national regulator for compulsory specifications

RISK ASSESSMENT METHODOLOGY FOR COMPULSORY SPECIFICATIONS

1. Introduction

Purpose

The methodology is based on current international best practice and, although ISO 31000 (Risk Management - Principles and Guidelines for Implementation) does not prescribe methodology, it is aligned with all the requirements of the Standard.

1.1. Risk and Risk Management

1.1.1. Risk is defined in the latest draft of the ISO Standard as the “effect of uncertainty on objectives”. In the context as applicable to the NRCS there can be two aspects to risk; the risk posed by the product under consideration and the risk that can arise as a result of regulation. Whilst the primary objective of a product is to perform a certain function, there is a secondary objective that it will do this in a way that does not negatively affect the safety or health of persons or harm the environment.

1.1.2. Whilst the primary objective of regulation is to ensure safety, health and environmental protection, there are also constraints, due to the obligation to avoid creating barriers to trade. Risk Management is defined as “coordinated activities to direct and control an organization with regard to risk.” Organisation in this context can be taken to mean the NRCS, its mandate to protect safety, health and the environment and its regulatory process.

1.2. Risk Assessment

1.2.1. Risk management comprises a number of processes within a framework or system. NRCS is only concerned at this stage with Risk Assessment, which is the overall process of risk identification, risk analysis and risk evaluation. Risk assessment provides the means to compare various risks that may

affect objectives; rank them in order of importance and use the information to inform decisions, which may be to continue, modify, or discontinue a particular course of action.

1.2.2. Before the risk assessment process can commence it is necessary to establish the risk criteria against which the risks can be measured. These reflect the internal and external contexts in which the organisation or particular activity operates. In the case of NRCS these relate to its mandate to regulate in the interests of safety, health and the environment, whilst also considering the impact of regulation on the market and stakeholders.

1.2.3. Risk identification is the “process of finding, recognizing and describing risks”, relative to particular objectives. It looks at and qualifies sources and causes, such as hazards and events and where possible quantifies the effects and consequences.

1.2.4. Risk analysis is the “process to comprehend the nature of risk and to determine the level of risk”. Thus the information provided in risk identification is given meaning through the examination and discussion of aspects such as severity and likelihood to determine the “level of risk”. Both severity and likelihood can be influenced by the effectiveness of existing control measures, which enables the level of risk to be considered as “inherent” (assuming controls fail) and “residual” (assuming controls work as designed).

1.2.5. Risk evaluation is the “process of comparing the results of risk analysis against risk criteria to determine whether the level of risk is acceptable or

tolerable". As applied to NRCS the evaluation will inform the decision to accept, modify, or reject a proposed regulation.

1.3. Risk Rating and Ranking

1.3.1. NRCS has adopted a particular methodology for rating and ranking risks that facilitates consistent measurement and comparability across the spectrum of relevant consequences. It utilises the parameters of Severity and Likelihood to rate either Inherent or Residual Risk. Likelihood is itself influenced by Risk Control Effectiveness.

1.3.2. In determining the likelihood of occurrence of a particular risk event, the duration or frequency of Exposure to the underlying sources or causes must be considered. These parameters and outputs are defined and used as follows;

1.3.3 Residual Risk - Residual Risk is the level of risk that remains after the existing (and claimed) controls that are in place and their effectiveness are taken into account. These may require verification by audit. It is a numerical rating calculated by the multiplication of three factors:

Severity Factor x **Exposure** Factor x **Probability** Factor = **Residual Risk** Rating

1.3.4 Inherent Risk - While decision-making should normally be based on the ranking of risks and actions by residual risk, sometimes it may need to be based on the assumption (or knowledge) that the existing protection measures and controls are ineffective. The rating is calculated in the same manner as residual risk. This definition is given here for completeness of

understanding of risk assessment. It is not intended to be used in the NRCS process.

1.3.5 Severity - A measure of the degree of consequences that are most likely to occur associated with the risk being rated. Those consequences would, in the case of products to be regulated by way of the NRCS process, be the negative impacts on the users or the community at large. Although existing controls usually influence likelihood rather than severity, there are sometimes conditions in which a control would limit the magnitude of the event and in these cases the control should be taken into account when choosing the severity level.

