A REVIEW OF THE INTERNATIONAL STATE OF THE ART IN RISK ASSESSMENT GUIDELINES AND PROPOSED TERMINOLOGY FOR USE IN CO_2 GEOLOGICAL STORAGE

Technical Study

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OVERVIEW: A review of the international state of the art in risk assessment guidelines and proposed terminology for use in CO_2 geological storage

Background to the Study

The IEA Greenhouse Gas R&D Programme (IEA GHG) commissioned Imperial College London, to undertake a review of the international state of the art in risk assessment guidelines and proposed terminology for use in CO_2 geological storage.

The need for this study was identified during the 3rd meeting of the IEA GHG international storage research network on risk assessment, held at Imperial College.

Scope of the Study

The work carried out included the following key elements:

- Review of the international terminology and regulations with a focus on public health and engineering systems risk assessment and management;
- Compilation of generic and specific terminology for risk assessment and management relevant for CO_2 geological storage;
- A formal report of the methods used, results and conclusions.

The report includes an updated version of the risk management framework that incorporates the Framework for Risk Assessment and Management of Storage of CO_2 Streams in Geological Formations (FRAM) and the European Union CO_2 Capture and Storage (EU CCS) directive steps, which is also consistent with the human health and ecological risk assessment workflows, as well as the Standards Australian/ Standards New Zealand (AS/NZS) for environmental risk management and security risk management. The report also includes a comprehensive list of terms used in various risk publications and extensive reference list.

The findings of the study were also presented at the 4th meeting of the IEA GHG international storage research network on risk assessment, held in Melbourne, Australia during April 2009.

Conclusions and Recommendations

The study report provides an important reference document on risk management frameworks and risk terminology in the context of CO_2 geological storage.

The report should be made widely available to practitioners in geological storage through future meetings of the IEA GHG risk assessment network and the International Performance Assessment Centre (IPAC).

Imperial College London

A review of the international state of the art in risk assessment guidelines and proposed terminology for use in CO_2 geological storage

IEA GHG R&D Programme

Anna Korre and Sevket Durucan
[5 November 2009]

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1 Executive summary

The objective of this project was to review the existing international guidelines as applied to hazard/risk assessment in various disciplines and develop a proposal for an internationally harmonised generic and technical terminology for use in CO_2 storage hazard/risk assessment, which will ensure the widespread acceptance and use of the methods and terminology utilised for the assessment of CO_2 storage projects between countries, saving resources for both governments and the industry.

The target user groups for the harmonised terms are CO_2 storage and environment professionals and political actors at all levels. The harmonised terms may also be used as a basis for preparing other publications primarily aimed at public information and CO_2 storage education.

In preparing this harmonised terminology, it was essential to review the methodologies and tools utilised in CO_2 storage risk assessment and develop an inventory of these as a precursor to the harmonisation of risk assessment approaches used worldwide. In line with the international methodologies and harmonised terminology produced the authors propose the generic risk assessment, management and communication framework for CO_2 storage projects depicted in Figure 1 below.

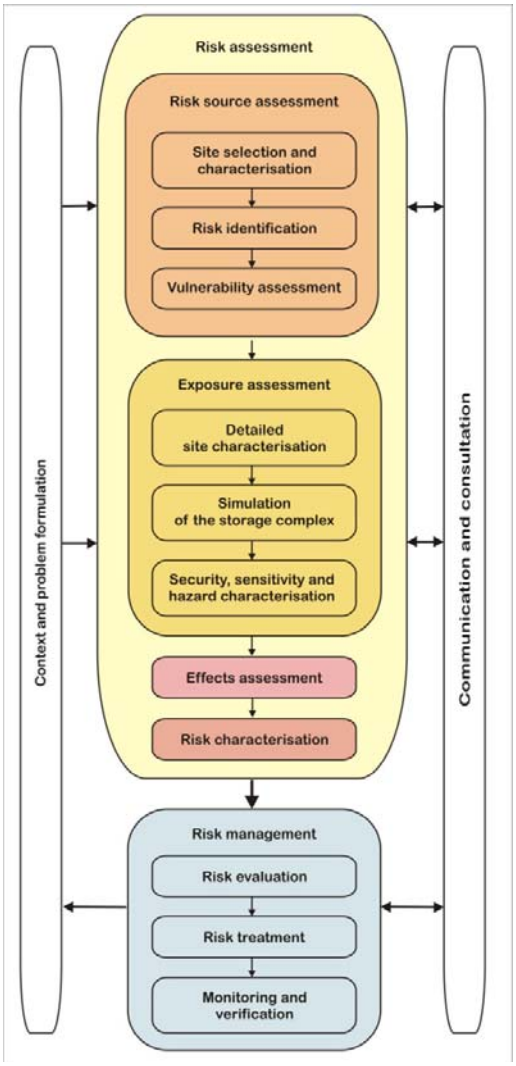

Figure 1. Risk assessment, management and communication framework for CO_2 storage projects.

The project has covered two categories of terms:

- Generic terms: general terms used in the process of determining hazards and risks that are relevant for CO_2 storage projects.
- Technical terms: those terms used in reservoir performance, human health and environmental hazard and risk assessment, including scientific–technical terms used in effects assessment.

The project team formulated the current report through their work within the IEA GHG International Risk Assessment Network and the feedback provided by the members during the 3rd IEA GHG Risk Assessment Meeting in London, as well as through their contacts with the scientific community and the industry. The work carried out includes the following key elements:

- Review of the international terminology and regulations with a focus on public health and engineering systems risk assessment and management;
- Compilation of generic and specific terminology for risk assessment and management relevant for CO_2 geological storage;
- A formal report of the methods used, results and conclusions.

2 Introduction

During its second meeting held in Berkley California on 4-6 October 2006, the IEA GHG Risk Assessment Network on CO_2 storage agreed on prioritising its future actions to ensure that:

- a harmonised terminology is available for use in CO_2 storage risk assessment,
- the methodologies currently in use are harmonised, and
- that common principles for the assessment should be adopted wherever possible.

The generic terms reviewed by the project team were presented and informally discussed with the Network members during the third IEA GHG Risk Assessment Network meeting held in London on 15-16 August 2007.

The Risk Assessment Network is conscious of the fact that "harmonisation," in the context of CO_2 storage risk assessment, should not simply be seen as standardisation. It is not the objective of the IEA GHG RA network to standardise risk assessments globally, as this is considered to be neither appropriate nor feasible. Instead, harmonisation is thought of as an effort to strive towards consistency among approaches and to enhance understanding of various approaches to CO_2 storage risk assessment worldwide. Thus, harmonisation is defined, in a step-wise fashion, as an understanding of the methods and practices used by various countries and organizations so as to develop confidence in, and acceptance of, assessments that use different approaches. It further involves a willingness to work towards convergence of these approaches or methods as a longer-term goal.

Achieving harmonisation of methodologies is considered to provide a framework for comparing information on risk assessment; understanding of the basis for the development of standards for CO_2 storage in different countries; savings of time and expense by sharing information and avoiding duplication of work; and credible science through better communication among organisations and peer review of assessments and assessment procedures.

Although some previous work has been done on the development of internationally agreed definitions for terms used in CO_2 storage risk assessment, inconsistencies in the definitions and use of many of these terms are well known amongst the practitioners.

Inconsistencies in terminology used can be an impediment to the harmonisation of risk assessment methodologies by preventing the mutual understanding of different approaches currently in use. Furthermore, the barriers created by these inconsistencies in terminology reduce the possibility for the sharing and use of knowledge between countries. Resolving these differences is therefore a high priority for the CO_2 storage research and implementation communities.

2.1 Objectives and Scope of the work

The objective of this project has been to develop and propose internationally harmonised generic and technical terms used in CO_2 storage hazard/risk assessment, which will ensure the widespread acceptance and use of methods and terminology utilised for the assessment of CO_2 storage projects between countries, saving resources for both governments and the industry.

The project focused on the harmonisation of terms used in the hazard/risk assessment of CO_2 storage projects in the context of storage site management (i.e., site selection, notification, registration, classification, etc.). The target user groups for the harmonised terms are CO_2 storage and environment professionals and political actors at all levels. The harmonised terms may also be used as a basis for preparing other publications primarily aimed at public information and CO_2 storage education.

The project covered two categories of terms:

- Generic terms: general terms used in the process of determining hazards and risks related to CO_2 storage projects.
- Technical terms: those terms used in reservoir performance, human health and environmental hazard and risk assessment, including scientific–technical terms used in effects assessment (e.g., nomenclature for storage site features and technical terms used in hazard characterisation, such as cap rock failure, and effects on the biosphere).

The work was organised under the following key elements:

- Development of generic terminology for CO_2 storage projects;
- Development of specific terminology related to the different settings foreseen for CO_2 geological storage, including an inventory of tools used CO_2 geological storage performance and risk assessment;
- A formal report of the methods used, results and conclusions.

3 Review of the international state of the art in risk assessment and management guidelines

In providing this harmonising terminology, it was considered essential to review the international literature and regulations on risk assessment and management (EU, US EPA, AS/NZ Standards, US NAS/NRC) and key glossaries and terminology compilations developed by international organisations, regulatory agencies and authoritative associations (e.g. WHO, EU, US EPA, US NRC, IPCC). The current section provides a brief distillation of the materials collected from these sources and key ideas that have been considered in developing the generic and specific terminology proposals presented in this report.

Historically, risk assessment has been dominated by two parallel methodological developments in the fields of 1) public-health risk assessment, with a major focus on the health effects of chronic exposures to chemicals, contaminants, and pollutants in the water, the air, and the food chain, and (2) engineered-systems risk assessment, with the primary focus on immediate and delayed effects due to the failure of systems, such as aerospace vehicles, chemical process plants, and nuclear power plants. More recently, there has been heightened interest in other risks, including ecological risks, risks related to severe natural phenomena and risks associated with malicious human acts. Each domain raises its own intellectual challenges, sometimes involving extension of public-health and engineered-systems methods, at other times requiring dedicated methods. (NRC, 2007)

Risk assessment, in both cases, involves a search for “causal links” or “causal chains” verified by “objective” analytic and experimental techniques. In the case of engineered systems the objective is to quantify the behaviour of various elements of the system in terms of failure-rate data. On the other hand, in public health risk assessment the focus is mainly on exposure and dose-response data. Risk assessments for engineered systems focus on the questions: What can go wrong? How likely is it to happen? (Kaplan and Garrick 1981). The analysis is typically organized around fault and event trees, delineating the impacts of initiating events and failure rates. Public-health risk assessment focuses on the question: What are the consequences? in terms of exposure assessment and dose-response assessment, using quantitative estimates of behaviours like ingestion and metabolism. Each field has generated its own analytic methods and experimental protocols, with the common goal of quantifying overall system performance in terms of valued consequences. (NRC, 2007)

3.1 Risk assessment, management and analysis from the public health risk assessment perspective

In the field of public health risk assessment regulatory actions are based on two distinct elements: risk assessment and risk management. Risk assessment is the use of the factual base to define the health effects of exposure of individuals or populations to hazardous materials and situations, while risk management is the process of weighing policy alternatives and selecting the most appropriate regulatory action, integrating the results of risk assessment with engineering data and with social, economic, and political concerns to reach a decision (The Red Book NRC, 1983; NRC, 2007).

The International Programme on Chemical Safety, established in 1980, is a joint programme of three Cooperating Organizations - WHO, ILO (International Labour Organisation) and UNEP, implementing activities related to chemical safety. In 2001 IPCS published their report on the harmonization of Approaches to the Assessment of Risk from Exposure to Chemicals. In agreement with earlier work Risk is defined as "the probability of an adverse effect in an organism, system or (sub) population caused under specified circumstances by exposure to an agent". Risk Assessment is defined as "a process intended to calculate or estimate the risk to a given target organism, system or (sub)population, including the identification of attendant uncertainties, following exposure to a particular agent, taking into account the inherent characteristics of the agent of concern as well as the characteristics of the specific target system". According to this definition, the Risk Assessment process includes four components: hazard identification, dose-response assessment (also referred to as hazard characterisation), exposure assessment, and risk characterisation. Risk assessment is considered to be the first component in a risk analysis process, which also includes Risk Management and Risk Communication as distinct separate components (Figure 2).

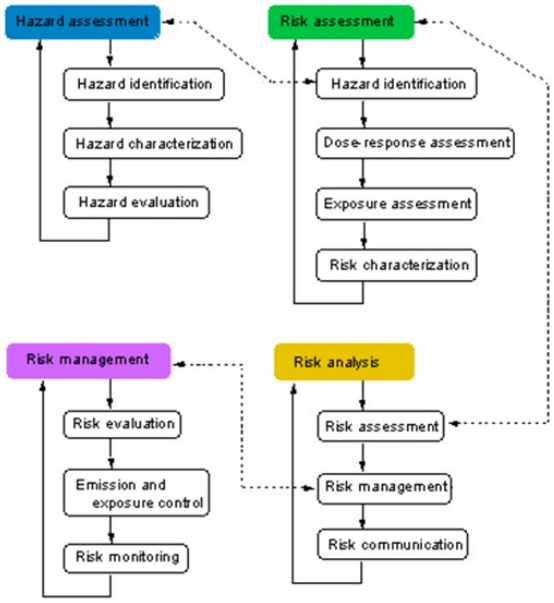

Figure 2. The risk analysis process as defined by the IPCS Terminology Standardization and Harmonization project (1999).

The component steps of the risk analysis are as follows:

(a) *Hazard assessment* is the process designed to determine factors contributing to the possible adverse effects of a substance to which a human population or an environmental compartment could be exposed. The process includes three steps:

- hazard identification: consisting of the determination of substances of concern, the adverse effects they may have inherently on target systems under certain conditions of exposure, taking into account toxicity data

- hazard characterisation: consisting in the qualitative and, wherever possible, quantitative description of the nature of the hazard associated with a biological, chemical, or physical agent, based on one or more elements, such as mechanisms of action involved, biological extrapolation, dose-response and dose-effect relationships, and their respective attendant uncertainties
- hazard evaluation: aiming at the determination of the qualitative and quantitative relationship between exposure to a hazard under certain conditions, including attendant uncertainties and the resultant adverse effect

(b) *Risk assessment* is the process intended to calculate or estimate the risk for a given target system following exposure to a particular substance, taking into account the inherent characteristics of a substance of concern as well as the characteristics of the specific target system. The process includes four steps: hazard identification (already explained), dose-response assessment, exposure assessment, and risk characterization.
- dose-response assessment: consisting of the analysis of the relationship between the total amount of an agent absorbed by a group of organisms and the changes developed in the group in reaction to the agent, and inferences derived from such an analysis with respect to the entire population
- exposure assessment: consisting of a quantitative and qualitative analysis of the presence of an agent (including its derivatives) that may be present in a given environment and the inference of the possible consequences it may have for a given population of particular concern
- risk characterisation: integration of evidence, reasoning, and conclusions collected in hazard identification, dose-response assessment, and exposure assessment and the estimation of the probability, including attendant uncertainties, of occurrence of an adverse effect if an agent is administered, taken, or absorbed by a particular organism or population. It is the last step of risk assessment.

(c) *Risk management* is the decision-making process involving considerations of political, social, economic, and technical factors with relevant risk assessment information relating to a hazard so as to develop, analyse, and compare regulatory and nonregulatory options and to select and implement the optimal decisions and actions for safety from that hazard. Essentially, risk management is the combination of three steps: risk evaluation, emission and exposure control, and risk monitoring.
- risk evaluation: establishment of a qualitative or quantitative relationship between risks and benefits, involving the complex process of determining the significance of the identified hazards and estimated risks to those organisms or people concerned with or affected by them.
- risk monitoring: process of following up the decisions and actions within risk management in order to ascertain that risk containment or reduction with respect to a particular hazard is assured

(d) *Risk analysis* is the process for controlling situations where populations or ecological systems could be exposed to a hazard. It usually comprises three steps, namely risk assessment, risk management, and risk communication.
- risk communication: interactive exchange of information about risks among risk assessors, managers, news media, interested groups, and the general public

3.2 Risk assessment and security risk management from the engineered systems perspective

According to the Australian / New Zealand Environmental risk management standard (HB 203:2006) and Security risk management standard (HB 167:2006) the risk management process involves communicating and consulting with stakeholders, setting the context, identifying risks, then analysing, evaluating, treating and monitoring risks. As illustrated by the feedback pathways in Figure 3, the entire risk management

process proposed is iterative and may be repeated with additional or modified risk evaluation criteria, leading to a process of continual improvement.

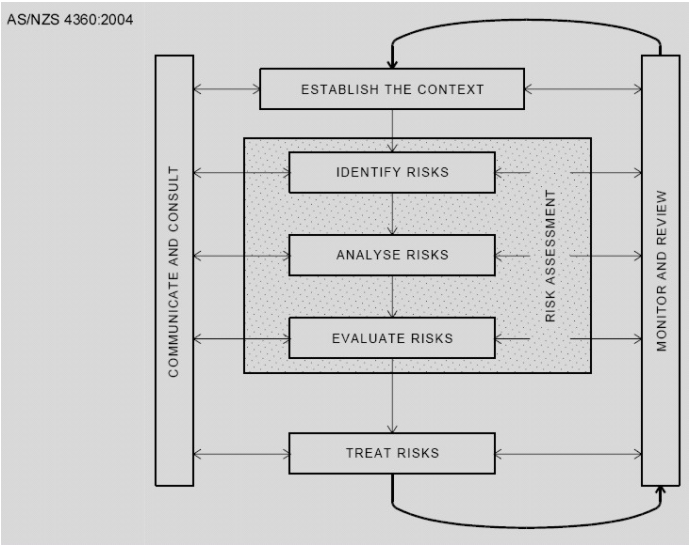

Figure 3. Risk management process overview (AS/NZS 4360:2004)

The steps of the generic risk management process according to the AS/NZS 4360:2004 standard are:

(a) Communicate and consult
Communicate with and consult the internal and external stakeholders as appropriate at each step of the risk management process and concerning the process as a whole. It is important to develop a communication plan at the earliest stage of the risk management process which should address issues relating to both the risk itself and the process to manage it.

(b) Establish the context
Determine the external, internal and risk management context by defining the basic parameters within which risks must be managed and setting the scope for the rest of the risk management process. Establish the structure of the analysis including the goals, objectives, strategies, scope and parameters of the activity, or part of the organization to which the risk management process is being applied.

Decide the criteria against which risk is to be evaluated. Decisions concerning whether risk treatment is required may be based on operational, technical, financial, legal, social, environmental, humanitarian or other criteria. The criteria often depend on an organisation's internal policies, goals and objectives and the interests of stakeholders and may be affected by the perceptions of stakeholders and by legal or regulatory requirements.

(c) Identify risks
According to the AS/NZS Security risk management standard (AS/NZS HB 167:2006) the identification of risks involves three steps, threat analysis, criticality analysis and vulnerability analysis. Identifying risk is therefore about understanding the nature of the threat (the source of the risk), interacting with important elements such as the community, organisational assets, etc (with importance expressed through criticality) and in what manner the nature of these elements will facilitate or inhibit this interaction (expressed through vulnerability) (Figure 4).

Threat analysis involves identifying hazards, environmental aspects and environmental impacts. Comprehensive identification using a well-structured systematic process is critical and occurs at

several stages. Initially, environmental issues and aspects are identified both at the strategic and the operational or project level. Subsequently, a more detailed examination may consider natural ecosystems, the general environment, people and communities, and the business.

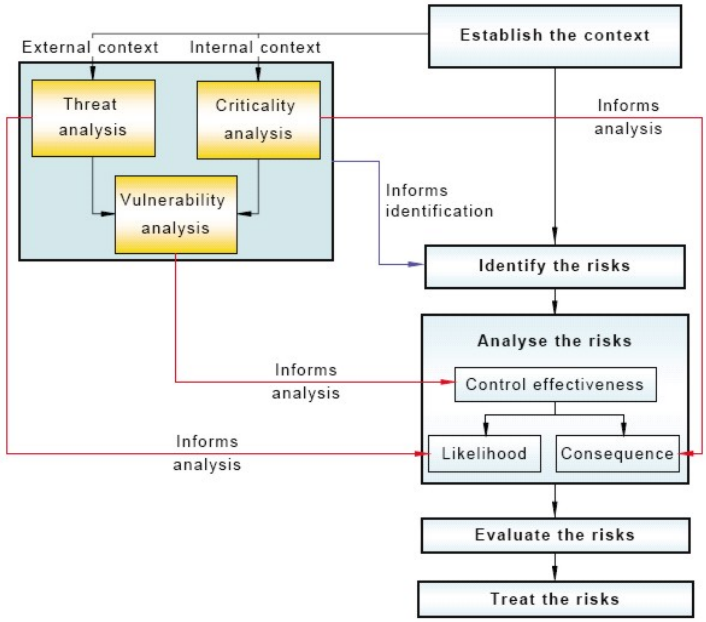

Figure 4. Using threat, criticality and vulnerability to inform risk analysis (AS/NZS HB 167:2006)

The criticality assessment (in some methodologies known as the ‘asset assessment), involves the identification of the critical assets (people, property, information and the processes that support them) that may be exposed to, or harmed by the threat.

(d) Analyse risks

Risks are analysed by combining their possible consequences and the likelihood of the occurrence of those consequences, in the context of existing measures to control the risk. The consequences of each risk and their likelihood determine the level of risk. Factors that affect consequences and likelihood should be identified and estimated either quantitatively or qualitatively. Consequence and likelihood may be combined to produce an estimated level of risk.

The aim of undertaking risk analysis is to:

- determine the adequacy and appropriateness of existing controls to manage identified risks;
- prioritise risks for subsequent evaluation of tolerance or need for further treatment; and
- provide an improved understanding of the vulnerability of critical assets to identified risks.

The risk analysis involves the consideration of the risk description, developed in the previous identification step, along with the combined outputs of those analyses (threat, criticality, and vulnerability analyses) that contributed to its formulation. The risk analysis should examine how these factors interact to determine an overall level of risk (Figure 4) through a consideration of the consequences of the event occurring combined with the likelihood of the event with that consequence.

(e) Evaluate risks

The purpose of risk evaluation is to compare the level of risk found during the analysis process against previously established criteria to determine whether to proceed or continue with an activity, whether risk treatment is required; and to prioritise (rank) the risks for treatment.

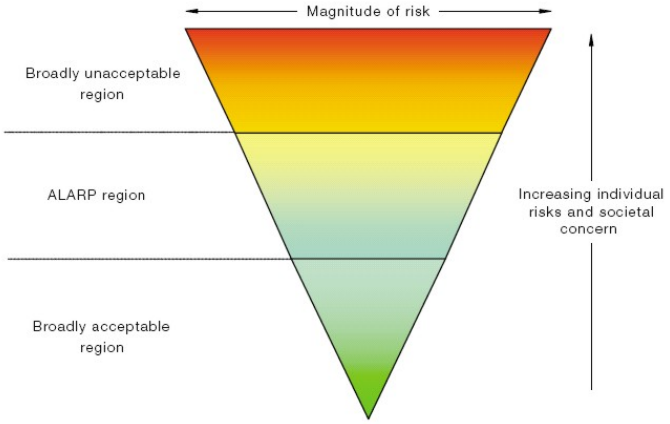

Figure 5. The ALARP approach for tolerability.

The most common approach to viewing risk tolerability is based on the ALARP approach ('As Low As Reasonably Practical') which divides the gradient of tolerability into three broad bands (Figure 5).

Risks that are unacceptable in any circumstances or at any level are deemed as intolerable. Risks identified as low priority can possibly be accepted without treatment, but subject to monitoring and review. For risks that are currently too high to be acceptable, risk treatment measures have to be considered to bring them to an acceptable level.

Evaluating risk must account for variability, lack of knowledge or understanding of the possible outcomes that may result from making a decision, and the implications of those outcomes.

