and safeguards

Each of those areas is then assigned a letter grade from A (exceeds requirements) to E (unacceptable) on a Licence Report Card. Additionally, inspection worksheets outlining the sections to be reviewed and a table containing the verification and compliance status of various requirements as dictated by the NSCA and other regulations are created. From all these documents, a number of reports will be created including but not limited to: non-corrected items on any worksheet, work assignments, work performed, licensee performance, frequency of non-compliance and compliance by use type for all licensees, and average grades. Finally, staff feedback is continually collected; training in the form of workshops, site visits and email instructions is available to the operators and workers, and reports are made to the CNSC's Directorate of Nuclear Substance Regulation all in an effort to continuously improve and maintain the process.

3.4.4. <u>CNSC experience with applying an RIDM process in power reactor regulation:</u>
In 2004/2005, CNSC power reactor staff developed an RIDM process on the basis of CSA Standard Q850. That process is now being applied in power reactor compliance as described in 3.4.1. Additionally, it was applied satisfactorily in several power reactor and non-power reactor licensing applications requiring regulatory decisions. It has most recently been used to risk-rank about 75 CANDU safety issues and to develop the path forward for resolution of the most significant ones. A CNSC-Industry exercise, completed in August 2009, validated the process and identified mutually acceptable resolution paths for the outstanding safety issues. That process's successful applications have resulted in RIDM being applied with increasing frequency in regulatory decisions for both power reactor and non-power reactor issues. An example of RIDM application in nuclear power regulation is given in a separate paper, presented in this conference, entitled, " Application of the CNSC Risk-Informed Decision-Making Process in Nuclear Power Regulation: An Example."

3.4.5. <u>Implications of wider and more systematic use of an RIDM process:</u>
More systematic use of an RIDM process at the CNSC necessitates:
- more CNSC staff and management training in using the process;
- licensees' submission of improved PSAs for their respective facilities;
- development of a regulatory cost-benefit methodology for use in conjunction with the RIDM process; and
- completion of the current initiatives pertaining to licensing reform.

Applying the RIDM process systematically would, furthermore, contribute to ensuring that the benefits of regulation justify the costs, regulatory responses are proportional to the degree and type of risk, recommended regulatory approaches are superior to non-regulatory activities, and the regulatory program is structured such that the excess of benefits over costs is maximized.

4. Some International Perspectives: the US and the UK

4.1. <u>United States Nuclear Regulatory Commission (USNRC):</u>

In 1995, the USNRC [9, 10, 11] issued a policy statement on “probabilistic risk assessment - (PRA)” which states that, “the use of PRA technology should be increased in all regulatory matters......in a manner that complements the NRC's deterministic approach and supports the NRC's traditional defence-in-depth philosophy.”

Using this guidance, NRC staff undertook several projects to make the regulations contained in 10 CFR Part 50 impose regulatory burdens on licensees that are commensurate with their safety importance. For instance, NRC staff studied its reactor safety requirements in 10 CFR Part 50 to identify areas of unnecessary conservatism and potential additional safety requirements and to assess the feasibility of alternative approaches to changing the requirements, acknowledging that PRA does not account for human or organizational factors.

In 2000, USNRC staff issued a report to the Commissioners on the status of risk-informed changes to various parts of 10 CFR Part 50. The framework used a combined defence-in-depth and risk-informed approach. The risk insights set guidelines that limit: the frequency of accident initiating events, the probability of core damage given accident initiation, and public health effects caused by core damage accidents; the safety function success probabilities (commensurate with accident frequencies, consequences, and uncertainties) are achieved via appropriate redundancy, independence, and diversity, defenses against common-cause failure mechanisms, defences against human errors, and safety margins. The defence-in-depth elements employed independently of risk insights are: prevention and mitigation are maintained, reasonable balance is provided among prevention, containment and consequence mitigation, over-reliance is avoided on programmatic activities to compensate for weaknesses in plant design, and independence of barriers is not degraded. Furthermore, staff considered uncertainties and used safety goals to define “how safe is safe enough.” Finally, NRC staff recommended that licensees’ implementation of the risk-informed approach be voluntary.

In 2008, the US Electric Power Research Institute (EPRI) issued a “white paper” [12] entitled “Safety and Operational Benefits of Risk-Informed Initiatives.” That document extolled the safety and operational benefits of the risk-informed activities and requirements, and concludes that “Expanded application of PRA and risk-informed initiatives provide nuclear power plants with unprecedented opportunities for improving safety in a cost-effective manner. Successful but limited deployment in the nuclear industry to date has resulted in significant safety and operational benefits.” Operational benefits include high plant capacity factors, hence shorter and fewer outages; safety benefits include an estimated downward trend in the industry’s average core damage frequency. The EPRI document, however, places emphasis on numbers and does not mention any instances of tightening requirements, as opposed to relaxing them, as a result of applying a risk-informed approach.

4.2 United Kingdom Health and Safety Executive (UKHSE):

In 2001, the UKHSE published the document “Reducing risks, protecting people,” to set out, primarily, an overall framework for decision-making by HSE which would ensure coherence and consistency across the full range of risks falling within the scope of HSE’s mandate. It states that “…policy approach to major hazards regulation is broadly risk-based” and draws on established safety management principles. The document shows how HSE’s approach to risk assessment and management shapes HSE’s regulations and guidance, and how it affects compliance activities; it also asserts that:

* health, safety and welfare at work could not be ensured by an ever-expanding body of legal regulations enforced by an ever-increasing army of inspectors,
* primary responsibility for ensuring health and safety should lie with those who create risks and those who work with them, and
* the law should provide a statement of principles and definitions of duties of general application, with regulations setting more specific goals and standards.

The HSE holds the view [15, 16] that there is overwhelming evidence that, properly used, the results of a risk assessment often provide an essential ingredient in reaching decisions on the management of hazards; the proper use of risk assessment also requires that:

* the risk problem is properly framed,
* the nature and limitations of the risk assessment are clear and understood,
* the results of the risk assessment are used to inform rather than to dictate decisions and are only one of the many factors taken into account in reaching a decision.

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5. Conclusion

This paper describes basic concepts of hazards, risks, risk management and risk-informed decision-making, in the context of nuclear regulation in Canada. The snapshot of principles applied in countries with major nuclear power programs, such as the United States and the United Kingdom (Section 4), suggests that the CNSC approach, with respect to factoring risk in decision-making, is consistent with those countries' approaches.

6. References

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