1.3.6 Exposure - A measure of the frequency of occurrence of the risk during which the product users and/or the community could be exposed to consequences at the specified level of severity. It reflects the “window of opportunity”. Often the exposure is related to some form of “trigger”, in that some pre-condition or activity has to occur before the consequences can become manifest. Or it can be a period of time that has a reasonable relevance to the type of risk. For application in the NRCS process it has been decided to use a single exposure period of one year for all risks and all product types. This will provide for consistency of interpretation across a range of applications where, in many cases, there may be an absence of statistics or other information.

1.3.7 Probability - Represents the chance of consequences of a specified level of severity occurring when the exposure is present; that is the chance of harm or damage actually manifesting during the selected exposure period.

1.3.8 Likelihood - Likelihood is defined as “the chance of something happening”. As explained, *Exposure and Probability* can be considered as two components of likelihood, the former providing the timeframe in which the latter can be more reasonably estimated. Because, in the NRCS process, it has been decided to use only one *Exposure* period for all products and risk issues, the definition for Probability given above will have the same meaning for likelihood.

1.3.9 Risk Control Effectiveness (RCE) - A measure of the completeness, relevance and efficacy of the existing risk controls. The actual level of control that is currently present and effective, expressed as a percentage of that reasonably achievable for that particular risk. Or a measure of how effective the existing controls are in relation to how effective all the reasonable controls could be. If, after all reasonable controls have been applied and the RCE is close to 100%, there may still be risk causing factors that are beyond control. The RCE is a measure to be taken into account when deciding the Likelihood Factor and that will depend on the degree to which the application of all reasonable controls can actually manage the risk. So it is possible to achieve a high measure of risk control effectiveness although a high probability still exists for the particular risk.

1.4 Using the Results - The results of the risk rating and ranking can be used to assign priority to identified risks, based on Residual Risk Rating.

1.5 Risk Assessment Tables

1.5.3 Severity Table

Severity Level		Consequence Types			Severity Factor
		Safety	Health	Environment	
1	Catastrophic	Death, affecting one or more persons	Death, affecting one or more persons	Prolonged impact, exceeding 5 years and affecting more than 50 km radius	300
2	Critical	Permanent disability affecting one or more persons	Permanent disability affecting one or more persons	Prolonged impact, exceeding 5 years or affecting more than 50 km radius	100
3	Major	Temporary disability involving hospitalisation	Temporary disability involving hospitalisation	2 to 5 year impact, and/ or affecting 20 to 50 km radius	30
4	Moderate	Non-disabling injury involving 'lost time' of more than two days	Non-disabling injury involving 'lost time' of more than two days	Temporary, local impact (e.g. noise), causing nuisance	10
5	Minimal	Injury involving First Aid treatment only	Injury involving First Aid treatment only	No significant impact	3

1.5.4 Likelihood Table

Likelihood	Description	Factor
Almost Certain	Expected to happen often in given conditions	10
Likely	Could easily happen in given conditions	3
Possible	Even chance of happening in given conditions	1
Unlikely	Unusual, even in given conditions	0.3
Remote	Could occur but only under extreme conditions	0.1

1.5.5 Risk Control Effectiveness Table

Level	Effectiveness Description	RCE
1	Little control in place – a lot more to be done	0 – 25%
2	Some elements in place and working, not yet half way	26% - 50%

3	About half needed elements in place and working	51% - 70%
4	Nearly all elements in place and working, minor exceptions	71% - 90%
5	Nothing more to be done, except monitor existing controls	91% - 100%

1.5.6 Priority Guide

Priority	Risk Rating	Requirements
1	>300	**Pre-approval**; mandatory conformity of production; high level of surveillance
2	>100-299	**Pre-approval**; high level of surveillance
3	>10-99	**Pre-approval**, moderate level of surveillance
4	>1.0-09	**Pre-approval**, lower level of surveillance
5	<1.0	No requirements; proposed regulation not justified

Appendix 1

CE	Risk Control Effectiveness %
SF	Severity Factor
LF	Likelihood Factor
RR	Residual Risk Rating

Risk Assessment Form

Standard _____ **Regulation** _____ **Facilitator:** _____ **Date:** _____

Identification	Qualification	Reduction	Rating

#	Risk	Causes	Consequences	Existing Controls	Control Proposed in Specification	CE	SF	LF	RR