(f) Treat risks

Risk treatment is the process of identifying the range of options, assessing the options for minimizing adverse impacts, preparing risk treatment plans, and implementing them. The purpose of establishing treatment objectives is to ensure that the subsequent development of treatment options meets organisational needs, will effectively manage the risk and will be sustainable.

Risk treatment options should be designed and developed, if necessary, to minimize adverse impacts. The options for the treatment of risk follow one or more of the following: strategies to reduce the consequences and likelihood of the risk; actions to avoid the risk; if the risk is tolerable and retention of the risk is determined as a potential treatment strategy, retain and continue to monitor the risk (Figure 6).

The evaluation of treatment objectives should include consideration of funding and other resources, and time frames. Once an appropriate treatment option or options have been selected, it will be necessary to undertake a detailed design. The purpose of the design review is to ensure that the detailed design of the treatment options are 'fit for purpose' prior to implementation commencing. Successful implementation of risk treatment will depend to a great extent upon the success of the communications undertaken prior to, and during the implementation.

(g) Monitor and review

The objective of the monitor and review stage of the risk management process is to assess the effectiveness of the risk management strategy and plan adopted, and to reassess their relevance. Risks and the effectiveness of control measures need to be monitored to ensure changing circumstances do not alter risk priorities. It is therefore necessary to regularly repeat the risk management cycle and treat review as an integral part of the risk management treatment plan.

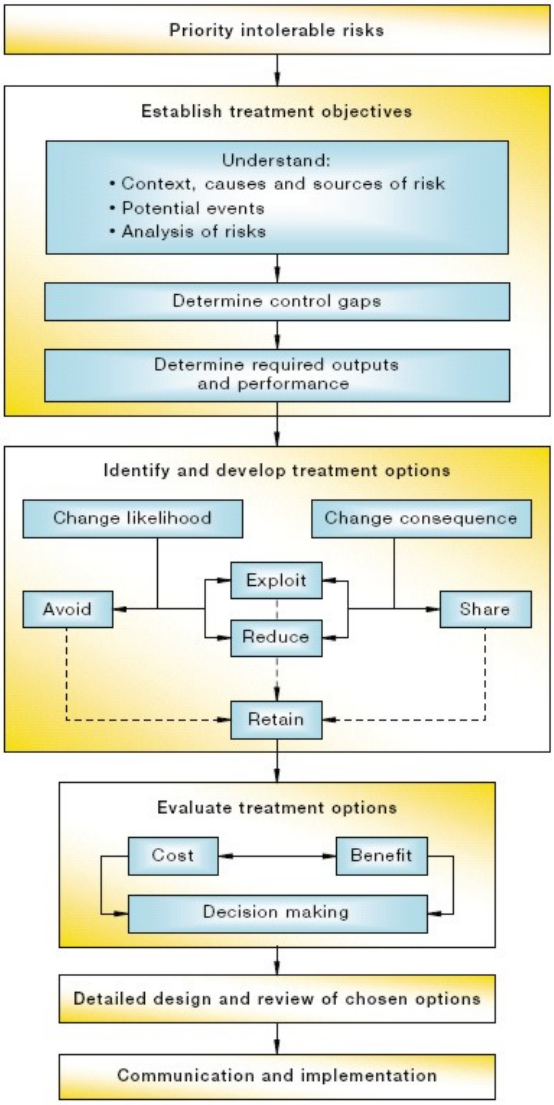

Figure 6. The Key stages of treating risk (AS/NZS HB 167: 2006)

Although they are shown as separate activities, in practice the above steps interact. For example, when risks are being identified the context and criteria will also need to be reviewed, and some aspects of analysis considered. The two steps, (a) Communicate and consult and (g) Monitor and review, engage overarching concepts and activities. At each step of the process, and for the process as a whole, there should be appropriate communication and consultation, both within the organisation and between the organisation and external parties. There should also be appropriate review and monitoring of the risks, the performance of the risk management system and the changes that may affect it. It is also essential that each step of the risk management process should be documented.

4 Risk assessment and management for CO_2 storage projects

The early work on CO_2 geological storage performance and risk assessment has enormously benefitted from the experience gained in analogous disciplines. The disposal of nuclear waste in geologic formations has been extensively studied in several countries for more than three decades. Some of the approaches and

methodologies developed in this context are of potential use to the problem of CO_2 geological storage. The main similarities between the two problems are (Benson, 2002):

- Prediction of future performance is required over very large periods of time.
- Site characterisation and modelling of the long-term processes governing the system behaviour are needed for areas over tens to hundreds of square kilometres.

However, transfer of any method or approach needs to take into consideration that there are also significant differences between the two kinds of projects (Benson, 2002):

- CO_2 is not toxic and is hazardous only at abnormal concentrations.
- Unlike the case of radioactive materials, CO_2 effects are not thought to be cumulative.
- Sites for CO_2 storage will need to be numerous and to handle large volumes of gas, whereas in the case of radioactive wastes very few sites will be selected for maximum isolation capability.
- In the case of nuclear wastes underground disposal, an engineered system is designed to enhance isolation, while in the CO_2 storage case this will be unfeasible.

The main concept borrowed so far from the nuclear industry is that of a systematic approach for identification of the Features, Events and Processes (FEPs) relevant to long-term performance of geological repositories as a first step towards risks identification (Espie, 2004; Benson, 2002; Wildenborg *et al*., 2004; Savage *et al*., 2004). The concept has been investigated by some groups and two databases, one by Quintessa working on behalf of the Weyburn project (Savage *et al*., 2004) and the other by TNO on behalf of the Carbon Dioxide Capture Project (CCP) have been developed (Wildenborg *et al*., 2003).

A second area that could significantly benefit from the use of tools developed in other disciplines is that of subsurface modelling. The oil and natural gas industry in particular has well-established tools for modelling of sub-surface flow of fluids (Espie, 2004), some of which have long been used for simulation of CO_2 injection for enhanced oil recovery.

A key challenge to researchers involved in geological storage of CO_2 has been to develop appropriate methodologies to assess and compare alternative CO_2 storage projects on the basis of risk. Technical aspects, such as the risk of leakage and the effective containment of the intended reservoir need to be considered, but so do less tangible aspects such as the value of storage, the safety of the project and potential impacts on the community and the environment (Bowden and Rigg, 2004a, b).

The majority of published work on geological storage risk assessment deal with conceptual and descriptive risk characterisation. However, decision makers need meaningful quantitative indicators, such as leakage rate and volumes and CO_2 concentration at a leakage site. Quantifying site-specific risks is not easy as there are uncertainties in almost all aspects of the project including reservoir characterisation, field operations, and particularly in assessing the future evolution of the storage site. This is why most CO_2 storage risk assessment studies conducted to date (Wildenborg, 2001; Lewis, 2002; Wo et al. 2005; Larsen et al., 2007), including the probabilistic ones, are based on inference logic. The truly quantitative assessment of uncertainty and risk associated with CO_2 storage can only be achieved if the reservoir parameters and physical processes involved are used to quantify these risks. To date, relatively limited measurement data are available as compared to the data needs of the predictive models. The scarcity of data makes it even more important to use the available data in the most efficient way and to estimate the uncertainty associated with the model predictions. It is in this context that stochastically based methodologies are being developed making a contribution to the wide scale industrial implementation of CCS technology worldwide (Korre et al., 2007).

One important question that divides practitioners is how the two principal terms CO_2 storage *Risk Assessment* and *Performance Assessment* relate. As defined by US DOE M 435.1-1, *Performance Assessment* is “the analysis of a radioactive waste disposal facility conducted to demonstrate that there is a reasonable expectation that the performance objectives established for the long-term protection of the public and the environment will not be exceeded following closure of the facility.” In addition, DOE M

435.1-1 also states that the method used for the performance assessment must include uncertainty analyses. A method that addresses these requirements has been used for the Waste Isolation Pilot Plant (DOE, 1996), the Yucca Mountain Project (DOE, 1998), and the intermediate-depth Greater Confinement Disposal Boreholes (Cochran et al., 2001) to assess the long-term performance of nuclear waste repositories (Sandia National Laboratories, 2008). What is also important to note is that ecological aspects are also being considered as part of the performance assessment of the Yucca mountain project and documented under the biosphere model report (DOE, 2000, 2002).

4.1 OSPAR Framework for CO_2 Storage Risk / Performance Assessment

In parallel to the above mentioned work on risk and performance assessment for CO_2 storage projects, teams of researchers have been working to update international agreements such as the London Convention (regulating the environmental protection of the oceans) and the OSPAR agreement (regulating the environmental protection of the North Sea) and provide a set of guidelines that cover the specifics of CO_2 storage. Recently, the Framework for Risk Assessment and Management of Storage of CO_2 Streams in Geological Formations (FRAM) has been developed to provide generic guidance to the Contracting Parties to the OSPAR Convention (OSPAR, 2007).

The OSPAR Framework for Risk Assessment and Management (FRAM) of Storage of CO2 Streams in Geological Formations describes an iterative process that is proposed for continual improvement of the management of a storage project during its lifetime. It has been designed to meet the requirements of off-shore storage, however, the same framework with small adjustments would also be applicable for onshore CO_2 storage settings. It is suggested that a simple conservative deterministic assessment is sufficient if the adverse consequences are insignificant, but if they are likely not to be, then as a precautionary approach the assessment should include probabilistic approaches to achieve acceptable results. The six stages of this framework are summarised from the original document (OSPAR, 2007) with highlighted modifications to address the on shore storage requirements as follows:

a. *Problem Formulation* is a critical scoping step as it defines the boundaries of the assessment, including the scenarios and pathways to be considered. Major issues to include in the assessment are:
   (i) the suitability of deep geological formations to permanently retain the CO_2 stream reliably;
   (ii) the nature of the overburden;
   (iii) the characteristics of the marine/land environment above the site; and
   (iv) the need for monitoring over a long period (also after site-closure). The latter is especially important with respect to the long-term safety of storage and any future handover of the responsibility for the storage site (liability for future risk);

b. *Site Selection and Characterisation* concerns the collection of data necessary for describing the physical, geological, chemical, and biological conditions necessary for determining the suitability of a site proposed for storage (and its surrounding area) and to establish a baseline for management and monitoring;

c. *Exposure Assessment* is concerned with the characterisation and movement of the CO_2 stream within geological formations and, potentially, the marine environment as a basis for an effects assessment. The processes and pathways of potential migration of CO_2 streams from geological storage formations and leakage to the environment, during and after injection of the CO_2 stream, should be assessed. This should include an assessment of additional substances, already present in or mobilised by the CO_2 stream and displaced saline formation water, based on an informed decision of the relevance of such substances. The probabilities of the exposure processes, the amount of CO_2 and the spatial and temporal scale of fluxes may be assessed using appropriate numerical modelling tools. The processes involved in such migration behaviour will be governed

by site-specific factors. The uncertainties associated with such an assessment should be identified and, wherever possible, quantified;

d. *Effects Assessment* assembles the information necessary to describe the response of receptors within the marine environment resulting from potential exposure to the CO_2 stream if leakage were to occur. The main effects of concern to such an assessment include effects on human health, water resources (underground, fresh and marine), relevant biological communities, habitats, ecological processes, and other legitimate uses. Effects of exposure to other contaminants in the CO_2 stream, as well as metals and other substances mobilised in a decreased pH environment, should be included in the assessment;

e. *Risk Characterisation* integrates the exposure and effects information to provide an estimate of the likelihood of adverse impacts. Risk characterisation should be performed on the basis of site-specific information. Factors evaluated in a risk characterisation may change over time given the operational status of the project and ongoing data collection used to update predictive models. The sources and levels of uncertainty associated with a risk estimate will be a function of the data and modelling assumptions used. Given the long time-scales involved for the intended storage of CO_2 streams in geological formations, it will be useful to distinguish between processes relevant to characterizing risks in the near-term during the period of active operations and injection at a site and long-term processes operating after site closure;

f. *Risk Management* (including Monitoring and Mitigation). In the planning phase, risk management is used to design preventive measures based on prediction (derived from the risk assessment process and in particular the outcome of the risk characterisation stage). Risk management further includes the definition of the requirements for monitoring, during and after injection of CO_2 streams. When injection starts, the results of monitoring are valuable and, if necessary, can lead to the identification of additional preventive and/or mitigating measures. Although the process of monitoring continues after site closure, its intensity is expected to decrease and, eventually, monitoring may be discontinued when there is confirmation that the probability of any future adverse environmental effects has been reduced to an insignificant level.

The OSPAR guidelines explained above encompass the iterative process described in the FRAM that should be used for continual improvement of the management of a CO_2 storage project during the project life time, in accordance with the principles of internationally- recognised environmental management standards (OSPAR, 2007):

a. Problem formulation: critical scoping step, describing the boundaries of the assessment;

b. Site selection and characterisation: collection and evaluations of data concerning the site;

c. Exposure assessment: characterisation and movement of the CO_2 stream;

d. Effects assessment: assembly of information to describe the response of receptors;

e. Risk characterisation; integration of exposure and effect data to estimate the likely impact; and

f. Risk management: including monitoring, mitigation and remediation measures.

The FRAM approach is relevant to all phases throughout the life time of a CO_2 storage project defined by OSPAR (2007) including planning, construction, operation, site-closure, and post-closure.

Clearly, the planning, including design, construction and operation should lead to an inherently safe storage site. Each phase of the project requires all, or a selection of, the above-mentioned stages of the FRAM to be carried out. The following table indicates which stages are applicable to each phase of the project:

	Problem formulation	Site selection & characterisation	Exposure assessment	Effects assessment	Risk characterisation	Risk management (monitoring & mitigation)
Planning	☑	☑	☑	☑	☑	☑
Construction		☑	☑	☑	☑	☑
Operation		☑	☑	☑	☑	☑
Site-closure			☑	☑	☑	☑
Post-closure			☑	☑	☑	☑

The explicit choice of models and tools that may be used to carry out the stages in FRAM are expected to vary from project and data requirements and the choice of appropriate models will be very much dependent on the scope and the expected results of the study as well as the life time phase of the CO_2 storage project.

4.2 EC Directive for CO_2 storage projects

On 23 January 2008 the Commission proposed a Directive to enable environmentally-safe capture and geological storage of carbon dioxide (CO_2) in the EU as part of a major legislative package. The final version of the directive (2009/31/EC) was published in the Official Journal of the European Union on 23rd April 2009. The EU member states are now responsible for the transposition of the directive to national legislation. The following paragraphs are extracts from the Annex I and II of the directive and describe the criteria for the characterisation and assessment of potential storage complex and surrounding area, and the criteria for establishing and updating the monitoring plan.

4.2.1 *Criteria for the characterisation and assessment of storage sites*

The characterisation and assessment of the potential storage complex and surrounding area referred to in Article 4(3) shall be carried out in three steps according to best practices at the time of the assessment and to the following criteria. Derogations from one or more of these criteria may be permitted by the competent authority provided the operator has demonstrated that the capacity of the characterisation and assessment to enable the determinations pursuant to Article 4 is not affected.

Step 1: Data collection
Sufficient data shall be accumulated to construct a volumetric and dynamic three-dimensional (3-D)-earth model for the storage site and storage complex including the caprock, and the surrounding area including the hydraulically connected areas. This data shall cover at least the following intrinsic characteristics of the storage complex: geology and geophysics; hydrogeology (in particular existence of ground water intended for consumption); reservoir engineering (including volumetric calculations of pore volume for CO_2 injection and ultimate storage capacity); geochemistry (dissolution rates, mineralisation rates); geomechanics (permeability, fracture pressure); seismicity; presence and condition of natural and man-made pathways, including wells and boreholes which could provide leakage pathways.

The following characteristics of the complex vicinity shall be documented: domains surrounding the storage complex that may be affected by the storage of CO_2 in the storage site; population distribution in the region overlying the storage site; proximity to valuable natural resources (including in particular Natura 2000 areas pursuant to Council Directive 79/409/EEC of 2 April 1979 on the conservation of wild birds and Council Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora, potable groundwater and hydrocarbons); activities around the storage complex and possible interactions with these activities (for example, exploration, production and storage of

hydrocarbons, geothermal use of aquifers and use of underground water reserves); proximity to the potential CO_2 source(s) (including estimates of the total potential mass of CO_2 economically available for storage) and adequate transport networks.

Step 2: Building the three-dimensional static geological earth model

Using the data collected in Step 1, a three-dimensional static geological earth model, or a set of such models, of the candidate storage complex, including the caprock and the hydraulically connected areas and fluids shall be built using computer reservoir simulators. The static geological earth model(s) shall characterise the complex in terms of: geological structure of the physical trap; geomechanical, geochemical and flow properties of the reservoir, overburden (caprock, seals, porous and permeable horizons) and surrounding formations; fracture system characterisation and presence of any human-made pathways; areal and vertical extent of the storage complex; pore space volume (including porosity distribution); baseline fluid distribution; any other relevant characteristics.

The uncertainty associated with each of the parameters used to build the model shall be assessed by developing a range of scenarios for each parameter and calculating the appropriate confidence limits. Any uncertainty associated with the model itself shall also be assessed.

Step 3: Characterisation of the storage dynamic behaviour, sensitivity characterisation, risk assessment

The characterisations and assessment shall be based on dynamic modelling, comprising a variety of time-step simulations of CO_2 injection into the storage site using the three-dimensional static geological earth model(s) in the computerised storage complex simulator constructed under Step 2.

Step 3.1 Characterisation of the storage dynamic behaviour At least the following factors shall be considered: possible injection rates and CO_2 stream properties; the efficacy of coupled process modelling (that is, the way various single effects in the simulator(s) interact); reactive processes (that is, the way reactions of the injected CO_2 with in situ minerals feedback in the model); the reservoir simulator used (multiple simulations may be required in order to validate certain findings); short and long-term simulations (to establish CO_2 fate and behaviour over decades and millennia, including the rate of dissolution of CO_2 in water).

The dynamic modelling shall provide insight into: pressure and temperature of the storage formation as a function of injection rate and accumulative injection amount over time; areal and vertical extent of CO_2 vs time; the nature of CO_2 flow in the reservoir, including phase behaviour; CO_2 trapping mechanisms and rates (including spill points and lateral and vertical seals); secondary containment systems in the overall storage complex; storage capacity and pressure gradients in the storage site; the risk of fracturing the storage formation(s) and caprock; the risk of CO_2 entry into the caprock; the risk of leakage from the storage site (for example, through abandoned or inadequately sealed wells); the rate of migration (in open-ended reservoirs); fracture sealing rates; changes in formation(s) fluid chemistry and subsequent reactions (for example, pH change, mineral formation) and inclusion of reactive modelling to assess affects; displacement of formation fluids; increased seismicity and elevation at surface level.

Step 3.2 Sensitivity characterisation: Multiple simulations shall be undertaken to identify the sensitivity of the assessment to assumptions made about particular parameters. The simulations shall be based on altering parameters in the static geological earth model(s), and changing rate functions and assumptions in the dynamic modelling exercise. Any significant sensitivity shall be taken into account in the risk assessment.

Step 3.3 Risk assessment shall comprise, inter alia, the following:

3.3.1 Hazard characterisation shall be undertaken by characterising the potential for leakage from the storage complex, as established through dynamic modelling and security characterisation described above. This shall include consideration of *inter alia* potential leakage pathways; potential magnitude of leakage events for identified leakage pathways (flux rates); critical parameters affecting potential leakage (for

example maximum reservoir pressure, maximum injection rate, temperature, sensitivity to various assumptions in the static geological Earth model(s)); secondary effects of storage of CO_2 including displaced formation fluids and new substances created by the storing of CO_2; any other factors which could pose a hazard to human health or the environment (for example physical structures associated with the project).

The hazard characterisation shall cover the full range of potential operating conditions to test the security of the storage complex.

3.3.2 Exposure assessment – based on the characteristics of the environment and the distribution and activities of the human population above the storage complex, and the potential behaviour and fate of leaking CO_2 from potential pathways identified under Step 3.3.1. 3.3.3.

3.3.3 Effects assessment – based on the sensitivity of particular species, communities or habitats linked to potential leakage events identified under Step 3.3.1. Where relevant it shall include effects of exposure to elevated CO_2 concentrations in the biosphere (including soils, marine sediments and benthic waters (asphyxiation; hypercapnia) and reduced pH in those environments as a consequence of leaking CO_2). It shall also include an assessment of the effects of other substances that may be present in leaking CO_2 streams (either impurities present in the injection stream or new substances formed through storage of CO_2). These effects shall be considered at a range of temporal and spatial scales, and linked to a range of different magnitudes of leakage events.

3.3.4 Risk characterisation – this shall comprise an assessment of the safety and integrity of the site in the short and long term, including an assessment of the risk of leakage under the proposed conditions of use, and of the worst-case environment and health impacts. The risk characterisation shall be conducted based on the hazard, exposure and effects assessment. It shall include an assessment of the sources of uncertainty identified during the steps of characterisation and assessment of storage site and when feasible, a description of the possibilities to reduce uncertainty.

4.2.2 *Criteria for establishing and updating the monitoring plan and for post-closure monitoring*

1. Establishing and updating the monitoring plan

The monitoring plan referred to in Article 13(2) shall be established according to the risk assessment analysis carried out in Step 3 of Annex I, and updated with the purpose of meeting the monitoring requirements laid out in Article 13(1) according to the following criteria:

1.1 Establishing the plan - The monitoring plan shall provide details of the monitoring to be deployed at the main stages of the project, including baseline, operational and post-closure monitoring. The following shall be specified for each phase: parameters monitored; monitoring technology employed and justification for technology choice; monitoring locations and spatial sampling rationale; frequency of application and temporal sampling rationale.

The parameters to be monitored are identified so as to fulfil the purposes of monitoring. However, the plan shall in any case include continuous or intermittent monitoring of the following items: fugitive emissions of CO_2 at the injection facility; CO_2 volumetric flow at injection wellheads; CO_2 pressure and temperature at injection wellheads (to determine mass flow); chemical analysis of the injected material; reservoir temperature and pressure (to determine CO_2 phase behaviour and state).

The choice of monitoring technology shall be based on best practice available at the time of design. The following options shall be considered and used as appropriate: technologies that can detect the presence, location and migration paths of CO_2 in the subsurface and at surface; technologies that provide information about pressure-volume behaviour and areal/vertical distribution of CO_2-plume to refine numerical 3-D simulation to the 3-D-geological models of the storage formation established pursuant to Article 4 and

Annex I; technologies that can provide a wide areal spread in order to capture information on any previously undetected potential leakage pathways across the areal dimensions of the complete storage complex and beyond, in the event of significant irregularities or migration of CO_2 out of the storage complex.

1.2 Updating the plan - The data collected from the monitoring shall be collated and interpreted. The observed results shall be compared with the behaviour predicted in dynamic simulation of the 3-D-pressure-volume and saturation behaviour undertaken in the context of the security characterisation pursuant to Article 4 and Annex I Step 3.

Where there is a significant deviation between the observed and the predicted behaviour, the 3-D model shall be recalibrated to reflect the observed behaviour. The recalibration shall be based on the data observations from the monitoring plan, and where necessary to provide confidence in the recalibration assumptions, additional data shall be obtained.

Steps 2 and 3 of Annex I shall be repeated using the recalibrated 3-D model(s) so as to generate new hazard scenarios and flux rates and to revise and update the risk assessment.

Where new CO_2 sources, pathways and flux rates or observed significant deviations from previous assessments are identified as a result of history matching and model recalibration, the monitoring plan shall be updated accordingly.

2. Post-closure monitoring

Post-closure monitoring shall be based on the information collected and modelled during the implementation of the monitoring plan referred to in Article 13(2) and above in point 1.2 of this Annex. It shall serve in particular to provide information required for the determination of Article 18(1).

4.3 Description of tools and models used in risk assessment of CO_2 geological storage

4.3.1 *FEP and Scenario Analysis Tools*

Approaches for analysing Features, Events and Processes (FEPs) and scenarios relevant to understanding the evolution of the geosphere have been developed internationally for nearly thirty years. Since the early work that aimed at evaluating the safety of undersground repositories (e.g. d'Alessandro and Bonne 1981; IAEA, 1981; Cranwell et al. 1982; Nagra 1985 a,b; Andersson et al. 1989; NEA/OECD, 2000), methodologies for analysing FEPs and developing scenarios have continued to be developed. While the methodological details have differed in different programmes, FEP analysis has become a standard activity during safety assessments and performance assessments. In recent years there has been a move to develop standard lists of FEPs as a basis for these assessments. Several different institutes have developed generic FEPs databases for the geological storage of CO_2 among which are the ones developed by TNO (Wildenborg et al., 2005) and Quintessa (Savage et al. 2004). These inventories are necessarily dynamic and will eventually be augmented or better defined as the knowledge of the CO_2 geological storage technology expands.

The FEP process chart essentially comprises FEP analysis, qualitative scenario definition, and conceptual modelling. For some of the approaches there is one final step that involves process level modelling based on the FEPs and scenario analysis.

Approaches to FEP analysis

The initial development of a comprehensive project-specific FEP list is invariably based upon expert judgement about a particular site, initially undertaken independently of any generic FEP database and followed by an audit using a generic database.

This is followed by ranking including the semi-quantitative probability and potential impact of individual events and processes to occur and their relevance for assessment. EPs are then divided between reference and variant scenarios or regarded irrelevant for the safety assessment and Features are then correlated with EPs.

The next stage is to classify the retained FEPs in both spatial and contextual terms (Savage et al., 2004). The relationships between them can be represented using different approaches: the Master Directed Diagram (MDD) approach (Nirex, 1998); the construction of a Process Influence Diagram (PID); or a FEP interaction matrix. Among these approaches, the PID has been used for the risk assessment the Weyburn CO_2 storage project (Stenhouse et al., 2005) and matrix representations of FEP interactions applied to a hypothetical CO_2 storage project can be found in Savage et al. (2004).

Approaches to scenario development

The future evolution of a geological system can never be known precisely. Therefore, the approach is typically to develop scenarios for possible evolutions of the system and situations of particular interest, including high consequence, low probability. In conjunction with FEPs analysis, scenarios are invariably developed by using expert judgement, though the precise ways in which different expert opinions are captured varies between programmes.

The most commonly adopted approach is to define one scenario for initial consideration and then a series of alternative scenarios to represent alternative possible future system states and/or evolutions. The characteristics and details of different scenario construction methodologies and their application can be found in the following literature references: the TNO Methodology (TNO, 2003a); NIREX methodology (Bailey et al., 1998); the PROSA methodology (NRG, 2002); and the Sandia Laboratories Methodology (Sandia, 2005; Ho et al., 2002; Cochran et al, 2001; Stein, 2004); Quintessa's QPAC system level modelling methodology (Metcalfe et al., 2009).

Conceptual Modelling

Once scenarios have been created and agreement has been reached about their capacity to comprehensively describe all possible future evolutions of the system, conceptual models are developed to depict discrete aspects of the storage system under the conditions of each scenario. Conceptual models aim to provide information concerning the scope of the assessment and its interactions with other parts of the system in sufficient detail to form the basis for mathematical model and software development (Bailey et al., 1998). Rigorous computational models are then used to simulate the processes contained within the conceptual models; they must meet the expectations of the technical community and hence should be verified and validated preferably against existing data. The construction and analysis of each of these models will allow for the identification of the key processes to be simulated by engineering codes of possibly different levels of complexity. Information about the different approaches to conceptual model development can be found in the following literature references: the NIREX conceptual model development methodology (Bailey et al., 1998); the Sandia Laboratories conceptual model development methodology (Cochran et al., 2001).

Process level modelling

The next major step towards the development of a system level performance assessment model involves the use of advanced numerical modelling techniques to simulate the behaviour of the major compartments of the system. These tools should be verified and validated, preferably against field data from natural or industrial analogues (Wildenborg et al., 2004). The term validation has been largely applied in the context of performance assessment of projects of this nature, but it is important to remark that formal validation is seldom possible when large spatial and temporal scales are modelled (Wilmot, 2002). One way of achieving a certain level of verification consists in the prediction of site characteristics. The idea is to forecast conditions before they are actually measured (Wilmot, 2002).

For applications targeted at CO_2 storage, Quintessa has developed a collection of modules for its QPAC general purpose modelling code, collectively termed QPAC-CO2. These modules are tailored to simulating

specific fundamental processes and new processes can be added. Individual modules can be combined to represent coupled phenomena (Maul et al., 2007).

4.3.2 *Quantitative Performance Assessment Tools*

Computational models used to predict, assess and optimise the geological storage of CO_2 are valuable tools that will enable this technology to gain public confidence and wide scale industrial application worldwide. Modelling is intrinsic to the design of any storage system as it allows for capacity estimation and, within the context of performance assessment, provides for the quantitative analysis of the selected scenarios.

For nearly three decades, many models have been developed across different disciplines to predict the migration of fluids in the subsurface environment. Some of the fields in which these tools have been routinely used include: oil and gas production, natural gas storage, environmental assessment and site remediation, disposal of toxic industrial wastes and groundwater flow simulation for various purposes. However, the timeframe of the projects modelled so far within these disciplines is much shorter that that considered for CO_2 storage projects. In addition, the success of modelling codes for the purposes referred to is based on extensive calibration, history matching and relevant experience from related field applications, similar experience is required for the development of reliable CO_2 storage models.

There is a range of tools that can contribute to PA, in the broadest sense, and each one produces one output or several outputs that may indicate how well all or part of a system performs relative to some criterion or criteria. The relative value of these different tools during any particular PA will depend to a large extent on the purpose of the PA, the data available and the indicators of performance that are considered.

A geological system, such as that envisaged for CO_2 storage will be extremely complex and its temporal evolution will involve many different chemical and physical processes. Given the limitations of present computing technology, it is not feasible to calculate the effects of all these processes on all system components explicitly using a single software tool. Instead, it will be necessary to employ a range of software tools, each focusing on different aspects of the problem. There is also considerable merit in employing more than one software tool to address each aspect (e.g. more than one fluid flow simulator, more than one geochemical modelling tool, or a coupled process simulator etc). This approach can be used to build confidence in the overall results, and leads to a demonstration that different tools produce similar results.

Generally, the following types of tools are typically used:

- several kinds of detailed “process simulation tools/system understanding tools”, each of which is targeted at a particular aspect of the system, for example:
    - reservoir simulators, simulating multi-phase fluid flow through the geosphere;
    - geochemical simulation codes, simulating fluid/rock reactions, aqueous chemical speciation etc;
    - geomechanical simulation codes, modelling the changes in reservoir stresses in response to the changes in pore pressure, temperature and mechanical properties of rocks due to the storage process;
    - coupled chemistry-transport codes, simulating the coupling between mass transport (by advection and/or diffusion) and geochemical reactions;
    - specialist gas-migration codes.
- system-level modelling tools, which represent all safety-relevant components of the system under consideration (these representations are simplifications of the real system).
- decision support tools, which are aimed at documenting and supporting decisions concerning:
    - choice of conceptual models underlying simulations by other codes;
    - parameterisation of simulations by other codes;
    - integration of results from a range of other codes.

4.4 Conclusions from the review of international literature and proposed guidelines for CO_2 storage projects

As part of the CO_2ReMoVe project, Imperial College developed the framework presented in Figure 7. Special attention was devoted to maintaining the use of terms that are familiar to regulatory authorities and maintaining consistency between different disciplines (human health risk assessment, engineering, ecologic, or behavioural risk assessment). The OSPAR FRAM was also considered in this context, ensuring that the proposed framework is in agreement with the proposed structure and, most importantly, preserves the clear conventional distinctions between risk assessment and risk management.

The terminology used in the proposed framework has attracted considerable support during discussions and presentations to the industry and research community, including the presentation of this framework at the IEA GHG 3rd Risk Assessment Network meeting held in London (15-16th August 2007). However, there also has been an important criticism in that the hierarchy of steps and terms used was not apparent due to the cyclic presentation of the framework components.

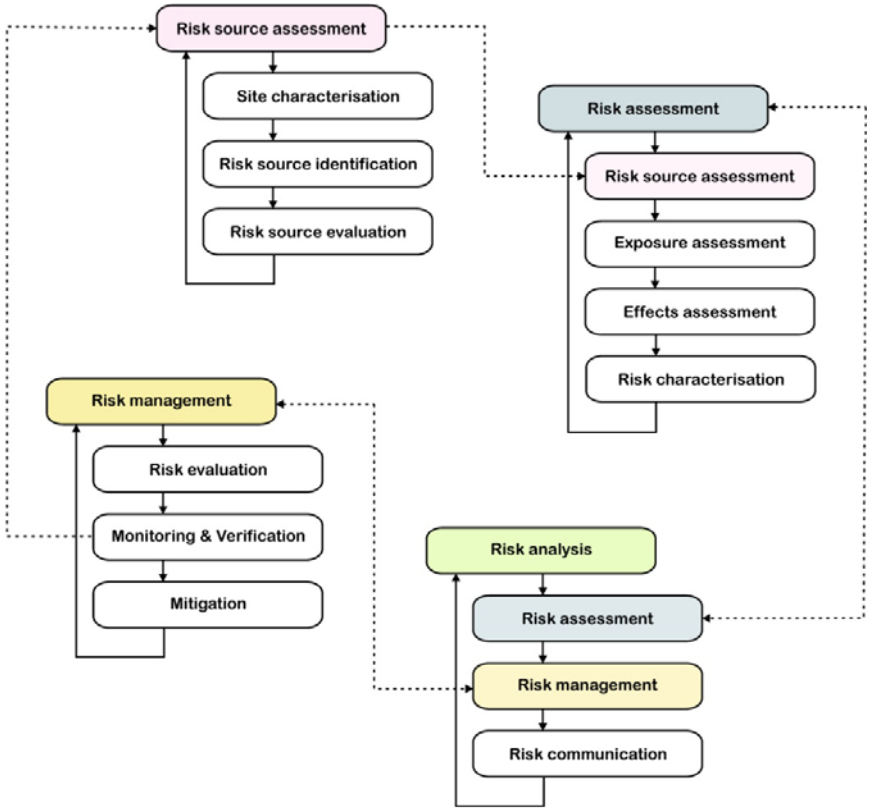

Figure 7. Risk assessment, management and communication framework for CO_2 storage projects.

While reviewing the literature for the purposes of this project, it became apparent that despite the differences observed in the graphical representations utilised by different frameworks, the core structure and the workflows used were similar (FRAM and the EU CCS directive fashion linear workflows, while the WHO/ IPCS human health and ecological risk assessment workflows highlight the interaction and cyclic nature of the workflows). Subtle differences in the definition of terms and the detailed work that is expected under each heading were also found.

However, one particularly helpful feature of the human health risk assessment framework and the engineered systems focused safety assessment was that they are complimentary, providing more detail at

different stages of their respective workflows. For example, in human health risk assessment and ecological risk assessment workflows, the focus is on the hazard assessment (evaluation of the risk that is related to the source or stressor), the effects assessment and the consequences. On the other hand, for engineered systems, the focus is on establishing the context and vulnerability of potential receptors and the risk management steps, particularly the treatment of risk, monitoring and review.

Figure 8 presents an updated version of the framework that incorporates the FRAM and the EU CCS directive steps, which is also consistent with the human health and ecological risk assessment workflows, as well as the AS/NZS for environmental risk management and security risk management.

The definitions of the terms used are included as options in the following CCS risk assessment terminology compilation for consideration by the IEA GHG Risk Assessment Network community.

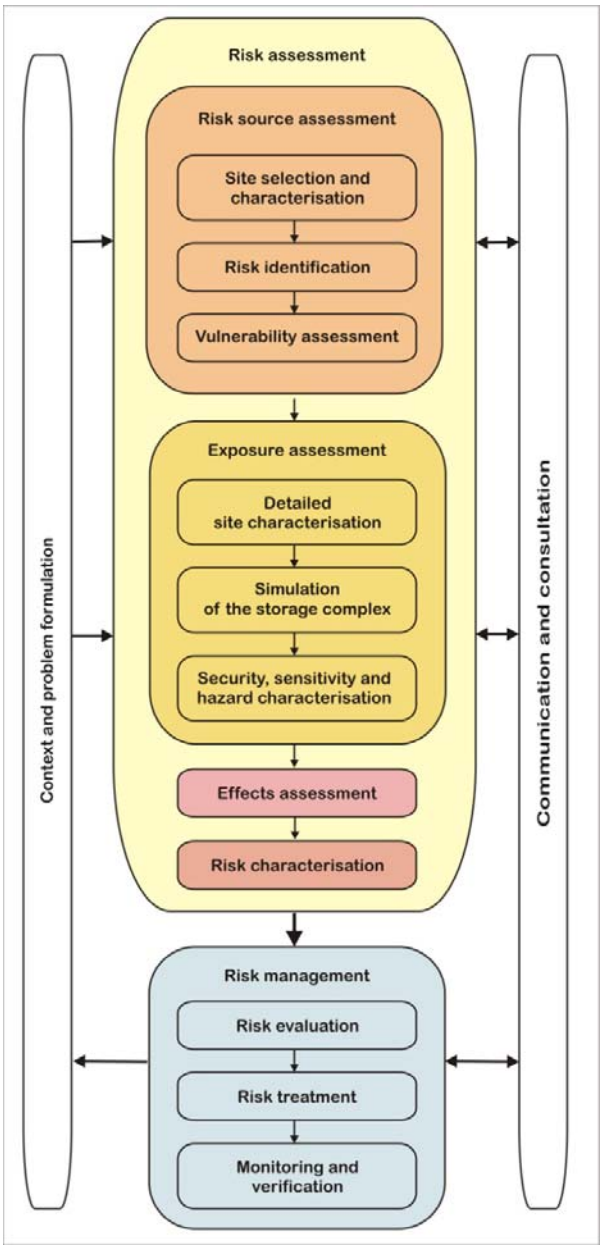

Figure 8. Updated risk assessment, management and communication framework for CO_2 storage projects

5 The criteria used in defining generic and specific terms for CO_2 storage risk assessment

Generic terms are defined as the general terms used in the process of determining risks from CO_2 leakage and exposure to CO_2, regardless of the subject-specific fields. Examples of such terms include hazard identification, risk characterization, and risk assessment.

Technical terms are defined as those used in describing the reservoir performance, human health, environmental hazard and risk assessment, including the scientific and technical terms used in effects assessment (e.g., nomenclature for storage site features and technical terms used in (risk source) hazard characterisation, such as cap rock failure and effects on the biosphere). It is considered unnecessary to provide a comprehensive and long list of terms used in reservoir performance assessment as these are well known and agreed upon amongst the IEA GHG Risk Assessment Network practitioners. A comprehensive list of technical terms used in human health and environmental effects assessment has been compiled and is provided in Annex I.

Existing definitions for generic terms have been extracted from the “key documents and sources” and are presented in this report for review and comments. Respondents are asked to:

– identify or provide their preferred definition for each term
– identify terms considered as synonyms
– indicate whether any important key documents or sources have been omitted.

In agreement with the IPCS glossary of exposure assessment related terms, the terms identified and listed in this project fall in to two categories: the base terms or "data-oriented terms" and their combinations with action concepts defined as "action-oriented terms".

Examples of data-oriented terms include "risk" and "hazard", which are the key data-oriented terms used together with clusters of related terms around them. Action-oriented terms are used in conjunction with single-word terms like analysis and characterisation; risk analysis and risk characterisation for example. Here the term "assessment" is an exception which is also defined in isolation.

The following sections present the key data oriented terms first, followed by key action oriented terms in alphabetical order. Finally, an additional list of terms that are considered relevant but judged to be of secondary importance is also provided.

5.1 Key data oriented terms

Agent Any physical, chemical, or biological entity that can induce an adverse response (synonymous with stressor).(USEPA, 2007c)

Benefit The gain to a human population. Expected benefit incorporates an estimate of the probability of achieving the gain (Royal Society, 1992) (Standards Australia/Standards New Zealand, 2008).
Benefit The degree to which effects are judged desirable. (SRA, 2007)

Consequence outcome or impact of an event (Standards Australia/Standards New Zealand, 2008)
NOTES: There can be more than one consequence from one event. Consequences can range from positive to negative; can be expressed qualitatively or quantitatively, are considered in relation to the achievement of objectives.

Cost of activities, both direct and indirect, involving any negative impact, including money, time, labour, disruption, goodwill, politicaland intangible losses. (Standards Australia/Standards New Zealand, 2008)

Damage Damage is the severity of injury or the physical, functional, or monetary loss that could result if control of a hazard is lost. (SRA, 2007)

Danger Expresses a relative exposure to a hazard. A hazard may be present, but there may be little danger because of the precautions taken. (SRA, 2007)

Ecosystem The biotic and abiotic environment within a specified location in space and time. (Guidelines for Ecological Risk Assessment, United States Environmental Protection Agency, 1998).(Standards Australia/Standards New Zealand, 2006)

Effect A biological change caused by an exposure. (SRA, 2007)
Effect Change in the state or dynamics of an organism, system, or (sub)population caused by the exposure to an agent. (WHO, 2004)

Adverse effect Change in the morphology, physiology, growth, development, reproduction, or life span of an organism, system, or (sub)population that results in an impairment of functional capacity, an impairment of the capacity to compensate for additional stress, or an increase in susceptibility to other influences. (WHO, 2004)
Adverse Effect A biochemical change, functional impairment, or pathologic lesion that affects the performance of the whole organism, or reduces an organism's ability to respond to an additional environmental challenge. (USEPA, 2007b)

Indirect effect An effect where the stressor acts on supporting components of the ecosystem, which in turn have an effect on the ecological component of interest. (USEPA, 2007c)

Measure of effect Describes change assessment endpoint (or surrogate) attributes in response to a stressor to which it is exposed. Dose-response data are an example. (USEPA, 2007a)
Measure of effect A change in an attribute of an assessment endpoint or its surrogate in response to a stressor to which it is exposed. (USEPA, 2007c)

Adverse ecological effects Changes that are considered undesirable because they alter valued structural or functional characteristics of ecosystems or their components. An evaluation of adversity may consider the type, intensity, and scale of the effect as well as the potential for recovery. (USEPA, 2007a)(USEPA, 2007c)

Environmental target A detailed performance requirement, quantified where practicable, applicable to the organization or parts of the organization, that arises from the environmental objectives and that needs to be set and met in order to achieve those objectives.(Standards Australia/Standards New Zealand, 2006)

Environmental performance The measurable results of the environmental management system, related to an organization's control of its environmental aspects, based on its environmental policy, objectives and targets.(Standards Australia/Standards New Zealand, 2006)
NOTE: Performance requirements must encompass requirements for regulatory compliance, and objectives should include improving overall environmental performance.

Environment: surroundings in which an organization operates, including air, water, land, natural resources, flora, fauna, humans and their interrelations.(Standards Australia/Standards New Zealand, 2006)
NOTE: Surroundings in this context extend from within an organization to the global system.

Event: occurrence of a particular set of circumstances (Standards Australia/Standards New Zealand, 2006)
NOTES: The event can be certain or uncertain; can be a single occurrence or a series of occurrences. (ISO/IEC Guide 73, in part)

Endpoint: A biological effect used as an index of the effect of a substance on an organism. (NATIONAL RESEARCH COUNCIL, 1994)
Endpoint: An observable or measurable biological event or chemical concentration (e.g., metabolite concentration in a target tissue) used as an index of an effect of a chemical exposure. (USEPA, 2007b)

Exposure Concentration or amount of a particular agent that reaches a target organism, system, or (sub)population in a specific frequency for a defined duration. (WHO, 2004)
Exposure Qualitatively, contact between a potentially harmful agent and a receptor (e.g., a human or other organism) that could be affected. [S. L. Brown] (SRA, 2007)
Exposure: the contact or co-occurrence of a stressor with a receptor (Guidelines for Ecological Risk Assessment, United States Environmental Protection Agency, 1998).(Standards Australia/Standards New Zealand, 2006) (USEPA, 2007a) (USEPA, 2007c)
Exposure – Contact between an agent and a target. Contact takes place at an exposure surface over an exposure period, which is the time of continuous contact between an agent and a target (Committee on Models in the Regulatory Decision Process, 2007)
Exposure The time integral of the concentration of a toxicant which is in the immediate vicinity of various ports of entry (such as lung, GI tract and skin). (SRA, 2007)
Exposure: Contact made between a chemical, physical, or biological agent and the outer boundary of an organism. Exposure is quantified as the amount of an agent available at the exchange boundaries of the organism (e.g., skin, lungs, gut). (USEPA, 2007b)

Frequency: a measure of the number of occurrences per unit of time. (Standards Australia/Standards New Zealand, 2006)
NOTE: Frequency may also be expressed in other suitable measures, such as per million units, per head of population, per thousand births. Guidelines (human health risk assessment): Official, peer-reviewed documentation stating current U.S. EPA methodology in assessing risk of harm from environmental pollutants to populations. (USEPA, 2007b)

Harm Physical injury or damage to the health of people, or damage to property or the environment(Standards Australia/Standards New Zealand, 2006)

Hazard: a source of potential harm, or a situation with a potential to cause loss or adverse effect (adapted from ISO/IEC Guide 51:1999).(Standards Australia/Standards New Zealand, 2006)
Hazard A condition or physical situation with a potential for an undesirable consequence, such as harm to life or limb. (SRA, 2007)
Hazard Inherent property of an agent or situation having the potential to cause adverse effects when an organism, system, or (sub)population is exposed to that agent. (WHO, 2004)
Hazard The likelihood that a substance will cause an injury or adverse effect under specified conditions. (USEPA, 2007c)
Hazard: A potential source of harm. (USEPA, 2007b)

Likelihood used as a general description of probability or frequency. (Standards Australia/Standards New Zealand, 2006)

Loss any negative consequence or adverse effect, financial or otherwise.(Standards Australia/Standards New Zealand, 2006)

Probability: a measure of the chance of occurrence expressed as a number between 0 and 1.(Standards Australia/Standards New Zealand, 2006)
NOTE 1: ISO/IEC Guide 73 defines probability as the ‘extent to which an event is likely to occur’; ISO 3534-1:1993, definition 1.1, gives the mathematical definition of probability as ‘a real number in the scale 0 to 1 attached to a random event’. It goes on to note that probability ‘can be related to a long-run relative

frequency of occurrence or to a degree of belief that an event will occur. For a high degree of belief, the probability is near 1.'; 'Frequency' or 'likelihood' rather than 'probability' may be used in describing risk.

Release A "release" is defined by CERCLA as "any spilling, leaking, pumping, pouring, emitting, emptying, discharging, injecting, escaping, leaching, dumping, or disposing into the environment (including the abandonment or discarding of barrels, containers and other closed receptacles containing any hazardous substance or pollutant or contaminant". *See also Resource Conservation and Recovery Act.* (USEPA, 2007)

Receptor The ecological entity exposed to the stressor. (USEPA, 2007a) (USEPA, 2007c) Standards Australia/Standards New Zealand, 2006)

Source An entity or action that releases to the environment or imposes on the environment a chemical, physical, or biological stressor or stressors. (USEPA, 2007a) (USEPA, 2007c)
Source Term As applied to chemical stressors, the type, magnitude, and patterns of chemical(s) released. (USEPA, 2007c)
Source A place where pollutants are emitted, for example a chimney stack. (SRA, 2007)

Source term The release rate of hazardous agent from a facility or activity. (SRA, 2007)

Stressor Any physical, chemical, or biological entity that can induce an adverse response. (USEPA, 2007a) (USEPA, 2007c)

Risk The potential for realization of unwanted, adverse consequences to human life, health, property, or the environment; estimation of risk is usually based on the expected value of the conditional probability of the event occurring times the consequence of the event given that it has occurred.
(SRA, 2007)
Risk (in the context of human health): The probability of adverse effects resulting from exposure to an environmental agent or mixture of agents. (USEPA, 2007b)
Risk The expected frequency or probability of undesirable effects resulting from exposure to known or expected stressors. (USEPA, 2007c)
Risk The probability of an adverse effect in an organism, system, or (sub)population caused under specified circumstances by exposure to an agent. (WHO, 2004)
Risk The chance of something happening that will have an impact on objectives(Standards Australia/Standards New Zealand, 2006)
NOTES: A risk is often specified in terms of an event or circumstance and the consequences that may flow from it. Risk is measured in terms of a combination of the consequences of an event and their likelihoods. Risk may have a positive or negative impact. See ISO/IEC Guide 51, for issues related to safety. In the context of this guide, risk is the chance of something happening that will have an impact on the environment.

Acceptable risk This is a risk management term. The acceptability of the risk depends on scientific data, social, economic, and political factors, and the perceived benefits arising from exposure to an agent. (WHO, 2004)
Acceptable risk the outcome of a decision process of determining an acceptable option. The choice of an option (and its associated risks, costs, and benefits) depends on the set of options, impacts, values, and facts examined in the decision-making process.(Fischhoff, 1983)(Standards Australia/Standards New Zealand, 2008)
NOTE: The expression 'acceptable level of risk' refers to the level at which it is decided that further restricting or otherwise altering the activity is not worthwhile; e.g. will not result in significant reduction in risk; or the additional expenditure will not result in significant advantages of increased safety.
Acceptable risk level Level of risk judged to be outweighed by corresponding benefits or one that is of such a degree that it is considered to pose minimal potential for adverse effects.(Source: EPAGLOa)

European Environment Agency (EEA), European Topic Centre on Catalogue of Data Sources (ETC/CDS) : General Multilingual Environmental Thesaurus Term Detail

Additional risk (Added, Attributable Risk or Risk Difference) (AR): The calculated difference in risk of a particular condition between those who are exposed and those who are not. This measure is derived by subtracting the rate (usually incidence or mortality) of the disease among the unexposed persons from the corresponding rate among the exposed (Pe), i.e., AR= Pe-Pu. The AR is an absolute measure of the excess risk attributed to exposure. (USEPA, 2007b)
Attributable risk The rate of a disease in exposed individuals that can be attributed to the exposure. This measure is derived by subtracting the rate (usually incidence or mortality) of the disease among nonexposed persons from the corresponding rate among exposed individuals. (SRA, 2007)
Comparative risk An expression of the risks associated with two (or more) actions leading to the same goal; may be expressed quantitatively (a ratio of 1.5) or qualitatively (one risk greater than another risk). Any comparison among the risks of two or more hazards with respect to a common scale. [S. L. Brown] (SRA, 2007)
Cumulative risk The combined risks from aggregate exposures to multiple agents or stressors.
De minimis risk From the legal maxim "de minimis non curat lex" or "the law is not concerned with trifles." (SRA, 2007)
Environmental risk Environmental risk is the chance that human health or the environment will suffer harm as the result of the presence of environmental hazards. (USEPA, 2007c)
Extra Risk (ER): A calculation of risk of adverse effects which adjusts for background incidence rates of the same effects, by estimating risk at dose d only among the fraction of the population not expected to respond to the secondary (background) causes: ER = [P(d)-P(0)/1-P(0)]. For example, if the background rate (P(0)) = 0.8 and the response rate at dose d, P(d) = .9, then ER = (0.9 - 0.8)/(1-0.8) = 0.1/0.2 = 0.5. That is, at dose d, an additional 10% of the population is expected to respond adversely. But since only 20% of the population was expected to be free of adverse effects without the exposure of interest, this 10% represents 50% of the population that would otherwise have been unharmed by this exposure. (USEPA, 2007b)
Health risk Risk in which an adverse event affects human health. (SRA, 2007)
Individual risk The risk to an individual rather than to a population. (SRA, 2007)
Individual Risk: The probability that an individual will experience an adverse effect. (USEPA, 2007b)
Relative risk (or Risk Ratio (RR)): The relative measure of the difference in risk between the exposed and unexposed populations in a cohort study. The relative risk is defined as the rate of disease among the exposed divided by the rate of the disease among the unexposed. A relative risk of 2 means that the exposed group has twice the disease risk as the unexposed group. (USEPA, 2007b)
Relative risk The ratio of the rate of the disease (usually incidence or mortality) among those exposed to the rate among those not exposed. (SRA, 2007)
residual risk Remaining potential for harm to persons, property or the environment following all possible efforts to reduce predictable hazards.(Source: TOE) European Environment Agency (EEA), European Topic Centre on Catalogue of Data Sources (ETC/CDS) : General Multilingual Environmental Thesaurus Term Detail).(Standards Australia/Standards New Zealand, 2006)
Perceived risk: see risk perception.
Risk perception: the way in which individuals estimate risk. Risk perception cannot be reduced to a single parameter of a particular aspect of risk, such as the product of the probabilities and consequences of any event. Risk perception is inherently multidimensional and personal, with a particular risk or hazard meaning different things to different people and different things in different contexts. (Adapted from Royal Society, 1992).(Standards Australia/Standards New Zealand, 2006)
Residual risk: risk remaining after implementation of risk treatment (Standards Australia/Standards New Zealand, 2006)
Tolerable risk: risk which is accepted in a given context based on the current values of society (ISO/IEC Guide 51:1999). (Standards Australia/Standards New Zealand, 2006)

Safety Relative protection from adverse consequences. (SRA, 2007)

Safety Practical certainty that adverse effects will not result from exposure to an agent under defined circumstances. It is the reciprocal of risk. (WHO, 2004)
Safety: freedom from unacceptable risk (ISO/IEC Guide 51:1999) (Standards Australia/Standards New Zealand, 2006)
NOTE: The use of the words 'safety' and 'safe' as descriptive adjectives should be avoided because they convey no useful extra information. In addition they are likely to be interpreted as an assurance of guaranteed freedom from risk. Safety is achieved by reducing risk to a tolerable level.

Stressor: a physical, chemical or biological entity that induces an adverse response (Guidelines for Ecological Risk Assessment, United States Environmental Protection Agency, 1998).(Standards Australia/Standards New Zealand, 2006)

Uncertainty: a lack of knowledge arising from changes that are difficult to predict or events whose likelihood and consequences cannot be accurately predicted. (Standards Australia/Standards New Zealand, 2006)
Uncertainty Imperfect knowledge concerning the present or future state of the system under consideration; a component of risk resulting from imperfect knowledge of the degree of hazard or of its spatial and temporal distribution. (USEPA, 2007c)
Uncertainty Imperfect knowledge concerning the present or future state of an organism, system, or (sub)population under consideration. (WHO, 2004)
Uncertainty: Uncertainty occurs because of a lack of knowledge. It is not the same as variability. For example, a risk assessor may be very certain that different people drink different amounts of water but may be uncertain about how much variability there is in water intakes within the population. Uncertainty can often be reduced by collecting more and better data, whereas variability is an inherent property of the population being evaluated. Variability can be better characterized with more data but it cannot be reduced or eliminated. Efforts to clearly distinguish between variability and uncertainty are important for both risk assessment and risk characterization. (USEPA, 2007b)

Variability Observed differences attributable to true heterogeneity or diversity and the result of natural random processes—usually not reducible by further measurement or study (although it can be better characterized). (Committee on Models in the Regulatory Decision Process, 2007)
Variability: Variability refers to true heterogeneity or diversity. For example, among a population that drinks water from the same source and with the same contaminant concentration, the risks from consuming the water may vary. This may be due to differences in exposure (i.e., different people drinking different amounts of water and having different body weights, different exposure frequencies, and different exposure durations) as well as differences in response (e.g., genetic differences in resistance to a chemical dose). Those inherent differences are referred to as variability. Differences among individuals in a population are referred to as inter-individual variability, differences for one individual over time is referred to as intra-individual variability. (USEPA, 2007b)

5.2 Key action oriented terms

Assessment Evaluation or appraisal of an analysis of facts and the inference of possible consequences concerning a particular object or process. (WHO, 2004)

Analysis Detailed examination of anything complex, made in order to understand its nature or to determine its essential features. (WHO, 2004)

Characterization: Site sampling, monitoring, and analysis to determine the extent and nature of releases.

Effect assessment Combination of analysis and inference of possible consequences of the exposure to a particular agent based on knowledge of the dose–effect relationship associated with that agent in a specific target organism, system, or (sub)population. (WHO, 2004)

Risk acceptance: an informed decision to accept the consequences and the likelihood of a particular risk.(Standards Australia/Standards New Zealand, 2006)

Risk analysis: systematic process to understand the nature of and to deduce the level of risk.(Standards Australia/Standards New Zealand, 2006)
NOTES: Provides the basis for risk evaluation and decisions about risk treatment. See ISO/IEC Guide 51 for risk analysis in the context of safety.
Risk analysis A detailed examination including risk assessment, risk evaluation, and risk management alternatives, performed to understand the nature of unwanted, negative consequences to human life, health, property, or the environment; an analytical process to provide information regarding undesirable events; the process of quantification of the probabilities and expected consequences for identified risks. (SRA, 2007)
Risk analysis A process for controlling situations where an organism, system, or (sub)population could be exposed to a hazard. The risk analysis process consists of three components: risk assessment, risk management, and risk communication. (WHO, 2004)

Risk assessment: the overall process of risk identification, risk analysis and risk evaluation.(Standards Australia/Standards New Zealand, 2006)
Risk assessment A process intended to calculate or estimate the risk to a given target organism, system, or (sub)population, including the identification of attendant uncertainties, following exposure to a particular agent, taking into account the inherent characteristics of the agent of concern as well as the characteristics of the specific target system. The risk assessment process includes four steps: hazard identification, hazard characterization (related term: Dose–response assessment), exposure assessment, and risk characterization. It is the first component in a risk analysis process. (WHO, 2004)
Risk assessment (in the context of human health) – The evaluation of scientific information on the hazardous properties of environmental agents (hazard identification), the dose-response relationship (dose-response assessment), and the extent of human exposure to those agents (exposure assessment). The product of the risk assessment is a statement describing the populations or individuals that are likely to be harmed and to what degree (risk characterization). (Committee on Models in the Regulatory Decision Process, 2007)
Risk assessment (in the context of human health): The evaluation of scientific information on the hazardous properties of environmental agents (hazard characterization), the dose-response relationship (dose-response assessment), and the extent of human exposure to those agents (exposure assessment). The product of the risk assessment is a statement regarding the probability that populations or individuals so exposed will be harmed and to what degree (risk characterization). (USEPA, 2007b)
Risk assessment The process of establishing information regarding acceptable levels of a risk and/or levels of risk for an individual, group, society, or the environment. (SRA, 2007)
Risk assessment Qualitative or quantitative evaluation of the risk posed to human health and/or the environment by the actual or potential presence or release of hazardous substances, pollutants or contaminants. (USEPA, 2007c)
Qualitative risk assessment: As explained in the text, where the likelihood or the magnitude of the consequences are not quantified, the risk assessment is referred to as qualitative.(Standards Australia/Standards New Zealand, 2006)
Quantitative risk assessment: risk assessment where the probability or frequency of the outcomes can be estimated numerically and the magnitude of consequences quantified so that risk is calculated in terms of probable extent of harm or damage over a given period.(Standards Australia/Standards New Zealand, 2006)
Comparative risk assessment A process that generally uses a professional judgment approach to evaluate the relative magnitude of effects and set priorities among a wide range of environmental problems (e.g.,

U.S. EPA, 1993d). Some applications of this process are similar to the problem formulation portion of an ecological risk assessment in that the outcome may help select topics for further evaluation and help focus limited resources on areas having the greatest risk reduction potential. In other situations, a comparative risk assessment is conducted more like a preliminary risk assessment. For example, EPA's Science Advisory Board used professional judgment and an ecological risk assessment approach to analyze future ecological risk scenarios and risk management alternatives (U.S. EPA, 1995e). (USEPA, 2007c)

Relative risk rssessment A process similar to comparative risk assessment. It involves estimating the risks associated with different stressors or management actions. To some, relative risk connotes the use of quantitative risk techniques, while comparative risk approaches more often rely on professional judgment. Others do not make this distinction. (USEPA, 2007c)

Risk avoidance: a decision not to become involved in, or to withdraw from, a risk situation.(Standards Australia/Standards New Zealand, 2006)

Risk control: that part of risk management which involves the implementation of policies, standards, procedures and physical changes to eliminate or minimize adverse risks.(Standards Australia/Standards New Zealand, 2006)
NOTE: Some literature uses the term 'risk management' to describe a range of activities similar to what AS/NZS 4360:2004 defines as risk control, i.e. a limited range of activities that omits parts of the overall process of risk management.

Risk characterization Integrates exposure and stressor-response to evaluate the likelihood of adverse ecological effects associated with exposure to a stressor. (USEPA, 2007a)
Risk characterization (in the context of human health) – The integration of information on hazard, dose-response, and exposure to provide an estimate of the likelihood that any of the identified adverse effects will occur in exposed people. (Committee on Models in the Regulatory Decision Process, 2007)
Risk characterization A phase of risk assessment that integrates the results of the exposure and effects analyses to evaluate the likelihood of adverse effects associated with exposure to the stressor. The ecological significance of the adverse effects is discussed, including consideration of the types and magnitudes of the effects, their spatial and temporal patterns, and the likelihood of recovery. (USEPA, 2007c)
Risk characterization The qualitative and, wherever possible, quantitative determination, including attendant uncertainties, of the probability of occurrence of known and potential adverse effects of an agent in a given organism, system, or (sub)population, under defined exposure conditions. Risk characterization is the fourth step in the risk assessment process. (WHO, 2004)
Risk characterization: The integration of information on hazard, exposure, and dose-response to provide an estimate of the likelihood that any of the identified adverse effects will occur in exposed people. (USEPA, 2007b)

Risk communication Interactive exchange of information about (health or environmental) risks among risk assessors, managers, news media, interested groups, and the general public. (WHO, 2004)
Risk communication Risk communication, the exchange of information about health or environmental risks among risk assessors, risk managers, the local community, news media and interest groups, is the process of informing members of the local community about environmental risks associated with a site and the steps that are being taken to manage those risks. (USEPA, 2007c)

Risk estimation Quantification of the probability, including attendant uncertainties, that specific adverse effects will occur in an organism, system, or (sub)population due to actual or predicted exposure. (WHO, 2004)
Risk estimation The scientific determination of the characteristics of risks, usually in as quantitative a way as possible. These include the magnitude, spatial scale, duration and intensity of adverse

consequences and their associated probabilities as well as a description of the cause and effect links. (SRA, 2007)
Risk estimation: a systematic use of available information to determine how often specified events may occur and the magnitude of their likely consequences.(Standards Australia/Standards New Zealand, 2006)
NOTE: AS/NZS 3931 defines risk estimation as 'Process used to produce a measure of the level of risks being analysed. Risk estimation consists of the following steps: frequency analysis, consequence analysis and their integration.'

Risk evaluation A component of risk assessment in which judgments are made about the significance and acceptability of risk. (SRA, 2007)
Risk evaluation Establishment of a qualitative or quantitative relationship between risks and benefits of exposure to an agent, involving the complex process of determining the significance of the identified hazards and estimated risks to the system concerned or affected by the exposure, as well as the significance of the benefits brought about by the agent. Risk evaluation is an element of risk management. Risk evaluation is synonymous with risk–benefit evaluation. (WHO, 2004)
Risk evaluation: the process in which judgements are made on the tolerability of the risk on the basis of risk analysis and taking into account factors such as socio-economic and environmental aspects (AS/NZS 3931).(Standards Australia/Standards New Zealand, 2006)
NOTE: Risk evaluation is also defined as the process of comparing the level of risk against risk criteria. It assists in decisions about risk treatment. (AS/NZS 4360:2004).

Risk identification: the process of determining what, where, when, why and how something could happen.(Standards Australia/Standards New Zealand, 2006)
Risk identification Recognizing that a hazard exists and trying to define its characteristics. Often risks exist and are even measured for some time before their adverse consequences are recognized. In other cases, risk identification is a deliberate procedure to review, and it is hoped, anticipate possible hazards. (SRA, 2007)

Risk management: the culture, processes and structures that are directed towards realizing potential opportunities whilst managing adverse effects.(Standards Australia/Standards New Zealand, 2006)
Risk management Decision-making process involving considerations of political, social, economic, and technical factors with relevant risk assessment information relating to a hazard so as to develop, analyse, and compare regulatory and non-regulatory options and to select and implement appropriate regulatory response to that hazard. Risk management comprises three elements: risk evaluation; emission and exposure control; and risk monitoring. (WHO, 2004)
Risk management (in the context of human health) – A decision-making process that accounts for political, social, economic, and engineering implications together with risk-related information to develop, analyze, and compare management options and select the appropriate managerial response to a potential adverse health risk. (Committee on Models in the Regulatory Decision Process, 2007)
Risk Management (in the context of human health): A decision making process that accounts for political, social, economic and engineering implications together with risk-related information in order to develop, analyze and compare management options and select the appropriate managerial response to a potential chronic health hazard. (USEPA, 2007b)
Risk management process: the systematic application of management policies, procedures and practices to the tasks of communicating, establishing the context, identifying, analysing, evaluating, treating, monitoring and reviewing risk.(Standards Australia/Standards New Zealand, 2006)
NOTE: Environmental risk management deals with the risks associated with past, present, and future activities on humans, flora and fauna.

Risk monitoring Process of following up the decisions and actions within risk management in order to ascertain that risk containment or reduction with respect to a particular hazard is assured. Risk monitoring is an element of risk management. (WHO, 2004)

Risk mitigation: steps taken to reduce the probability of occurrence or the magnitude of the consequences(Standards Australia/Standards New Zealand, 2006)

Risk reduction: a selective application of appropriate techniques and management principles to lessen either the likelihood of an occurrence or the negative consequences associated with a risk, or both.(Standards Australia/Standards New Zealand, 2006)

Risk treatment: process of selection and implementation of measures to modify risk.(Standards Australia/Standards New Zealand, 2006)
NOTES: The term 'risk treatment' is sometimes used for the measures themselves. Risk treatment measures can include avoiding, modifying, sharing or retaining risk. (ISO/IEC Guide 73, in part)
Additional note: Some literature refers to risk treatment as risk control.
Comparative risk assessment: can be used as a means of setting environmental priorities. Comparative risk assessment uses the methods of risk analysis, but applies them to problems in which the actual probabilities and impacts cannot be determined from actual historic data. Instead, the probabilities and impacts need to be determined on the basis of community polling or other subjective elicitation techniques in which the various risks are compared.(Standards Australia/Standards New Zealand, 2006)

Ecological risk assessment: a set of formal scientific methods for estimating the likelihoods and magnitudes of effects on plants, animals and ecosystems of ecological value resulting from the release of chemicals, other human actions or natural incidents (modified from EC, 1994).(Standards Australia/Standards New Zealand, 2006)

Exposure assessment The process of characterizing the magnitude, frequency, and duration of exposure to an agent, along with the number and characteristics of the population exposed. Ideally, it describes the sources, pathways, routes, and uncertainties in the assessment. (Committee on Models in the Regulatory Decision Process, 2007)
Exposure assessment The process of measuring or estimating the intensity, frequency, and duration of human exposures to an agent currently present in the environment or of estimating hypothetical exposures that might arise from the release of new chemicals into the environment. (SRA, 2007)
Exposure assessment: An identification and evaluation of the human population exposed to a toxic agent, describing its composition and size, as well as the type, magnitude, frequency, route and duration of exposure. (USEPA, 2007b)
Exposure assessment Evaluation of the exposure of an organism, system, or (sub)population to an agent (and its derivatives). Exposure assessment is the third step in the process of risk assessment. (WHO, 2004)

Hazard assessment The process of determining whether exposure to an agent can cause an increase in the incidence or severity of a particular health effect (e.g., cancer, birth defect).(Committee on Models in the Regulatory Decision Process, 2007)
Hazard assessment A process designed to determine the possible adverse effects of an agent or situation to which an organism, system, or (sub)population could be exposed. The process includes hazard identification and hazard characterization. The rocess focuses on the hazard, in contrast to risk assessment, where exposure assessment is a distinct additional step. (WHO, 2004)
Hazard assessment An analysis and evaluation of the physical, chemical and biological properties of the hazard. (SRA, 2007)
Hazard assessment This term has been used to mean either (SRA, 2007) evaluating the intrinsic effects of a stressor (U.S. EPA, 1979) or (Committee on Models in the Regulatory Decision Process, 2007) defining a margin of safety or quotient by comparing a toxicologic effects concentration with an exposure estimate (SETAC, 1987). (USEPA, 2007c)
Hazard assessment: The process of determining whether exposure to an agent can cause an increase in the incidence of a particular adverse health effect (e.g., cancer, birth defect) and whether the adverse health effect is likely to occur in humans. (USEPA, 2007b)

Hazard characterization The qualitative and, wherever possible, quantitative description of the inherent property of an agent or situation having the potential to cause adverse effects. This should, where possible, include a dose–response assessment and its attendant uncertainties. Hazard characterization is the second stage in the process of hazard assessment and the second of four steps in risk assessment. Related terms: Dose–effect relationship, Effect assessment, Dose–response relationship, Concentration–effect relationship (WHO, 2004)
Hazard characterization: A description of the potential adverse health effects attributable to a specific environmental agent, the mechanisms by which agents exert their toxic effects, and the associated dose, route, duration, and timing of exposure. (USEPA, 2007b)

Hazard identification The identification of the type and nature of adverse effects that an agent has an inherent capacity to cause in an organism, system, or (sub)population. Hazard identification is the first stage in hazard assessment and the first of four steps in risk assessment. (WHO, 2004)
Hazard identification The process of determining whether exposure to an agent can cause an increase in the incidence of a health condition. (SRA, 2007)
Hazard identification The process of determining whether exposure to a stressor can cause an increase in the incidence or severity of a particular adverse effect, and whether an adverse effect is likely to occur. (USEPA, 2007c)

Performance assessment Simulation of an environmental system that includes some man-made components (e.g., a waste disposal facility) in which one is attempting to predict the performance or the degree of safety or reliability of the system. http://www.goldsim.com/Solutions/probPA.htm

5.3 Additional terms

Accuracy – Closeness of a measured or computed value to its "true" value, where the true value is obtained with perfect information. Due to the natural heterogeneity and stochasticity of many environmental systems, this true value exists as a distribution rather than a discrete value. In these cases, the true value will be a function of spatial and temporal aggregation. (Committee on Models in the Regulatory Decision Process, 2007)
Accuracy The degree of agreement between a measured value and the true value; usually expressed as +/- percent of full scale. (SRA, 2007)
Accuracy The degree to which a measurement reflects the true quantitative value of a variable. (USEPA, 2007c)

Assessment endpoint — An explicit expression of the environmental value that is to be protected, operationally defined by an ecological entity and its attributes. For example, salmon are valued ecological entities; reproduction and age class structure are some of their important attributes. Together "salmon reproduction and age class structure" form an assessment endpoint. (USEPA, 2007a) (USEPA, 2007c)
Assessment end-point Quantitative/qualitative expression of a specific factor with which a risk may be associated as determined through an appropriate risk assessment. (WHO, 2004)

Assessment factor Numerical adjustment used to extrapolate from experimentally determined (dose–response) relationships to estimate the agent exposure below which an adverse effect is not likely to occur. Related terms: Safety factor, Uncertainty factor (WHO, 2004)

Attributable risk The rate of a disease in exposed individuals that can be attributed to the exposure. This measure is derived by subtracting the rate (usually incidence or mortality) of the disease among nonexposed persons from the corresponding rate among exposed individuals. (SRA, 2007)

Baseline risk assessment A baseline risk assessment is an assessment conducted before cleanup activities begin at a site to identify and evaluate the threat to human health and the environment. After remediation

has been completed, the information obtained during a baseline risk assessment can be used to determine whether the cleanup levels were reached. (USEPA, 2007c)

Bias Systematic deviation between a measured (observed) or computed value and its "true" value. Bias is affected by faulty instrument calibration and other measurement errors, systematic errors during data collection, and sampling errors, such as incomplete spatial randomization during the design of sampling programs. (Committee on Models in the Regulatory Decision Process, 2007)
Bias Any difference between the true value and that actually obtained due to all causes other than sampling variability. (SRA, 2007)

Characterization of ecological effects A portion of the analysis phase of ecological risk assessment that evaluates the ability of a stressor(s) to cause adverse effects under a particular set of circumstances. (USEPA, 2007a) (USEPA, 2007c)
Characterization of ecological Effects A portion of the analysis phase of ecological risk assessment that evaluates the ability of a stressor to cause adverse effects under a particular set of circumstances.

Characterization of exposure A portion of the analysis phase of ecological risk assessment that evaluates the interaction of the stressor with one or more ecological components. Exposure can be expressed as co-occurrence, or contact depending on the stressor and ecological component involved. (USEPA, 2007a)(USEPA, 2007c)

Chronic effect An effect that occurs as a result of repeated or long term (chronic) exposures. (USEPA, 2007b)

Chronic exposure Long-term exposure usually lasting 1 year to a lifetime. (Committee on Models in the Regulatory Decision Process, 2007)
Chronic exposure Repeated exposure by the oral, dermal, or inhalation route for more than approximately 10% of the life span in humans (more than approximately 90 days to 2 years in typically used laboratory animal species). (USEPA, 2007b)

Cumulative ecological risk assessment A process that involves consideration of the aggregate ecological risk to the target entity caused by the accumulation of risk from multiple stressors. (USEPA, 2007a) (USEPA, 2007c)

de minimis contamination limit A level of contamination below which the effects are not considered by regulators to warrant regulatory control. (NATIONAL RESEARCH COUNCIL, 1994)

decision analysis Any of the several techniques that attempt to provide decision-makers with information about the implications of alternative possible decisions. Benefit-cost analysis is probably the most familiar form of decision analysis. (NATIONAL RESEARCH COUNCIL, 1994)

Ecological impact The total effect of an environmental change, natural or man-made, on the community of living things. (SRA, 2007)

Ecological relevance One of the three criteria for assessment endpoint selection. Ecologically relevant endpoints reflect important characteristics of the system and are functionally related to other endpoints. (USEPA, 2007a) (USEPA, 2007c)

Ecological risk assessment The process that evaluates the likelihood that adverse ecological effects may occur as a result of exposure to a stressor. (USEPA, 2007a)
Ecological risk assessment The application of a formal framework, analytical process, or model to estimate the effects of human actions(s) on a natural resource and to interpret the significance of those effects in light of the uncertainties identified in each component of the assessment process. Such analysis

includes initial hazard identification, exposure and dose-response assessments, and risk characterization. (USEPA, 2007c)

Environmental aspect: element of an organization's activities, products or services that can interact with the environment.(Standards Australia/Standards New Zealand, 2006)
NOTE: A significant environmental aspect is an environmental aspect that has or can have a significant environmental impact.

Environmental audit: systematic, documented verification process of objectively obtaining and evaluating audit evidence to determine whether specified environmental activities, events, conditions, management systems, or information about these matters conform with audit criteria, and communicating the results of this process to the client (Standards Australia/Standards New Zealand, 2006)

Environmental effect: see environmental impact. (Standards Australia/Standards New Zealand, 2006)

Environmental impact: any change to the environment, whether adverse or beneficial, wholly or partially resulting from an organization's activities, products or services. (Standards Australia/Standards New Zealand, 2006)

Environmental management system: part of the overall management system that includes organizational structure, planning activities, responsibilities, practices, procedures, processes and resources for developing, implementing, achieving, reviewing and maintaining the environmental policy. (Standards Australia/Standards New Zealand, 2006)

Environmental policy: a statement by the organization of its intentions and principles in relation to its overall environmental performance which provides a framework for action and for the setting of its environmental objectives and targets. (Standards Australia/Standards New Zealand, 2006)

Environmental objective: the overall environmental goal, arising from the environmental policy, that an organization sets itself to achieve, and which is quantified where possible. (Standards Australia/Standards New Zealand, 2006)

Event tree analysis: a technique that describes the possible range and sequence of the outcomes which may arise from an initiating event. (Standards Australia/Standards New Zealand, 2006)

Expected loss The quantity obtained by multiplying the magnitude of health or environmental effect loss by the probability (or risk) of that loss and adding the products. The expected loss is the average loss over a large number of trials; one must reflect on the appropriateness of its use in cases for which there will be only one, or a few, trials. (SRA, 2007)

Expert elicitation A process for obtaining expert beliefs about subjective quantities and probabilities. Typically, structured interviews and questionnaires are used to elicit the necessary knowledge. Expert elicitations may also include "coaching" techniques to help the expert conceptualize, visualize, and quantify the knowledge being sought. (Committee on Models in the Regulatory Decision Process, 2007)

Expert judgement Opinion of an authoritative person on a particular subject. (WHO, 2004)

Exposure medium The contaminated environmental medium to which an individual is exposed, such as soil, water, sediment and air. (USEPA, 2007c)

Exposure pathway The course a substance takes from its source (where it began) to its end point (where it ends), and how people can come into contact with (or get exposed to) it. An exposure pathway has five parts: a source of contamination (such as an abandoned business); an environmental media and transport

mechanism (such as movement through groundwater); a point of exposure (such as a private well); a route of exposure (eating, drinking, breathing, or touching), and a receptor population (people potentially or actually exposed). When all five parts are present, the exposure pathway is termed a completed exposure pathway. (Committee on Models in the Regulatory Decision Process, 2007)
Exposure pathway RAGS Volume I, Part A, Chapter 6 defines exposure pathway as "the course a chemical or physical agent takes from a source to an exposed organism. An exposure pathway describes a unique mechanism by which an individual or population is exposed to chemicals or physical agents at or originating from a site. Each exposure pathway includes a source or release from a source, an exposure point, and an exposure route. If the exposure point differs from the source, a transport/exposure medium (e.g. air) or media (in cases of intermedia transfer) also is included. (USEPA, 2007c)

Exposure pathway model A model in which potential pathways of exposure are identified for the selected receptor species. (USEPA, 2007c)

Exposure point The potential contact between a person and a contaminant within an exposure medium. (USEPA, 2007c)
Exposure point concentration The value that represents a conservative estimate of the chemical concentration available from a particular medium or route of exposure. See definitions for Medium EPC and Route EPC, which follow. (USEPA, 2007c)

Exposure profile A summary of the magnitude and spatial and temporal patterns of exposure for the scenarios described in the conceptual model. (USEPA, 2007a)
Exposure profile The product of characterizing exposure in the analysis phase of ecological risk assessment. The exposure profile summarizes the magnitude and spatial and temporal patterns of exposure for the scenarios described in the conceptual model. (USEPA, 2007c)

Exposure route The mechanism for which a contaminant comes in contact with a person (e.g., by ingestion, inhalation, dermal contact). (USEPA, 2007c)

Exposure scenario A set of assumptions concerning how an exposure may take place, including exposure setting, stressor characteristics, and activities that may lead to exposure. (USEPA, 2007a) (USEPA, 2007c)
Exposure scenario A set of conditions or assumptions about sources, exposure pathways, amounts or concentrations of agent(s)involved, and exposed organism, system, or (sub)population (i.e., numbers, characteristics, habits) used to aid in the evaluation and quantification of exposure(s) in a given situation. (WHO, 2004)

Failure mode and effects analysis (FMEA): a procedure by which potential failure modes in a system are analysed. An FMEA can be extended to perform what is called failure modes, effects and criticality analysis (FMECA). In a FMECA, each failure mode identified is ranked according to the combined influence of its likelihood of occurrence and the severity of its consequences. (Standards Australia/Standards New Zealand, 2006)

Fate Disposition of a material in various environmental compartments (e.g. soil or sediment, water, air, biota) as a result of transport, transformation, and degradation. (USEPA, 2007c)
Fate Pattern of distribution of an agent, its derivatives, or metabolites in an organism, system, compartment, or (sub)population of concern as a result of transport, partitioning, transformation, or degradation. (WHO, 2004)

Fault tree analysis (FTA): A systems engineering method for representing the logical combinations of various system states and possible causes which can contribute to a specified event, called the top event.(Standards Australia/Standards New Zealand, 2006)

NOTE: FTA is usually represented by a logic diagram beginning with an undesired consequence, and systematically deducing all the different possible root causes of action leading to the outcome or 'top' event.
Fault tree analysis A technique by which many events that interact to produce other events can be related using simple logical relationships permitting a methodical building of a structure that represents the system. (SRA, 2007)

Guidance value Value, such as concentration in air or water, that is derived after allocation of the reference dose among the different possible media (routes) of exposure. The aim of the guidance value is to provide quantitative information from risk assessment to the risk managers to enable them to make decisions. (See also Reference dose) (WHO, 2004)

Health risk analysis: Comprises four steps, i.e. hazard identification, dose-response relationship, exposure assessment and risk characterization. Dose-response functions are established either by laboratory experiments with animals or by epidemiology studies in humans. Exposure assessment is used to estimate the magnitude, duration and frequency of exposure (to pollutants of concern) and to determine pathways of exposure and the number of people likely to be exposed. Risk characterization combines the hazard identification, dose-response and exposure assessment to estimate the risk associated with each exposure scenario.(Standards Australia/Standards New Zealand, 2006)

Interested party: individual or group concerned with or affected by the environmental performance of an organization.(Standards Australia/Standards New Zealand, 2006)
NOTE: To be consistent with AS/NZS 4360, this document uses 'stakeholder' as the preferred term. However, when used in the broad sense, the terms are virtually interchangeable.

Life cycle assessment (LCA): compilation and evaluation of the inputs, outputs and the potential environmental impacts of a product system throughout its life cycle (AS/NZS ISO 14040).(Standards Australia/Standards New Zealand, 2006)
NOTE: The phases of an LCA are definition of goal and scope, inventory analysis, impact assessment and interpretation of results.
Life cycle assessment is an objective process to evaluate the environmental burdens associated with a product, process, or activity by identifying energy and materials used and wastes released to the environment, and to evaluate and implement opportunities to affect environmental improvements. (SETAC, 1990)

Lowest-Observable-Adverse-Effect Level (LOAEL) The lowest level of a stressor evaluated in a toxicity test or biological field survey that has a statistically significant adverse effect on the exposed organisms compared with unexposed organisms in a control or reference site. (USEPA, 2007c)
Lowest-observed-adverse-effect level (LOAEL) — The lowest level of a stressor evaluated in a test that causes statistically significant differences from the controls. (USEPA, 2007a)
Lowest-Observed-Adverse-Effect Level (LOAEL): The lowest exposure level at which there are biologically significant increases in frequency or severity of adverse effects between the exposed population and its appropriate control group. (USEPA, 2007b)

Lowest-Observed-Effect Level (LOEL or LEL): In a study, the lowest dose or exposure level at which a statistically or biologically significant effect is observed in the exposed population compared with an appropriate unexposed control group. (USEPA, 2007b)

Management goal A goal is a general statement of the desired outcome for the overall decision that would solve the problem or take maximum advantage of the opportunity, etc., (USEPA, 2007a)

Management objective An objective is a more specific statement of the desired outcome. It should be specific enough to allow scientists to develop measures from them for a risk assessment. Objectives

include an entity (e.g. organism), some attribute (population), and a desired state or direction of change (e.g self-sustainability). Note that assessments endpoints are similar in that they include an entity and an attribute, but do not include a desired state or direction of change. (USEPA, 2007a)

Margin of exposure (MOE): The LED10 or other point of departure divided by the actual or projected environmental exposure of interest. (USEPA, 2007b)
Margin of exposure Ratio of the no-observed-adverse-effect level (NOAEL) for the critical effect to the theoretical, predicted, or estimated exposure dose or concentration. Related term: Margin of safety (WHO, 2004)

Margin of safety For some experts, margin of safety has the same meaning as margin of exposure, while for others, margin of safety means the margin between the reference dose and the actual exposure. Related term: Margin of exposure (WHO, 2004)

Marginal benefit The additional benefit gained from one more unit of output. In terms of reducing emissions, it represents the benefits from reducing emissions by one more unit.(Committee on Models in the Regulatory Decision Process, 2007)

Marginal cost The additional cost associated with producing one more unit of output. In terms of reducing emissions, it represents the cost of reducing emissions by one more unit.(Committee on Models in the Regulatory Decision Process, 2007)

Measure of exposure Describes stressor existence and behavior in the environment and its contact or co-occurrence with the assessment endpoint. (USEPA, 2007a)
Measure of exposure A measure of stressor existence and movement in the environment and its contact or co-occurrence with the assessment endpoint. (USEPA, 2007c)

Measurement endpoint A measurable ecological characteristic that is related to the valued characteristic chosen as the assessment endpoint. (WHO, 2004) Measurement endpoints often are expressed as the statistical or arithmetic summaries of the observations that make up the measurement. As used in this guidance document, measurement endpoints can include measures of effect and measures of exposure, which is a departure from U.S. EPA's (1992a) definition which includes only measures of effect. (pertains to ecological assessments) (USEPA, 2007c)

Model A simplification of reality that is constructed to gain insights into select attributes of a particular physical, biological, economic, or social system. Models can be of many different forms. They can be computational. Computational models include those that express the relationships among components of a system using mathematical relationships. They can be physical, such as models built to analyze effects of hydrodynamic or aeronautical conditions or to represent landscape topography. They can be empirical, such as statistical models used to relate chemical properties to molecular structures or human dose to health responses. Models also can be analogues, such as when nonhuman species are used to estimate health effects on humans. And they can be conceptual, such as a flow diagram of a natural system showing relationships and flows among individual components in the environment or a business model that broadly shows the operations and organization of a business. The above definitions are not mutually exclusive. For example, a computational model may be developed from conceptual and physical models, and an animal analogue model can be the basis for an empirical model of human health impacts.(Committee on Models in the Regulatory Decision Process, 2007)
Model: A mathematical function with parameters that can be adjusted so the function closely describes a set of empirical data. A mechanistic model usually reflects observed or hypothesized biological or physical mechanisms, and has model parameters with real world interpretation. In contrast, statistical or empirical models selected for particular numerical properties are fitted to data; model parameters may or may not have real world interpretation. When data quality is otherwise equivalent, extrapolation from mechanistic

models (e.g., biologically based dose-response models) often carries higher confidence than extrapolation using empirical models (e.g., logistic model). (USEPA, 2007b)

Phase I environmental assessment A Phase I environmental assessment is an initial environmental investigation that is limited to a historical records search to determine ownership of a site and to identify the kinds of chemical processes that were carried out at the site. A Phase I assessment includes a site visit, but does not include any sampling. If such an assessment identifies no significant concerns, Phase II and III audits are not necessary. Phase I assessments also are commonly referred to as site assessments. (USEPA, 2007c)

Phase II environmental assessment A Phase II environmental assessment is an investigation that includes tests performed at the site to confirm the location and identity of environmental hazards. The assessment includes preparation of a report that includes recommendations for cleanup alternatives. Phase II assessments also are commonly referred to as site investigations. (USEPA, 2007c)

Prospective risk assessment An evaluation of the future risks of a stressor not yet released into the environment or of future conditions resulting from an existing stressor. (USEPA, 2007a) (USEPA, 2007c)

Relative risk (or Risk Ratio (RR)): The relative measure of the difference in risk between the exposed and unexposed populations in a cohort study. The relative risk is defined as the rate of disease among the exposed divided by the rate of the disease among the unexposed. A relative risk of 2 means that the exposed group has twice the disease risk as the unexposed group. (USEPA, 2007b)

Release rate The quantity of a pollutant released from a source over a specified period of time. (SRA, 2007)

Reliability The confidence that (potential) users have in a model and in the information derived from the model such that they are willing to use the model and the derived information. Specifically, reliability is a function of the performance record of a model and its conformance to best available, practicable science. (Committee on Models in the Regulatory Decision Process, 2007)
Reliability The probability a system performs a specified function or mission under given conditions for a prescribed time. (SRA, 2007)

Risk-based corrective action (RBCA) As defined by EPA, RBCA is a streamlined approach through which exposure and risk assessment practices are integrated with traditional components of the corrective action process to ensure that appropriate and cost-effective remedies are selected and that limited resources are allocated properly. RBCA refers specifically to the standard Guide for Risk-Based Corrective Action Applied At Petroleum Release Sites, published by ASTM. The RBCA process can be tailored to applicable state and local laws and regulatory practices. See also American Society for Testing and Materials. (USEPA, 2007c)

Risk-Based Decision-Making (RBDM) The term RBDM refers to a process through which decisions are made about contaminated sites according to the risk each site poses to human health and the environment. RBDM is a mechanism for identifying necessary and appropriate action at any phase of the corrective action process. Depending on known or anticipated risks to human health and the environment, appropriate action can include site closure, monitoring and data collection, active or passive remediation, containment, or imposition of institutional controls. (USEPA, 2007c)

Sensitivity analysis: examines how the results of a calculation or model vary as individual assumptions are changed. (Standards Australia/Standards New Zealand, 2006)

Threshold A pollutant concentration [or dose] below which no deleterious effect occurs. (SRA, 2007)

Threshold Dose or exposure concentration of an agent below which a stated effect is not observed or expected to occur. (WHO, 2004)
Threshold: The dose or exposure below which no deleterious effect is expected to occur. (USEPA, 2007b)

Threshold concentration A concentration above which some effect (or response) will be produced and below which it will not. (USEPA, 2007c)

Threshold dose The minimum application of a given substance required to produce an observable effect. (SRA, 2007)

Uncertainty analysis A detailed examination of the systematic and random errors of a measurement or estimate; an analytical process to provide information regarding the uncertainty. (SRA, 2007)

Validation Process by which the reliability and relevance of a particular approach, method, process, or assessment is established for a defined purpose. Different parties define "Reliability" as establishing the reproducibility of the outcome of the approach, method, process, or assessment over time. "Relevance" is defined as establishing the meaningfulness and usefulness of the approach, method, process, or assessment for the defined purpose. (WHO, 2004)

Zero order analysis The simplest approach to quantification of a risk with a limited treatment of each risk component (e.g. source terms, transport, health effects, etc.). (SRA, 2007)

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7 Annex I

Technical terms used in human health and environmental hazard and risk assessment

Abiotic Characterized by absence of life; abiotic materials include non-living environmental media (e.g., water, soils, sediments); abiotic characteristics include such factors as light, temperature, pH, humidity, and other physical and chemical influences. (USEPA, 2007c)

Absorbed dose The amount of a substance penetrating the exchange boundaries of an organism after contact. Absorbed dose for the inhalation and ingestion routes of exposure is calculated from the intake and the absorption efficiency. Absorbed dose for dermal contact depends on the surface area exposed and absorption efficiency. (USEPA, 2007c)

Absorption Absorption is the passage of one substance into or through another. (USEPA, 2007c)

Absorption efficiency A measure of the proportion of a substance that a living organism absorbs across exchange boundaries (e.g., gastrointestinal tract). (USEPA, 2007c)

Acceptable Daily Intake (ADI): The amount of a chemical a person can be exposed to on a daily basis over an extended period of time (usually a lifetime) without suffering deleterious effects. (USEPA, 2007b)
Acceptable daily intake Estimated maximum amount of an agent, expressed on a body mass basis, to which individuals in a (sub)population may be exposed daily over their lifetimes without appreciable health risk. Related terms: Reference dose, Tolerable daily intake (WHO, 2004)

Acidity The quantitative capacity of aqueous solutions to react with hydroxyl ions. It is measured by titration with a standard solution of a base to a specified end point. Usually expressed as milligrams per liter of calcium carbonate. (SRA, 2007)

Act of God An act occasioned by an unanticipated grave natural disaster. (SRA, 2007)

Acute Acute-diseases or responses with short and generally severe course (often due to high pollutant concentrations). (SRA, 2007)

Acute Having a sudden onset or lasting a short time. An acute stimulus is severe enough to induce a response rapidly. The word acute can be used to define either the exposure or the response to an exposure (effect). The duration of an acute aquatic toxicity test is generally 4 days or less and mortality is the response usually measured.(USEPA, 2007c)

acute effects: Effects that show up soon after exposure. (NATIONAL RESEARCH COUNCIL, 1994)

Acute exposure – One or a series of short-term exposures generally lasting less than 24 hours.(Committee on Models in the Regulatory Decision Process, 2007)
Acute exposure: Exposure over a short period.(NATIONAL RESEARCH COUNCIL, 1994)
Acute exposure: Exposure by the oral, dermal, or inhalation route for 24 hours or less. (USEPA, 2007b)

Acute Health Effect A health effect that occurs over a relatively short period of time (e.g., minutes or hours). The term is used to describe brief exposures and effects that appear promptly after exposure.(Committee on Models in the Regulatory Decision Process, 2007)

Acute Reference Concentration (RfC): An estimate (with uncertainty spanning perhaps an order of magnitude) of a continuous inhalation exposure for an acute duration (24 hours or less) to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime. It can be derived from a NOAEL, LOAEL, or benchmark concentration, with uncertainty factors generally applied to reflect limitations of the data used. Generally used in EPA's noncancer health assessments. (USEPA, 2007b)

Acute Reference Dose (RfD): An estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure for an acute duration (24 hours or less) to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime. It can be derived from a NOAEL, LOAEL, or benchmark dose, with uncertainty factors generally applied to reflect limitations of the data used. Generally used in EPA's noncancer health assessments. (USEPA, 2007b)

Acute Response The response of (effect on) an organisms which has a rapid onset. A commonly measured rapid-onset response in toxicity tests is mortality. (USEPA, 2007c)

Acute Tests A toxicity test of short duration, typically 4 days or less (i.e., of short duration relative to the lifespan of the test organism). (USEPA, 2007c)

Acute toxicity Any poisonous effect produced within a short period of time following exposure, usually up to 24-96 hours, resulting in biological harm and often death. (SRA, 2007)
Acute toxicity: Any poisonous effect produced within a short period of time following an exposure, usually 24 to 96 hours. (USEPA, 2007b)
Acute toxicity (1) A deleterious response (e.g. mortality, disorientation, immobilization) to a stimulus observed in ninety-six (96) hours or less. (2) The discernible adverse effects induced in an organism within a short period of time (days) of exposure to a substance or material. For aquatic animals this usually refers to continuous exposure to the substance or material in water for a period of up to four (4) days. The effects (lethal or sub-lethal) occurring may usually be observed within the period of exposure with aquatic organisms. Office of Research and Development : Glossary: A Listing of Commonly Used Terms with Definitions Used in Wet Weather Flow Term Detail
Acute toxicity Adverse effects that result from a single dose or single exposure of a chemical; any poisonous effect produced within a short period of time, usually less than 96 hours. This term normally is used to describe effects in experimental animals. Office of Enforcement and Compliance Assurance : Guide to Environmental Issues: Glossary of Terms & Acronyms Term Detail

Administered Dose The mass of a substance given to an organism and in contact with an exchange boundary (i.e., gastrointestinal tract) per unit wet body weight (BW) per unit time (e.g., mg/kgBW/day). (USEPA, 2007c)

Ambient level The level (of pollutant) in the general environment as characterized by an average over a suitably long time and large volume. (SRA, 2007)
ambient: Naturally occurring background amounts of a substance in a particular environmental medium; may also refer to existing amounts in a medium regardless of source. (NATIONAL RESEARCH COUNCIL, 1994)

Anecdotal Data: Data based on the description of individual cases rather than controlled studies. (USEPA, 2007b)

Anthropogenic Of human origin. (SRA, 2007)

Applicable or Relevant and Appropriate Requirements (ARARs) "Applicable" requirements are those clean-up standards of control, and other substantive environmental protection requirements, criteria, or limitations promulgated under federal or state law that specifically address a hazardous substance,

pollutant, contaminant, response action, location, or other circumstance at a Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) site. "Relevant and appropriate" requirements are those clean-up standards which, while not "applicable" at a CERCLA site, address problems or situations sufficiently similar to those encountered at the CERCLA site that their use is well-suited to the particular site. ARARs can be action-specific, location-specific, or chemical-specific. (USEPA, 2007c)
Application Niche – The set of conditions under which the use of a model is scientifically defensible. (Committee on Models in the Regulatory Decision Process, 2007)

Area Use Factor The ratio of an organism's home range, breeding range, or feeding/foraging range to the area of contamination of the site under investigation. (Pertains to Ecological Risk Assessments) (USEPA, 2007c)

Average Daily Dose (ADD): Dose rate averaged over a pathway-specific period of exposure expressed as a daily dose on a per-unit-body-weight basis. The ADD is usually expressed in terms of mg/kg-day or other mass-time units. (USEPA, 2007b)

Background level In air pollution, the level of pollutants present in ambient air from natural sources. More generally, the level of pollution present in any environmental medium attributable to natural or ubiquitous sources. [S. L. Brown] (SRA, 2007)
Background Levels: Two types of background levels may exist for chemical substances: (a) Naturally occurring levels: Ambient concentrations of substances present in the environment, without human influence; (NATIONAL RESEARCH COUNCIL, 1994) Anthropogenic levels: Concentrations of substances present in the environment due to human-made, non-site sources (e.g., automobiles, industries). (USEPA, 2007b)

Benchmark Dose (BMD) or **Concentration** (BMC): A dose or concentration that produces a predetermined change in response rate of an adverse effect (called the benchmark response or BMR) compared to background. (USEPA, 2007b)

Benchmark Response (BMR): An adverse effect, used to define a benchmark dose from which an RfD (or RfC) can be developed. The change in response rate over background of the BMR is usually in the range of 5-10%, which is the limit of responses typically observed in well-conducted animal experiments. (USEPA, 2007b)

Benthic Community The community of organisms dwelling at the bottom of a pond, river, lake, or ocean. (pertains to ecological risk assessments) (USEPA, 2007c)

Best available control technology An emission limitation (including a visible emission standard) based on the maximum degree of reduction for each pollutant subject to regulation under the [Clean Air] act which would be emitted from any proposed major stationary source or major modification which the Administrator, on a case-by-case basis, taking into account energy, environmental, and economic impacts and other costs, determines is achievable for such source or modification through application of production processes or available methods, systems, and techniques, including fuel cleaning or treatment or innovative fuel combustion techniques for control of such pollutant. (SRA, 2007)

Best Demonstrated Available Technology (BDAT) A BDAT is a technology that has demonstrated the ability to reduce a particular contaminant to a lower concentration than other currently available technologies. BDATs can change with time as technologies evolve. (USEPA, 2007c)
Bioaccumulation General term describing a process by which chemicals are taken up by an organism either directly from exposure to a contaminated medium or by consumption of food containing the chemical.(USEPA, 2007c)

Bioaccumulation The process whereby certain toxic substances collect in living tissues, thus posing a substantial hazard to human health or the environment. (SRA, 2007)

Bioassay Test used to evaluate the relative potency of a chemical by comparing its effect on living organisms with the effect of a standard preparation on the same type of organism. Bioassay and toxicity tests are not the same-see toxicity test. Bioassays often are run on a series of dilutions of whole effluents. (Pertains to Ecological Risk Assessments) (USEPA, 2007c)

Bioassay Using living organisms to measure the effect of a substance, factor, or condition. (SRA, 2007)
Bioassay: An assay for determining the potency (or concentration) of a substance that causes a biological change in experimental animals. (USEPA, 2007b)

Bioassessment A general term referring to environmental evaluations involving living organisms; can include bioassays, community analyses, etc. (Pertains to Ecological Risk Assessments) (USEPA, 2007c)

Bioavailability The degree to which a material in environmental media can be assimilated by an organism. (USEPA, 2007c)

Bioavailability: The degree to which a substance becomes available to the target tissue after administration or exposure.

Bioccumulation Factor (BAF) The ratio of the concentration of a contaminant in an organism to the concentration in the ambient environment at steady state, where the organism can take in the contaminant through ingestion with its food as well as through direct contact. (USEPA, 2007c)

Bioconcentration A process by which there is a net accumulation of a chemical directly from an exposure medium into an organism. (USEPA, 2007c)

Biodegradability Biodegradability is the capability of a substance to break down into simpler substances, especially into innocuous products, by the actions of living organisms (that is, microorganisms). (USEPA, 2007c)

Biodegrade Decompose into more elementary compounds by the action of living organisms, usually referring to microorganisms such as bacteria. (USEPA, 2007c)

Biologically Based Dose Response (BBDR) model: A predictive model that describes biological processes at the cellular and molecular level linking the target organ dose to the adverse effect. (USEPA, 2007b)
Biologically Based Dose-Response (BBDR) model A predictive model that describes biological processes at the cellular and molecular level linking the target organ dose to the adverse effect. BBDR models predict dose response relationships on the basis of principles of biology, pharmacokinetics.

Biomagnification Result of the process of bioaccumulation and biotransfer by which tissue concentrations of chemicals in organisms at one trophic level exceed tissue concentrations in organisms at the next lower trophic level in a food chain. (USEPA, 2007c)

Biomarker Biochemical, physiological, and histological changes in organisms that can be used to estimate either exposure to chemicals or the effects of exposure to chemicals. (USEPA, 2007c)
Biomarker: Indicators of changes or events in human biological systems. Biological markers of exposure refer to cellular, biochemical, or molecular measures that are obtained from biological media such as human tissues, cells, or fluids and are indicative of exposure to environmental contaminants. (NATIONAL RESEARCH COUNCIL, 1994)

Biomonitoring Use of living organisms as "sensors" in environmental quality surveillance to detect changes in environmental conditions that might threaten living organisms in the environment. (USEPA, 2007c)

Biota The sum total of the living organisms of any designated area. (SRA, 2007)

Body burden The concentration or total amount of a substance in a living organism; implies accumulation of a substance above background levels in exposed organisms. (USEPA, 2007c)
Body burden The total amount of a specific substance (for example, lead) in an organism, including the amount stored, the amount that is mobile, and the amount absorbed. (SRA, 2007)

Boundaries The spatial and temporal conditions and practical constraints under which environmental data are collected. Boundaries specify the area or volume (spatial boundary) and the time period (temporal boundary) to which a decision will apply. (Committee on Models in the Regulatory Decision Process, 2007)

Boundary conditions The physical conditions at the boundaries of a system or at the edges of the region being modeled. (Committee on Models in the Regulatory Decision Process, 2007)

Breeding range The area utilized by an organism during the reproductive phase of its life cycle and during the time that young are reared. (Pertains to Ecological Risk Assessments) (USEPA, 2007c)

Brownfields Brownfields sites are abandoned, idled, or under-used industrial and commercial facilities where expansion or redevelopment is complicated by real or perceived environmental contamination. (USEPA, 2007c)

Calibration The process of adjusting model parameters within physically defensible ranges until the resulting predictions give the best possible fit to the observed data. (Committee on Models in the Regulatory Decision Process, 2007)

Case-control study An inquiry in which groups of individuals are selected in terms of whether they do (the case) or do not (the controls) have the disease of which the etiology is to be studied, and the groups are then compared with respect to existing or past characteristics judged to be of possible relevance to the etiology of the disease. (SRA, 2007)
Case-control study: An epidemiologic study contrasting those with the disease of interest (Beauchamp and Bowie, 1997) to those without the disease (controls). The groups are then compared with respect to exposure history, to ascertain whether they differ in the proportion exposed to the chemical(s) under investigation. (USEPA, 2007b)

Chronic Having a persistent, recurring or long-term nature. As distinguished from acute. (SRA, 2007)
Chronic Involving a stimulus that is lingering or continues for a long time; often signifies periods from several weeks to years, depending on the reproductive life cycle of the species. Can be used to define either the exposure or the response to an exposure (effect). Chronic exposures typically induce a biological response of relatively slow progress and long duration. (USEPA, 2007c)
Chronic: Of long duration. Chronic exposure usually refers to long-term, low-level exposure. Chronic toxicity refers to the effects produced by such exposure. Chronic exposure may cause latent damage that does not appear until later. (NATIONAL RESEARCH COUNCIL, 1994)

Chronic Health Effect A health effect that occurs over a relatively long period of time (e.g., months or years). (Committee on Models in the Regulatory Decision Process, 2007)

Chronic Reference Concentration (RfC): An estimate (with uncertainty spanning perhaps an order of magnitude) of a continuous inhalation exposure for a chronic duration (up to a lifetime) to the human

population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime. It can be derived from a NOAEL, LOAEL, or benchmark concentration, with uncertainty factors generally applied to reflect limitations of the data used. Generally used in EPA's noncancer health assessments. (USEPA, 2007b)

Chronic Reference Dose (RfD): An estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure for a chronic duration (up to a lifetime) to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime. It can be derived from a NOAEL, LOAEL, or benchmark dose, with uncertainty factors generally applied to reflect limitations of the data used. Generally used in EPA's noncancer health assessments. (USEPA, 2007b)

Chronic response The response of (or effect on) an organism to a chemical that is not immediately or directly lethal to the organism. (USEPA, 2007c)

Chronic Study: A toxicity study designed to measure the (toxic) effects of chronic exposure to a chemical. (USEPA, 2007b)

Chronic Tests A toxicity test used to study the effects of continuous, long-term exposure of a chemical or other potentially toxic material on an organism. (USEPA, 2007c)

Chronic Toxicity: The capacity of a substance to cause adverse human health effects as a result of chronic exposure. (USEPA, 2007b)

Cleanup Cleanup is the term used for actions taken to deal with a release or threat of release of a hazardous substance that could affect humans and or the environment. The term sometimes is used interchangeably with the terms remedial action, removal action, response action, or corrective action. (USEPA, 2007c)

Code Instructions, written in the syntax of a computer language, which provide the computer with a logical process. Code may also be referred to as “computer program.” The term “code” describes the fact that computer languages use a different vocabulary and syntax than algorithms that may be written in standard language. (Committee on Models in the Regulatory Decision Process, 2007)

Cohort Study (or Prospective Study): An epidemiologic study comparing those with an exposure of interest to those without the exposure. These two cohorts are then followed over time to determine the differences in the rates of disease between the exposure subjects. (USEPA, 2007b)

Cohort study See prospective study. (SRA, 2007)

Common mode failures Several errors in a technological system occurring simultaneously. (SRA, 2007)

Community An assemblage of populations of different species within a specified location in space and time. (USEPA, 2007a) (USEPA, 2007c)

Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) The NCP defines CERCLIS, in part, as "EPA's comprehensive data base and management system that inventories and tracks released addressed or needing to be addressed by the Superfund program. CERCLIS contains the official inventory of CERCLA sites and supports EPA's planning and tracking functions." *See also Superfund*. (USEPA, 2007c)

Comprehensive Environmental Response, Compensation, and Liability Information System (CERCLIS) The NCP defines CERCLIS, in part, as "EPA's comprehensive data base and management system that inventories and tracks released addressed or needing to be addressed by the Superfund

program. CERCLIS contains the official inventory of of CERCLA sites and supports EPA's planning and tracking functions.". (USEPA, 2007c)

Computational Model A model that is expressed in formal mathematics using equations, statistical relationships, or a combination of the two. Although values, judgment, and tacit knowledge are inevitably embedded in the structure, assumptions, and default parameters, computational models are inherently quantitative, relating phenomena through mathematical relationships and producing numerical results. (Committee on Models in the Regulatory Decision Process, 2007)

Computational Toxicology The application of mathematical and computer models to predict the effect of an environmental agent and elucidate the cascade of events that result in an adverse response. It uses technologies developed in computational chemistry (computer-assisted simulation of molecular systems), molecular biology (characterization of genetics, protein synthesis, and molecular events involved in biological response to an agent), bioinformatics (computer-assisted collection, organization, and analysis of large data sets of biological information), and systems biology (mathematical modeling of biological systems and phenomena). The goals of using computational toxicology are to set priorities among chemicals on the basis of screening and testing data and to develop predictive models for quantitative risk assessment. (Committee on Models in the Regulatory Decision Process, 2007)

Concentration Amount of a material or agent dissolved or contained in unit quantity in a given medium or system. (WHO, 2004)

Concentration– effect relationship Relationship between the exposure, expressed in concentration, of a given organism, system, or (sub)population to an agent in a specific pattern during a given time and the magnitude of a continuously graded effect to that organism, system, or (sub)population. Related terms: Effect assessment, Dose–response relationship (WHO, 2004)

Concentration The relative amount of a substance in an environmental medium, expressed by relative mass (e.g., mg/kg), volume (ml/L), or number of units (e.g., parts per million). (USEPA, 2007c)
Concentration: The quantity of a substance per unit volume or weight. Examples: amount of a chemical in drinking water or air; amount of poison relative to an organism (for example, amount per unit of blood volume). (NATIONAL RESEARCH COUNCIL, 1994)

Concentration ratio The ratio of the concentration of a compound or radionuclide in an organism or its tissues to the concentration in the surrounding under equilibrium, or steady-state conditions. (SRA, 2007)

Concentration-Response Curve A curve describing the relationship between exposure concentration and percent of the test population responding. (USEPA, 2007c)

Conceptual model A conceptual model in problem formulation is a written description and visual representation of predicted relationships between ecological entities and the stressors to which they may be exposed. (USEPA, 2007a)

Conceptual Model An abstract representation that provides the general structure of a system and the relationships within the system that are known or hypothesized to be important. Many conceptual models have as a key component a graphical or pictorial representation of the system. (Committee on Models in the Regulatory Decision Process, 2007)

Conceptual Model Describes a series of working hypotheses of how the stressor might affect ecological components. Describes ecosystem or ecosystem components potentially at risk, and the relationships between measurement and assessment endpoints and exposure scenarios. (USEPA, 2007c)

Conceptual Site Model (CSM) A CSM, a key element used in facilitating cleanup decisions during a site investigation, is a planning tool that organizes information that already is known about a site and identifies the additional information necessary to support decisions that will achieve the goals of the project. The project team then uses the CSM to direct field work that focuses on the information needed to remove significant unknowns from the model. The CSM serves several purposes - as a planning instrument; as a modeling and data interpretation tool; and as a means of communication among members of a project team, decision makers, stakeholders, and field personnel. (USEPA, 2007c)

Confidence interval A range of values ($a1 < a < a2$) determined from a sample of definite rules so chosen that, in repeated random samples from the hypothesized population, an arbitrarily fixed proportion of that range will include the true value, x, of an estimated parameter. The limits, a1 and a2, are called confidence limits; the relative frequency with which these limits include a is called the confidence coefficient; and the complementary probability is called the confidence level. As with significance levels, confidence levels are commonly chosen as 0.05 or 0.01, the corresponding confidence coefficients being 0.95 or 0.99. Confidence intervals should not be interpreted as implying that the parameter itself has a range of values; it has only one value, a. On the other hand, the confidence limits (a1, a2) being derived from a sample, are random variables, the values of which on a particular sample either do or do not include the true value a of the parameter. However, in repeated samples, a certain proportion of these intervals will include a provided that the actual population satisfied the initial hypothesis. (SRA, 2007)

Confounder (or Confounding Factor): A condition or variable that is both a risk factor for disease and associated with an exposure of interest. This association between the exposure of interest and the confounder (a true risk factor for disease) may make it falsely appear that the exposure of interest is associated with disease. (USEPA, 2007b)

Confounding factors Variables that may introduce differences between cases and controls which do not reflect differences in the variables of primary interest. (SRA, 2007)

Contaminant A substance that is either present in an environment where it does not belong or is present at levels that might cause harmful (adverse) health effects. (Committee on Models in the Regulatory Decision Process, 2007)
Contaminant A contaminant is any physical, chemical, biological, or radiological substance or matter present in any media at concentrations that may pose a threat to human health or the environment. (USEPA, 2007c)

Contaminant of Potential Concern A substance detected at a hazardous waste site that has the potential to affect ecological receptors adversely due to its concentration, distribution, and mode of toxicity. (USEPA, 2007c)

Contaminants of Potential Concern Chemicals that are potentially site-related and whose data are of sufficient quality for use in a quantitative risk assessment. (USEPA, 2007c)

Contamination Contact with an admixture of an unnatural agent, with the implication that the amount is measurable. (SRA, 2007)

Control A treatment in a toxicity test that duplicates all the conditions of the exposure treatments but contains no test material. The control is used to determine the response rate expected in the test organisms in the absence of the test material. (USEPA, 2007c)

Control Group (or Reference Group): A group used as the baseline for comparison in epidemiologic studies or laboratory studies. This group is selected because it either lacks the disease of interest (case-control group) or lacks the exposure of concern (cohort study). (USEPA, 2007b)

Corrective Measure Study (CMS) If the potential need for corrective measures is verified during a RCRA Facility Investigation (RFI), the owner or operator of a facility is then responsible for performing a CMS. A CMS is conducted to identify, evaluate, and recommend specific corrective measures based on a detailed engineering evaluation. Using data collected during the RFI, the CMS demonstrates that proposed measures will be effective in controlling the source of contamination, as well as problems posed by the migration of substances from the original source into the environment. The measures also must be assessed in terms of technical feasibility, ability to meet public health protection requirements and protect the environment, possible adverse environmental effects, and institutional constraints. (USEPA, 2007c)

Correlation An estimate of the degree to which two sets of variables vary together, with no distinction between dependent and independent variables. (USEPA, 2007c)

Corroboration Quantitative and qualitative methods for evaluating the degree to which a model corresponds to reality. In some disciplines, this process has been referred to as validation. In general, the term "corroboration" is preferred because it implies a claim of usefulness and not truth. (Committee on Models in the Regulatory Decision Process, 2007)

Corrosivity Corrosive wastes include those that are acidic and capable of corroding metal such as tanks, containers, drums, and barrels. (USEPA, 2007c)

Cost-benefit analysis A formal quantitative procedure comparing costs and benefits of a proposed project or act under a set of preestablished rules. To determine a rank ordering of projects to maximize rate of return when available funds are unlimited, the quotient of benefits divided by costs is the appropriate form; to maximize absolute return given limited resources, benefits-costs is the appropriate form. (SRA, 2007)

Criteria As used in the Clean Air Act, information on adverse effects of air pollutants on human health or the environment at various concentrations. The information is collected pursuant to section 108 of the Clean Air Act and used to set national ambient air quality standards. (SRA, 2007)

Critical Concentration: An ambient chemical concentration expressed in units of µg/m3 and used in the operational derivation of the inhalation RfC. This concentration will be the NOAEL Human Equivalent Concentration (HEC) adjusted from principal study data. (USEPA, 2007b)

Critical Effect: The first adverse effect, or its known precursor, that occurs to the most sensitive species as the dose rate of an agent increases. (USEPA, 2007b)

Critical Exposure Pathway An exposure pathway which either provides the highest exposure levels or is the primary pathway of exposure to an identified receptor of concern. (USEPA, 2007c)

Critical Study: The study that contributes most significantly to the qualitative and quantitative assessment of risk. Also called Principal Study. (USEPA, 2007b)

Critical toxic effect The most sensitive and specific biological change which is outside of acceptable physiological variation. (SRA, 2007)

Cross-sectional study An epidemiological study design in which measurements of cause and effect are made at the same point in time. (SRA, 2007)

Cumulative distribution function (CDF) Cumulative distribution functions are particularly useful for describing the likelihood that a variable will fall within different ranges of x. F(x) (i.e., the value of y at x in a CDF plot) is the probability that a variable will have a value less than or equal to x. (USEPA, 2007a)

Data Quality Objective (DQO) RAGS Volume I, Part A, Chapter 4 defines a DQO as "qualitative and quantitative statements to ensure that data of know and documented quality are obtained during an RI/FS to support an Agency decision." DQOs are qualitative and quantitative statements specified to ensure that data of known and appropriate quality are obtained. The DQO process is a series of planning steps, typically conducted during site assessment and investigation, that is designed to ensure that the type, quantity, and quality of environmental data used in decision making are appropriate. The DQO process involves a logical, step-by-step procedure for determining which of the complex issues affecting a site are the most relevant to planning a site investigation before any data are collected. (USEPA, 2007c)

Data Quality The term data quality refers to all features and characteristics of data that bear on its ability to meet the stated or implied needs and expectations of the user. (USEPA, 2007c)

Death from accident A death which occurs within one year of the accident. (SRA, 2007)

Decommissioning: process of removing a facility from operation. (NATIONAL RESEARCH COUNCIL, 1994)

Degradation Conversion of an organic compound to one containing a smaller number of carbon atoms. (USEPA, 2007c)
Degradation Physical, metabolic, or chemical change to a less complex form. (SRA, 2007)

Dense Nonaqueous Phase Liquid (DNAPL) A DNAPL is one of a group of organic substances that are relatively insoluble in water and more dense than water. DNAPLs tend to sink vertically through sand and gravel aquifers to the underlying layer. (USEPA, 2007c)

Deposition The laying down or precipitation of mineral matter that may eventually form rocks or that creates secondary land forms such as deltas and sand dunes. (SRA, 2007)
Deposition The lying, placing, or throwing down of any material. (USEPA, 2007c)
Deposition The transfer of substances in air to surfaces, including soil, vegetation, surface water, or indoor surfaces, by dry or wet processes. [S. L. Brown] (SRA, 2007)

Depuration A process that results in elimination of toxic substances from an organism. (USEPA, 2007c)
Depuration Rate The rate at which a substance is eliminated from an organism. (USEPA, 2007c)

Design Standard A technology-based standard that requires emitters to use a specific technology to control emissions of a pollutant. These can also be called engineering standards. (Committee on Models in the Regulatory Decision Process, 2007)

Detection Limit The lowest concentration of a chemical that can be distinguished reliably from a zero concentration. (USEPA, 2007c)

Deterministic Analysis (as opposed to probabilistic analysis) Calculation and expression of health risks as single numerical values or "single point" estimates of risk. In risk assessments, the uncertainty and variability are discussed in a qualitative manner. (USEPA, 2007c)

Deterministic Model A mathematical model that contains no random (stochastic) components; consequently, each component and input is determined exactly. Because this type of model does not explicitly simulate the effects of data uncertainty or variability, changes in model outputs are solely due to changes in model components. (Committee on Models in the Regulatory Decision Process, 2007)

Developmental Toxicity: Adverse effects on the developing organism that may result from exposure prior to conception (either parent), during prenatal development, or postnatally until the time of sexual

maturation. The major manifestations of developmental toxicity include death of the developing organism, structural abnormality, altered growth, and functional deficiency. (USEPA, 2007b)

Direct Effect (toxin) An effect where the stressor itself acts directly on the ecological component of interest, not through other components of the ecosystem. (USEPA, 2007c)

Disabling injury An injury causing death, permanent disability, or any degree of temporary total disability beyond the day of the accident. (SRA, 2007)

Disease A general term describing a morbid condition which can be defined by objective, physical signs (e.g. hypertension), subjective symptoms or mental phobias, disorder of function (e.g. biochemical abnormality), or disorders of structure (anatomic or pathological change) . Existence of disease may be questioned in disorder of structure without associated disorder of function. (SRA, 2007)

Dispersion A suspension of particles in a medium; the opposite of flocculation; a scattering process. (SRA, 2007)

Disposal Disposal is the final placement or destruction of toxic, radioactive or other wastes; surplus or banned pesticides or other chemicals; polluted soils; and drums containing hazardous materials from removal actions or accidental release. Disposal may be accomplished through the use of approved secure landfills, surface impoundments, land farming, deep well injection, or ocean dumping. (USEPA, 2007c)

Disturbance Any event or series of events that disrupts ecosystem, community, or population structure and changes resources, substrate availability, or the physical environment (modified from White and Pickett, 1985). (USEPA, 2007c)

Diversity Pertaining to the variety of species within a given association of organisms. Areas with low diversity are characterized by a few species; often relatively large numbers of individuals represent each species. (SRA, 2007)

Domain (Spatial and Temporal) The limits of space and time that are specified within a model's boundary conditions (see Boundary Conditions). (Committee on Models in the Regulatory Decision Process, 2007)
Domain Boundaries (Spatial and Temporal) The spatial and temporal domain of a model are the limits of extent and resolution with respect to time and space for which the model has been developed and over which it should be evaluated. (Committee on Models in the Regulatory Decision Process, 2007)

Dose The amount of a contaminant that is absorbed or deposited in the body of an exposed person for an interval of time—usually from a single medium. Total dose is the sum of doses received by interactions with all environmental media that contain the contaminant. Units (mass) of dose and total dose are often converted to units of mass or contaminant per volume of physiological fluid or mass of tissue. (Committee on Models in the Regulatory Decision Process, 2007)
Dose A measure of exposure. Examples include (SRA, 2007) the amount of a chemical ingested, (Committee on Models in the Regulatory Decision Process, 2007) the amount of a chemical absorbed, and (NATIONAL RESEARCH COUNCIL, 1994) the product of ambient exposure concentration and the duration of exposure. (USEPA, 2007c)
Dose The amount or concentration of undesired matter or energy deposited at the site of effect.
Dose The amount of a contaminant that is absorbed or deposited in the body of an exposed organism for an increment of time--usually from a single medium. Total dose is the sum of doses received by a person from a contaminant in a given interval resulting from interaction with all environmental media that contain the contaminant. Units of dose and total dose (mass) are often converted to units of mass per volume of physiological fluid or mass of tissue. (NATIONAL RESEARCH COUNCIL, 1994)

Dose The amount of a substance available for interactions with metabolic processes or biologically significant receptors after crossing the outer boundary of an organism. The POTENTIAL DOSE is the amount ingested, inhaled, or applied to the skin. The APPLIED DOSE is the amount presented to an absorption barrier and available for absorption (although not necessarily having yet crossed the outer boundary of the organism). The ABSORBED DOSE is the amount crossing a specific absorption barrier (e.g. the exchange boundaries of the skin, lung, and digestive tract) through uptake processes. INTERNAL DOSE is a more general term denoting the amount absorbed without respect to specific absorption barriers or exchange boundaries. The amount of the chemical available for interaction by any particular organ or cell is termed the DELIVERED or BIOLOGICALLY EFFECTIVE DOSE for that organ or cell. (USEPA, 2007b)
Dose Total amount of an agent administered to, taken up by, or absorbed by an organism, system, or (sub)population. (WHO, 2004)

Dose–effect relationship Relationship between the total amount of an agent administered to, taken up by, or absorbed by an organism, system, or (sub)population and the magnitude of a continuously graded effect to that organism, system, or (sub)population. Related terms: Effect assessment, Dose–response relationship, Concentration– effect relationship (WHO, 2004)

Dose-effect The relationship between dose (usually an estimate of dose) and the gradation of the effect in a population, that is a biological change measured on a graded scale of severity, although at other times one may only be able to describe a qualitative effect that occurs within some range of exposure levels. (SRA, 2007)

Dose-related effect Any effect to an organism, system, or (sub)population as a result of the quantity of an agent administered to, taken up by, or absorbed by that organism, system, or (sub)population. (WHO, 2004)

Dose-response A correlation between a quantified exposure (dose) and the proportion of a population that demonstrates a specific effect (response). (SRA, 2007)

Dose–response assessment Analysis of the relationship between the total amount of an agent administered to, taken up by, or absorbed by an organism, system, or (Harrison and Hoberg, 1994)population and the changes developed in that organism, system, or (Harrison and Hoberg, 1994)population in reaction to that agent, and inferences derived from such an analysis with respect to the entire population. Dose–response assessment is the second of four steps in risk assessment. Related terms: Hazard characterization, Dose–effect relationship, Effect assessment, Dose–response relationship, Concentration–effect relationship (WHO, 2004)

Dose-response assessment The process of characterizing the relation between the dose of an agent administered or received and the incidence of an adverse health effect in exposed populations and estimating the incidence of the effect as a function of human exposure to the agent. (SRA, 2007)

Dose-response assessment: A component of risk assessment that describes the quantitative relationship between the amount of exposure to a substance and the extent of injury or disease. (NATIONAL RESEARCH COUNCIL, 1994)
Dose-response Assessment: A determination of the relationship between the magnitude of an administered, applied, or internal dose and a specific biological response. Response can be expressed as measured or observed incidence or change in level of response, percent response in groups of subjects (or populations), or the probability of occurrence or change in level of response within a population. (USEPA, 2007b)

Dose–response curve Graphical presentation of a dose–response relationship. (WHO, 2004)

Dose-Response Curve Similar to concentration-response curve except that the dose (i.e. the quantity) of the chemical administered to the organism is known. The curve is plotted as Dose versus Response. (USEPA, 2007c)
Dose-response curve: A graphical presentation of the relationship between degree of exposure to a substance (dose) and observed biological effect or response. (NATIONAL RESEARCH COUNCIL, 1994)
Dose-Response Relationship – The relationship between a quantified exposure (or dose) and a quantified effect. (Committee on Models in the Regulatory Decision Process, 2007)

Dose–response Relationship between the amount of an agent administered to, taken up by, or absorbed by an organism, system, or (sub)population and the change developed in that organism, system, or (sub)population in reaction to the agent. Synonymous with Dose–response relationship. Related terms: Dose–effect relationship, Effect assessment, Concentration– effect relationship (WHO, 2004)

Dose–response relationship Relationship between the amount of an agent administered to, taken up by, or absorbed by an organism, system, or (syb)population and the change developed in that organism, system, or (sub)population in reaction to the agent. Related terms: Dose–effect relationship, Effect assessment, Concentration– effect relationship (WHO, 2004)

Dose-response relationship: The relationship between a quantified exposure (dose) and the proportion of subjects demonstrating specific biologically significant changes in incidence and/or in degree of change (response). (USEPA, 2007b)

dose-response: A quantitative relationship between the dose of a substance (e.g., a chemical) and an effect caused by the substance. (NATIONAL RESEARCH COUNCIL, 1994)

Duplicate A sample taken from and representative of the same population as another sample. Both samples are carried through the steps of sampling, storage, and analysis in an identical manner. (USEPA, 2007c)

Dynamic Work Plan A dynamic work plan is a work plan that allows project teams to make decisions in the field about how site activities will progress. Dynamic work plans provide the strategy for the way in which dynamic field activities will take place. As such, they document a flexible, adaptive sampling and analytical strategy. Dynamic work plans are supported by the rapid turnaround of data collected, analyzed, and interpreted in the field. (USEPA, 2007c)

Easement An easement is a right to use the land of another for a specific purpose, such as a right-of-way or a utility. (USEPA, 2007c)

EC50 A concentration expected to cause an effect in 50% of a group of test organisms. (USEPA, 2007a)
EC50 A statistically or graphically estimated concentration that is expected to cause one or more specified effects in 50% of a group of organisms under specified conditions. (Pertains to ecological assessments) (USEPA, 2007c)

Ecological Component Any part of an ecosystem, including individuals, populations, communities, and the ecosystem itself. (USEPA, 2007c)

Ecological entity A general term that may refer to a species, a group of species, an ecosystem function or characteristic, or a specific habitat. (USEPA, 2007a)
Ecological entity A general term that may refer to a species, a group of species, an ecosystem function or characteristic, or a specific habitat. An ecological entity is one component of an assessment endpoint. (USEPA, 2007c)

Ecological fallacy The inference that a correlation between variables derived from data grouped in social or other aggregates (ecological units) will hold between persons (individual units). (SRA, 2007)

Ecology The science dealing with the relationship of all living things with each other and with their environment. (SRA, 2007)

Ecosystem The biotic community and abiotic environment within a specified location in space and time. (USEPA, 2007a)

Ecosystem The biotic community and abiotic environment within a specified location and time, including the chemical, physical, and biological relationships among the biotic and abiotic components. (USEPA, 2007c)

Ecosystem The interacting system of a biological community and its nonliving surroundings. (SRA, 2007)

ecosystem: The interacting system of a biological community and its nonliving environment. (NATIONAL RESEARCH COUNCIL, 1994)

Ecotoxicity The study of toxic effects on nonhuman organisms, populations, or communities. (USEPA, 2007c)

Effective Dose (ED10): The dose corresponding to a 10% increase in an adverse effect, relative to the control response. (USEPA, 2007b)

Efficacy A measure of the probability and intensity of beneficial effects. (SRA, 2007)

Emergency removal An emergency removal is an action initiated in response to a release of a hazardous substance that requires on-site activity within hours of a determination that action is appropriate. (USEPA, 2007c)

Emerging Technology An emerging technology is an innovative technology that currently is undergoing bench-scale testing. During bench-scale testing, a small version of the technology is built and tested in a laboratory. If the technology is successful during bench-scale testing, it is demonstrated on a small scale at field sites. If the technology is successful at the field demonstrations, it often will be used full scale at contaminated waste sites. As the technology is used and evaluated at different sites, it is improved continually. (USEPA, 2007c)

Empirical Model An empirical model is one where the structure is determined by the observed relationship among experimental data. These models can be used to develop relationships that are useful for forecasting and describing trends in behavior but may not necessarily be mechanistically relevant.(Committee on Models in the Regulatory Decision Process, 2007)

Enforcement Action An enforcement action is an action undertaken by EPA under authority granted to it under various federal environmental statutes, such as CERCLA, RCRA, CAA, CWA, TSCA, and others. For example, under CERCLA, EPA may obtain voluntary settlement or compel potentially responsible parties (PRP) to implement removal or remedial actions when releases of hazardous substances have occurred. (USEPA, 2007c)

Engineered Control An engineered control, such as barriers placed between a contaminated area and the rest of a site, is a method of managing environmental and health risks. Engineered controls can be used to limit exposure pathways. (USEPA, 2007c)

Environmental Audit An environmental audit usually refers to a review or investigation that determines whether an operating facility is in compliance with relevant environmental regulations. The audit may include checks for possession of required permits, operation within permit limits, proper reporting, and

record keeping. The typical result is a corrective action or compliance plan for the facility. (USEPA, 2007c)

Environmental impact appraisal An environmental review supporting a negative declaration, i.e., the action is not a major Federal action significantly affecting the environment. It describes a proposed EPA action, its expected environmental impact, and the basis for the conclusion that no significant impact is anticipated. (SRA, 2007)

Environmental Impact Statement (EIS) Environmental impact statements are prepared under the National Environmental Policy Act by Federal agencies as they evaluate the environmental consequences of proposed actions. EISs describe baseline environmental conditions; the purpose of, need for, and consequences of a proposed action; the no-action alternative; and the consequences of a reasonable range of alternative actions. A separate risk assessment could be prepared for each alternative, or a comparative risk assessment might be developed. However, risk assessment is not the only approach used in EISs. (USEPA, 2007c)

Environmental impact statement A document required of Federal agencies by the National Environmental Policy Act for major projects or legislative proposals. They provide information for decision makers on the positive and negative effects of the undertaking, and list alternatives to the proposed action, including taking no action. For example, an environmental impact assessment report, prepared by an applicant for an NPDES permit to discharge as a new source, identifies and evaluates the environmental impacts of the applicant's proposed source and feasible alternatives. (SRA, 2007)

Environmental pathway All routes of transport by which a toxicant can travel from its release site to human populations including air, food chain, and water. (SRA, 2007)

Environmental pathway The connected set of environmental media through which a potentially harmful substance travels from source to receptor. [S. L. Brown] (SRA, 2007)

Environmental Regulatory Model A computational model used to inform the environmental regulatory process. Some models are independent of a specific regulation, such as water quality or air quality models that are used in an array of application settings. Other models are created to provide a regulation-specific set of analyses completed during the development and assessment of specific regulatory proposals. The approaches can range from single parameter linear relationship models to models with thousands of separate components and many billions of calculations.(Committee on Models in the Regulatory Decision Process, 2007)

Environmental Site Assessment (ESA) An ESA is the process that determines whether contamination is present at a site. (USEPA, 2007c)

Epidemiology: The study of the distribution and determinants of health-related states or events in specified populations. (USEPA, 2007b)

Established Technology An established technology is a technology for which cost and performance information is readily available. Only after a technology has been used at many different sites and the results fully documented is that technology considered established. The most frequently used established technologies are incineration, solidification and stabilization, and pump-and-treat technologies for ground water. (USEPA, 2007c)

Estimated Exposure Dose (EED): The measured or calculated dose to which humans are likely to be exposed considering all sources and routes of exposure. (USEPA, 2007b)

Evaluation The process used to generate information to determine whether a model and its results are of a quality sufficient to serve as the basis for a regulatory decision.(Committee on Models in the Regulatory Decision Process, 2007)

Ex Ante Analysis of the effects of a policy based only on information available before the policy is undertaken. Also termed prospective analysis. (Committee on Models in the Regulatory Decision Process, 2007)

Ex Post Analysis of the effects of a policy based on information available after the policy has been implemented and its performance observed. Also termed retrospective analysis. (Committee on Models in the Regulatory Decision Process, 2007)

Extrapolation In risk assessment, this process entails postulating a biologic reality based on observable responses and developing a mathematical model to describe this reality. The model may then be used to extrapolate to response levels which cannot be directly observed. (SRA, 2007)
Extrapolation, low dose: An estimate of the response at a point below the range of the experimental data, generally through the use of a mathematical model. (USEPA, 2007b)

Failure modes and effects analysis A tool to systematically analyze all contributing component failure modes and identify the resulting effects on the system. (SRA, 2007)

False negative results Results which show no effect when one is there. (SRA, 2007)
False Negative The conclusion that an event (e.g., response to a chemical) is negative when it is in fact positive. (USEPA, 2007c)

False positive results Results which show an effect when one is not there. (SRA, 2007)
False Positive The conclusion that an event is positive when it is in fact negative. (USEPA, 2007c)

Fatal accident An accident which results in one or more deaths within one year. (SRA, 2007)

Forage (feeding) **Area** The area utilized by an organism for hunting or gathering food. (USEPA, 2007c)

Frank Effect Level: A level of exposure or dose that produces irreversible, adverse effects at a statistically or biologically significant increase in frequency or severity between those exposed and those not exposed. (USEPA, 2007b)

Gamma Multihit Model A generalization of the one-hit dose-response model which provides a better description of dose-response data. (SRA, 2007)

Gaussian distribution model A commonly used assumption about the distribution of values for a parameter, also called the normal distribution. For example, a Gaussian air dispersion model is one in which the pollutant is assumed to spread in air according to such a distribution and described by two parameters, the mean and standard deviation of the normal distribution. [Modified by S. L. Brown] (SRA, 2007)

Habitat Place where a plant or animal lives, often characterized by a dominant plant form and physical characteristics. (PERTAINING TO ECOLOGICAL ASSESSMENTS) (USEPA, 2007c)

Half-life The time in which half the atoms of a given quantity of a particular radioactive substance disintegrate to another nuclear form. Measured half-lives vary from millionths of a second to billions of years. Similarly, the time in which half the molecules of a chemical substance disappear as a result of chemical or biochemical transformation. [S. L. Brown] (SRA, 2007)

Half-life, biological The time required for a living organism to eliminate, by natural processes, half the amount of a substance that has entered it. (SRA, 2007)

Hazard Index The sum of more than one hazard quotient for multiple substances and/or multiple exposure pathways. The HI is calculated separately for chronic, subchronic, and shorter-duration exposures. (USEPA, 2007c)

Hazard Quotient The ratio of an exposure level to a substance to a toxicity value selected for the risk assessment for that substance (e.g., LOAEL or NOAEL). (USEPA, 2007c)

Hazard Ranking System (HRS) The NCP defines the HRS as "the method used by EPA to evaluate the relative potential of hazardous substance releases to cause health or safety problems, or ecological or environmental damage." The HRS is the primary screening tool used by EPA to assess the risks posed to human health or the environment by abandoned or uncontrolled hazardous waste sites. Under the HRS, sites are assigned scores on the basis of the toxicity of hazardous substances that are present and the potential that those substances will spread through the air, surface, water, or ground water, taking into account such factors as the proximity of the substance to nearby populations. Scores are used in determining which sites should be placed on the NPL. (USEPA, 2007c)

Hazardous Substance CERCLA defines a hazardous substance as "(A) any substance designated pursuant to section 1321(b0(2)(A) of Title 33, (NATIONAL RESEARCH COUNCIL, 1994) any element, compound, mixture, solution or substance designated pursuant to section 9602 of this title, (C) any hazardous waste having the characteristics identified in under or listed pursuant to section 3001 of the Solid Waste Disposal Act (but not including any waste the regulation of which the Solid Waste Disposal Act has been suspended by Act or Congress), (D) any toxic pollutant listed under section 1317(a) of Title 33, (E) any imminently hazardous chemical substance or mixture with respect to which the (EPA) Administrator has taken action pursuant to section 2606 of Title 15. The term does not (within the context of CERCLA) include petroleum, crude oil or any fraction thereof which is not otherwise specifically listed or designated as a hazardous substance (by CERCLA). The term (Harrison and Hoberg, 1994) does not include natural gas, natural gas liquids, liquified natural gas, or synthetic natural gas usable for fuel (or mixtures of natural gas and such synthetic gas). (USEPA, 2007c)

Hazardous waste Any waste or combination of wastes which pose a substantial present or potential hazard to human health or living organisms because such wastes are nondegradable or persistent in nature or because they can be biologically magnified, or because they can be lethal, or because they may otherwise cause or tend to cause detrimental cumulative effects; also, a waste or combination of wastes of a solid, liquid, contained gaseous, or semisolid form which may cause, or contribute to, an increase in mortality or an increase in serious irreversible, or incapacitating reversible illness, taking into account the toxicity of such waste, its persistence and degradability in nature, its potential for accumulation or concentration in tissue, and other factors that may otherwise cause or contribute to adverse acute or chronic effects on the health of persons or other organisms. (SRA, 2007)

Health and safety study Any study of any effect of a chemical substance or mixture on health or the environment or on both, including underlying data and epidemiological studies, studies of occupational exposure to a chemical substance or mixture, toxicological, clinical, and ecological studies of a chemical substance or mixture, and any test performed pursuant to this [TSCA] Act. (SRA, 2007)

Health Assessment An evaluation of available data on existing or potential risks to human health posed by a Superfund site. The Agency for Toxic Substances and Disease Registry (ATSDR) of the Department of Health and Human Services is required to perform such an assessment at every site on the National Priorities List. (USEPA, 2007c)

Health effect A deviation in the normal function of the human body. (SRA, 2007)

Health effect assessment The component of risk assessment which determines the probability of a health effect given a particular level or range of exposure to a hazard. (SRA, 2007)

Healthy worker effect The difference in mortality risk due to selection forces between a population of active workers healthy enough to have been (and remain) employed and the general population which includes sick and disabled persons. If working in a safe environment, such a population of active workers has been variously estimated to have a mortality risk 60-90% that of the general population. (SRA, 2007)
Hockey stick regression function A dose-response curve that shows zero response up to a presumed physiological threshold value and then a linear increase thereafter. [Modified by S. L. Brown] (SRA, 2007)
Home Range The area to which an animal confines its activities. (PERTAINING TO ECOLOGICAL ASSESSMENTS) (USEPA, 2007c)

Human Equivalent Concentration (HEC) or **Dose** (HED): The human concentration (for inhalation exposure) or dose (for other routes of exposure) of an agent that is believed to induce the same magnitude of toxic effect as the experimental animal species concentration or dose. This adjustment may incorporate toxicokinetic information on the particular agent, if available, or use a default procedure, such as assuming that daily oral doses experienced for a lifetime are proportional to body weight raised to the 0.75 power. (USEPA, 2007b)

Hydrocarbon A hydrocarbon is an organic compound containing only hydrogen and carbon, often occurring in petroleum, natural gas, and coal. (USEPA, 2007c)

Hypothesis A proposition set forth as an explanation for a specified phenomenon or group of phenomena. (USEPA, 2007c)

Impact The force of impression of one thing on another. (SRA, 2007)

Incidence Rate: The ratio of new cases within a population to the total population at risk given a specified period of time. (USEPA, 2007b)

Incidence The number of new cases of a disease in a population over a period of time. (SRA, 2007)
Incidence: The number of new cases of a disease that develop within a specified population over a specified period of time. (USEPA, 2007b)

Indicator organisms A species, whose presence or absence may be characteristic of environmental conditions in a particular area of habitat; however, species composition and relative abundance of individual components of the population or community are usually considered to be a more reliable index of water quality. (SRA, 2007)

Individual susceptibility The marked variability in the manner in which individuals will respond to a given exposure to a toxic agent. (SRA, 2007)

Ingestion Rate The rate at which an organism consumes food, water, or other materials (e.g., soil, sediment). Ingestion rate usually is expressed in terms of unit of mass or volume per unit of time (e.g.,kg/day, L/day). (USEPA, 2007c)

Integrated Risk Information System (USEPA, 2007b) IRIS is an electronic database that contains EPA's latest descriptive and quantitative regulatory information about chemical constituents. Files on chemicals maintained in IRIS contain information related to both noncarcinogenic and carcinogenic health effects. (USEPA, 2007c)

Interim Deliverables A series of Standard Tables, Worksheets, and Supporting Information, identified in the Workplan for each site, that should be developed by the risk assessment author, and evaluated by the EPA risk assessor, prior to development of the Draft Baseline Risk Assessment Report. After review and revision, as necessary, these documents should be included in the Baseline Risk Assessment Report. The Standard Tables should be prepared for each site to achieve standardization in risk assessment reporting.

The Worksheets and Supporting Information should also be prepared to further improve transparency, clarity, consistency, and reasonableness of risk assessments. (USEPA, 2007c)

Interspecies Dose Conversion: The process of extrapolating from animal doses to human equivalent doses. (USEPA, 2007b)

Latency period period of time from exposure to an agent to the onset of a health effect. (SRA, 2007)
Latency Period: The time between first exposure to an agent and manifestation or detection of a health effect of interest. (USEPA, 2007b)

LC50 A concentration expected to be lethal to 50% of a group of test organisms. (USEPA, 2007a)
LC50 A statistically or graphically estimated concentration that is expected to be lethal to 50% of a group of organisms under specified conditions. (USEPA, 2007c)

Leakage The entrance or escape of a fluid through a crack, fissure, or other aperture.

Lethal concentration fifty (LC50) A calculated concentration [in air] which when administered by the respiratory route is expected to kill 50% of a population of experimental animals during an exposure of four hours. Ambient concentration is expressed in milligrams per liter. (SRA, 2007)
Lethal concentration fifty (LC50) A calculated concentration in water which is expected to kill 50% of a population of aquatic organisms after a specified time of exposure. Concentration is usually expressed in milligrams per liter or ppm. [S. L. Brown] (SRA, 2007)

Lethal Causing death by direct action. (USEPA, 2007c)

Lethal dose fifty (LD50) A calculated dose of a chemical substance which is expected to kill 50% of a population of experimental animals exposed through a route other than respiration. Dose is expressed in milligrams per kilogram of body weight. (SRA, 2007)

Limited Evidence: A term used in evaluating study data for the classification of a carcinogen by the 1986 U.S. EPA guidelines for carcinogen risk assessment. This classification indicates that a causal interpretation is credible but that alternative explanations such as chance, bias, and confounding variables could not be completely excluded. (USEPA, 2007b)

Line source Consists of a number of point sources arranged in a straight line, usually across wind (see point source) (SRA, 2007)

Linear Dose Response: A pattern of frequency or severity of biological response that varies directly with the amount of dose of an agent. (USEPA, 2007b)

Linearized Multistage Procedure: A modification of the multistage model, used for estimating carcinogenic risk, that incorporates a linear upper bound on extra risk for exposures below the experimental range. (USEPA, 2007b)

Lines of evidence Information derived from different sources or by different techniques that can be used to describe and interpret risk estimates. Unlike the term “weight of evidence,” it does not necessarily assign quantitative weights to information. (USEPA, 2007a) (USEPA, 2007c)

Logit model A dose-response model which, like the probit model, leads to an S-shaped dose-response curve, symmetrical about the 50% response point. The logit model leads to lower "very safe doses" than the probit model even when both models are equally descriptive of the data in the observable range. (SRA, 2007)

Log-probit model A dose-response model which assumes that each animal has its own threshold dose, below which no response occurs and above which a tumor [or other effect] is produced by exposure to a chemical. (SRA, 2007)
Longer-Term Exposure: Repeated exposure by the oral, dermal, or inhalation route for more than 30 days, up to approximately 10% of the life span in humans (more than 30 days up to approximately 90 days in typically used laboratory animal species). (USEPA, 2007b)

Long-Term Monitoring Long-term monitoring of a site typically is performed to verify that contaminants pose no risk to human health or the environment and that natural processes are reducing contaminant levels and risk as predicted. (USEPA, 2007c)

Lower Limit on Effective Dose10 (LED10): The 95% lower confidence limit of the dose of a chemical needed to produce an adverse effect in 10 percent of those exposed to the chemical, relative to control. (USEPA, 2007b)

Matrix The substance in which an analyte is embedded or contained; the properties of a matrix depend on its constituents and form. (USEPA, 2007c)

Maximum Acceptable Toxic Concentration (MATC) For a particular ecological effects test, this term is used to mean either the range between the NOAEL and the LOAEL or the geometric mean of the NOAEL and the LOAEL. The geometric mean is also known as the chronic value. (USEPA, 2007c)

Maximum Likelihood (ML) Method, Maximum Likelihood Estimate (MLE): Statistical method for estimating a population parameter most likely to have produced the sample observations. (USEPA, 2007b)
Measure of ecosystem and receptor characteristics — Measures that influence the behavior and location of organisms of interest, stressor distribution, and organismal life-history characteristics that may affect exposure or response to the stressor. (USEPA, 2007a)

Measure of Ecosystem and Receptor Characteristics Measures that influence the behavior and location of ecological entities of the assessment endpoint, the distribution of a stressor, and lifehistory characteristics of the assessment endpoint or its surrogate that may affect exposure or response to the stressor. (USEPA, 2007c)

Media Specific environmental compartments-air, water, soil-which are the subject of regulatory concern and activities. (USEPA, 2007c)

Median Effective Concentration (EC50) The concentration of a substance to which test organisms are exposed that is estimated to be effective in producing some sublethal response in 50 percent of the test population. The EC50 usually is expressed as a time-dependent value (e.g., 24-hour EC50). The sublethal response elicited from the test organisms as a result of exposure must be clearly defined. (USEPA, 2007c)

Median Lethal Concentration (LC50) A statistically or graphically estimated concentration that is expected to be lethal to 50 percent of a group of organisms under specified conditions. (USEPA, 2007c)

Medium EPC The EPC, based on either a statistical derivation of measured data or modeled data. The Medium EPC differs from the Route EPC in that the Medium EPC does not consider the transfer of contaminants from one medium to another. (USEPA, 2007c)

Metric Relating to measurement; a type of measurement-for example a measurement of one of various components of community structure (e.g., species richness, % similarity). (USEPA, 2007c)

Migration Pathway A migration pathway is a potential path or route of contaminants from the source of contamination to contact with human populations or the environment. Migration pathways include air,

surface water, ground water, and land surface. The existence and identification of all potential migration pathways must be considered during assessment and characterization of a waste site. (USEPA, 2007c)
Mobility The ability of a chemical element or a pollutant to move into and through the environment (e.g., the mobilization of an element from a water column to sediment) (SRA, 2007)

Modifying Factor (MF): A factor used in the derivation of a reference dose or reference concentration. The magnitude of the MF reflects the scientific uncertainties of the study and database not explicitly treated with standard uncertainty factors (e.g., the completeness of the overall database). A MF is greater than zero and less than or equal to 10, and the default value for the MF is 1. [Use of a modifying factor was discontinued in 2004.] (USEPA, 2007b)

Module An independent or self-contained component of a model that is used in combination with other components and forms part of one or more larger programs. (Committee on Models in the Regulatory Decision Process, 2007)

Monitored Natural Attenuation The term monitored natural attenuation refers to the remedial approach that allows natural processes to reduce concentrations of contaminants to acceptable levels. Monitored natural attenuation involves physical, chemical, and biological processes that act to reduce the mass, toxicity, and mobility of subsurface contamination. Physical, chemical, and biological processes involved in monitored natural attenuation include biodegradation, chemical stabilization, dispersion, sorption, and volatilization. (USEPA, 2007c)

Monitoring Periodic or continuous sampling to determine the level of pollution or radioactivity. (SRA, 2007)

Monitoring Well A monitoring well is a well drilled at a specific location on or off a hazardous waste site at which ground water can be sampled at selected depths and studied to determine the direction of ground water flow and the types and quantities of contaminants present in the ground water. (USEPA, 2007c)

Monte Carlo Technique: A repeated random sampling from the distribution of values for each of the parameters in a calculation (e.g., lifetime average daily exposure), to derive a distribution of estimates (of exposures) in the population. (USEPA, 2007b)

Morbidity A departure from a state of physical or mental well-being, resulting from disease or injury. Frequently used only if the affected individual is aware of the condition. Awareness itself connotes a degree of measurable impact. Frequently, but not always, there is a further restriction that some action has been taken such as restriction of activity, loss of work, seeking of medical advice, etc. (SRA, 2007)

Mortality Death rate or proportion of deaths in a population. (USEPA, 2007c)
Mortality Death; the death rate; ratio of number of deaths to a given population. (SRA, 2007)

Mortality rate The number of deaths that occur in a given population during a given time interval; usually deaths per l03 or l05 people per year. Can be age, sex, race, and cause specific. (SRA, 2007)

Non-Linear Dose Response: A pattern of frequency or severity of biological response that does not vary directly with the amount of dose of an agent. (USEPA, 2007b)
Nonparametric Statistical methods that make no assumptions regarding the distribution of the data. (USEPA, 2007c)

Non-Point Source The term non-point source is used to identify sources of pollution that are diffuse and do not have a point of origin or that are not introduced into a receiving stream from a specific outlet. Common non-point sources are rain water, runoff from agricultural lands, industrial sites, parking lots, and timber operations, as well as escaping gases from pipes and fittings. (USEPA, 2007c)

No-observed-adverse-effect level (NOAEL) The highest level of a stressor evaluated in a test that does not cause statistically significant differences from the controls. (USEPA, 2007a)
No-Observed-Adverse-Effect Level (NOAEL) The highest level of a stressor evaluated in a toxicity test or biological field survey that causes no statistically significant difference in effect compared with the controls or a reference site. (USEPA, 2007c)
No-Observed-Adverse-Effect Level (NOAEL): The highest exposure level at which there are no biologically significant increases in the frequency or severity of adverse effect between the exposed population and its appropriate control; some effects may be produced at this level, but they are not considered adverse or precursors of adverse effects. (USEPA, 2007b)

No-Observed-Effect Level (NOEL): An exposure level at which there are no statistically or biologically significant increases in the frequency or severity of any effect between the exposed population and its appropriate control. (USEPA, 2007b)

Odds Ratio (OR): A relative measure of the difference in exposure between the diseased (Beauchamp and Bowie, 1997) and not diseased (controls) individuals in a case-control study. The OR is interpreted similarly to the relative risk. (USEPA, 2007b)

One-hit model The basic dose-response model based on the concept that a tumor can be induced by a single receptor that has been exposed to a single quantum or effective dose unit of a chemical.

Parameter Constants applied to a model that are obtained by theoretical calculation or measurements taken at another time and/or place, and are assumed to be appropriate for the place and time being studied. (USEPA, 2007c)
Parameters Terms in the model that are fixed during a model run or simulation but can be changed in different runs as a method for conducting sensitivity analysis or to achieve calibration goals. (Committee on Models in the Regulatory Decision Process, 2007)

Parametric Statistical methods used when the distribution of the data is known. (USEPA, 2007c)

Person-year The sum of the number of years each person in the study population is at risk; a metric used to aggregate the total population at risk assuming that 10 people at risk for one year is equivalent to 1 person at risk for 10 years. (SRA, 2007)

Physiologically Based Pharmacokinetic (PBPK) Model: A model that estimates the dose to a target tissue or organ by taking into account the rate of absorption into the body, distribution among target organs and tissues, metabolism, and excretion. (USEPA, 2007b)

PMR Proportionate mortality ratio. (SRA, 2007)

Point of Departure: The dose-response point that marks the beginning of a low-dose extrapolation. This point can be the lower bound on dose for an estimated incidence or a change in response level from a dose-response model (BMD), or a NOAEL or LOAEL for an observed incidence, or change in level of response. (USEPA, 2007b)

Point Source A point source is a stationary location or fixed facility from which pollutants are discharged or emitted or any single, identifiable discharge point of pollution, such as a pipe, ditch, or smokestack. (USEPA, 2007c)
Point source A single isolated stationary source of pollution. (SRA, 2007)
Point Source Pollution A specific discharge to a water body, ambient air, or land that is traceable to a distinct source (e.g., pipe, smokestack, and container) such as those from wastewater treatment plants, power plants, or industrial facilities.(Committee on Models in the Regulatory Decision Process, 2007)

Pollutant Any material entering the environment that has undesired effects. (SRA, 2007)

Pollution The presence of matter or energy whose nature, location or quantity produces undesired environmental effects. (SRA, 2007)

Population An aggregate of individuals of a species within a specified location in space and time. (USEPA, 2007a) (USEPA, 2007c)

Population at risk A limited population that may be unique for a specific dose-effect relationship; the uniqueness may be with respect to susceptibility to the effect or with respect to the dose or exposure itself. (SRA, 2007)

Population dose (population exposure) The summation of individual radiation doses received by all those exposed to the source or event being considered. (SRA, 2007)

Potentially Responsible Party (PRP) A PRP is an individual or company (such as owners, operators, transporters, or generators of hazardous waste) that is potentially responsible for, or contributing to, the contamination problems at a Superfund site. Whenever possible, EPA requires PRPs, through administrative and legal actions, to clean up hazardous waste sites they have contaminated. (USEPA, 2007c)

Power The power of a statistical test indicates the probability of rejecting the null hypothesis when it should be rejected (i.e., the null hypothesis is false). Can be considered the sensitivity of a statistical test. (USEPA, 2007c)

Precision The quality of being reproducible in amount or performance. With models and other forms of quantitative information, precision refers specifically to the number of decimal places to which a number is computed as a measure of the preciseness or exactness with which a number is computed.(Committee on Models in the Regulatory Decision Process, 2007)
Precision A measure of how consistently the result is determined by repeated determinations without reference to any "true" value. (SRA, 2007)
Precision A measure of the closeness of agreement among individual measurements. (USEPA, 2007c)

Preliminary Assessment and Site Inspection (PA/SI) A PA/SI is the process of collecting and reviewing available information about a known or suspected hazardous waste site or release. The PA/SI usually includes a visit to the site. (USEPA, 2007c)

Preliminary Remediation Goals Initial clean-up goals developed early in the remedy selection process based on readily available information and are modified to reflect results of the baseline risk assessment. They also are used during analysis of remedial alternatives in the remedial investigation/feasibility study (RI/FS). (USEPA, 2007c)

Premature death A death that occurs before statistical expectation, usually attributable to a specific cause, and usually referring to deaths statistically estimated in a population rather than to individuals. (SRA, 2007)

Presumptive Remedies Presumptive remedies are preferred technologies for common categories of CERCLA sites that have been identified through historical patterns of remedy selection and EPA's scientific and engineering evaluation of performance data on technology implementation. (USEPA, 2007c)

Prevalence The number of existing cases in a population who have the disease at a given point (or during a given period) of time. (SRA, 2007)

Prevalence: The proportion of disease cases that exist within a population at a specific point in time, relative to the number of individuals within that population at the same point in time. (USEPA, 2007b)

Primary effect An effect where the stressor acts on the ecological component of interest itself, not through effects on other components of the ecosystem (synonymous with direct effect; compare with definition for secondary effect). (USEPA, 2007a) (USEPA, 2007c)

Probabilistic Analysis (as opposed to deterministic analysis) Calculation and expression of health risks using multiple risk descriptors to provide the likelihood of various risk levels. Probabilistic risk results approximate a full range of possible outcomes and the likelihood of each, which often is presented as a frequency distribution graph, thus allowing uncertainty or variability to be expressed quantitatively. (USEPA, 2007c)

Probability A probability assignment is a numerical encoding of the relative state of knowledge. (SRA, 2007)

Probability density function (PDF) Probability density functions are particularly useful in describing the relative likelihood that a variable will have different particular values of x. The probability that a variable will have a value within a small interval around x can be approximated by multiplying f(x) (i.e., the value of y at x in a PDF plot) by the width of the interval. (USEPA, 2007a)(USEPA, 2007c)

Probable error The magnitude of error which is estimated to have been made in determination of results. (SRA, 2007)

Probit analysis A statistical transformation which will make the cumulative normal distribution linear. In analysis of dose-response, when the data on response rate as a function of dose are given as probits, the linear regression line of these data yields the best estimate of the dose-response curve. The probit unit is y = 5 + Z(Committee on Models in the Regulatory Decision Process, 2007) , where p = the prevalence of response at each dose level and Z(Committee on Models in the Regulatory Decision Process, 2007) = the corresponding value of the standard cumulative normal distribution. (SRA, 2007)

Proportionate mortality ratio (PMR) The fraction of all deaths from a given cause in the study population divided by the same fraction from a standard population. A tool for investigating cause-specific risks when only data on deaths are available. If data on the population at risk are also available, SMRs are preferred. (SRA, 2007)
Proportionate Mortality Ratio (PMR): The proportion of deaths due to the disease of interest in the exposed population divided by the proportion of deaths due to the disease of interest in the unexposed or reference population. It is frequently converted to a percent by multiplying the ratio by 100. (USEPA, 2007b)

Prospective study An inquiry in which groups of individuals are selected in terms of whether they are or are not exposed to certain factors, and then followed over time to determine differences in the rate at which disease develops in relation to exposure to the factor. Also called cohort study. (SRA, 2007)
Prospective Study: See cohort study. (USEPA, 2007b)

Public accident Any accident other than motor vehicle that occurs in the public use of any premises. Includes deaths in recreation (swimming, hunting, etc.), transportation except motor vehicle, public buildings, etc., and deaths from widespread natural disasters even though some may have happened on home premises. Excludes accidents to persons in the course of gainful employment. (SRA, 2007)

Pulmonary function The performance of the respiratory system in supplying oxygen to, and removing carbon dioxide from, the body (via the circulating blood). This requires that air move into and out of the alveoli at an adequate rate (ventilation), that blood circulate through pulmonary capillaries adjacent to

alveoli at an adequate rate (perfusion), and that oxygen pass freely from alveoli to blood as carbon dioxide passes in the opposite direction (diffusion). Pulmonary function tests are used to try to identify and locate abnormalities in performance capability. (SRA, 2007)

Quality Assurance (QA) QA is a system of management activities that ensure that a process, item, or service is of the type and quality needed by the user. QA deals with setting policy and implementing an administrative system of management controls that cover planning, implementation, and review of data collection activities. QA is an important element of a quality system that ensures that all research design and performance, environmental monitoring and sampling, and other technical and reporting activities conducted by EPA are of the highest possible quality. (USEPA, 2007c)

Quality Control (QC) QC refers to scientific precautions, such as calibrations and duplications, that are necessary if data of known and adequate quality are to be acquired. QC is technical in nature and is implemented at the project level. Like QA, QC is an important element of a quality system that ensures that all research design and performance, environmental monitoring and sampling, and other technical and reporting activities conducted by EPA are of the highest possible quality. (USEPA, 2007c)

Random error Indefiniteness of result due to finite precision of experiment. Measure of fluctuation in result upon repeated experimentation. (SRA, 2007)

Rate In epidemiologic usage, the frequency of a disease or characteristic expressed per unit of size of the population or group in which it is observed. The time at or during which the cases are observed is a further specification. (SRA, 2007)

RAUs Risk analysis units. (SRA, 2007)

Reactivity Reactive wastes are unstable under normal conditions. They can create explosions and or toxic fumes, gases, and vapors when mixed with water. (USEPA, 2007c)

Receptor Age The description of the exposed individual as defined by the EPA region or dictated by the site. (USEPA, 2007c)

Receptor Population The exposed individual relative to the exposure pathway considered. (USEPA, 2007c)

Recovery The rate and extent of return of a population or community to some aspect of its previous condition. (USEPA, 2007a)
Recovery The rate and extent of return of a population or community to some aspect(s) of its previous condition. Because of the dynamic nature of ecological systems, the attributes of a "recovered" system should be carefully defined. (USEPA, 2007c)

Reference Concentration (RfC): An estimate (with uncertainty spanning perhaps an order of magnitude) of a continuous inhalation exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime. It can be derived from a NOAEL, LOAEL, or benchmark concentration, with uncertainty factors generally applied to reflect limitations of the data used. Generally used in EPA's noncancer health assessments. [Durations include acute, short-term, subchronic, and chronic and are defined individually in this glossary].(USEPA, 2007b)

Reference dose An estimate of the daily exposure dose that is likely to be without deleterious effect even if continued exposure occurs over a lifetime. Related term: Acceptable daily intake (WHO, 2004)
Reference Dose (RfD): An estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime. It can be derived from a NOAEL, LOAEL, or

benchmark dose, with uncertainty factors generally applied to reflect limitations of the data used. Generally used in EPA's noncancer health assessments. [Durations include acute, short-term, subchronic, and chronic and are defined individually in this glossary]. (USEPA, 2007b)

Reference Site A relatively uncontaminated site used for comparison to contaminated sites in environmental monitoring studies, often incorrectly referred to as a control. (USEPA, 2007c)

Reference Value (RfV): An estimate of an exposure for a given duration to the human population (including susceptible subgroups) that is likely to be without an appreciable risk of adverse health effects over a lifetime. It is derived from a BMDL, a NOAEL, a LOAEL, or another suitable point of departure, with uncertainty/variability factors applied to reflect limitations of the data used. [Durations include acute, short-term, subchronic, and chronic and are defined individually in this glossary.] [Reference value is a term proposed in the report, "A Review of the Reference Dose and Reference Concentration Processes" (EPA, 2002), and is a generic term not specific to a given route of exposure. EPA develops numerical toxicity values for the RfD and RfC only; no numerical toxicity values are developed for the RfV.] (USEPA, 2007b)

Regional Deposited Dose (RDD): The deposited dose of particles calculated for a respiratory tract region of interest (r) as related to an observed toxicity. For respiratory effects of particles, the deposited dose is adjusted for ventilatory volumes and the surface area of the respiratory region effected (mg/min-sq. cm). For extra respiratory effects of particles, the deposited dose in the total respiratory system is adjusted for ventilatory volumes and body weight (mg/min-kg). (USEPA, 2007b)

Regional Deposited Dose Ratio (RDDR): The ratio of the regional deposited dose calculated for a given exposure in the animal species of interest to the regional deposited dose of the same exposure in a human. This ratio is used to adjust the exposure effect level for interspecies dosimetric differences to derive a human equivalent concentration for particles. (USEPA, 2007b)

Regional Gas Dose Ratio (RGDR): The ratio of the regional gas dose calculated for a given exposure in the animal species of interest to the regional gas dose of the same exposure in humans. This ratio is used to adjust the exposure effect level for interspecies dosimetric differences to derive a human equivalent concentration for gases with respiratory effects. (USEPA, 2007b)

Regional Gas Dose: The gas dose calculated for the region of interest as related to the observed effect for respiratory effects. The deposited dose is adjusted for ventilatory volumes and the surface area of the respiratory region effected (mg/min-sq.cm). (USEPA, 2007b)

Regression Analysis Analysis of the functional relationship between two variables; the independent variable is described on the X axis and the dependent variable is described on the Y axis (i.e. the change in Y is a function of a change in X). (USEPA, 2007c)

Regulatory Impact Analysis (RIA) – An analysis document produced by EPA for each major rulemaking listing the expected impacts of the rule, including environmental impacts, health impacts, cost–benefit analyses, economic impacts, and small business impacts. (Committee on Models in the Regulatory Decision Process, 2007)

Relative potency A comparison of the potency of two or more reference chemicals. Potency of a test chemical is reviewed at all levels of biological organization (subcellular, cellular, animal, human). (SRA, 2007)

Remedial Design and Remedial Action (RD/RA) Remedial Design is defined in the NCP as "the technical analysis and procedures which follow the selection of (a) remedy for a site and result in a detailed set of plans and specifications for implementation of the remedial action. *See also Remedial Investigation*

and Feasibility Study. "Remedial Action" is defined in the NCP in part as "those actions consistent with (a) permanent remedy taken instead of, or in addition to, (a) removal action(s) in the event of a release or threatened release of a hazardous substance into the environment, to prevent or minimize the release of hazardous substances so that they do not migrate or cause substantial danger to present or future public health or welfare, or the environment." CERCLA defines a removal action in part as "the cleanup or removal of hazardous substances from the environment, which may be taken in the event of the threat of release of hazardous substances into the environment." (USEPA, 2007c)

Remedial Investigation and Feasibility Study (RI/FS) The RI/FS is the step in the Superfund cleanup process that is conducted to gather sufficient information to support the selection of a site remedy that will reduce or eliminate the risks associated with contamination at the site. The RI involves site characterization -- collection of data and information necessary to characterize the nature and extent of contamination at the site. The RI also determines whether the contamination presents a significant risk to human health or the environment. The FS focuses on the development of specific response alternatives for addressing contamination at a site. (USEPA, 2007c)

Removal Action CERCLA defines a removal action in part as "the cleanup or removal of hazardous substances from the environment...which may be taken in the event of the threat of release of hazardous substances into the environment." (USEPA, 2007c)

Replicate Duplicate analysis of an individual sample. Replicate analyses are used for quality control. (USEPA, 2007c)

Reportable Quantity (RQ) The RQ is the quantity of hazardous substances that, when released into the environment, can cause substantial endangerment to public health or the environment. Under CERCLA, the federal government must be notified when quantities equaling or exceeding RQs specified in regulations are released. (USEPA, 2007c)

Representative Samples Serving as a typical or characteristic sample; should provide analytical results that correspond with actual environmental quality or the condition experienced by the contaminant receptor. (USEPA, 2007c)

Reproducibility The degree of variation obtained when the same measurement is made with similar instruments and many operators. (SRA, 2007)

Reserve Volume: The volume of air remaining in the lungs after a maximal expiration. (USEPA, 2007b)

Residence time The period of time during which a substance resides in a designated area. (SRA, 2007)

Residual Volume (RV): The lung volume after maximal expiration (TLC - VC). (USEPA, 2007b)

Resource Conservation and Recovery Act (RCRA) RCRA is a federal law enacted in 1976 that established a regulatory system to track hazardous substances from their generation to their disposal. The law requires the use of safe and secure procedures in treating, transporting, storing, and disposing of hazardous substances. RCRA is designed to prevent the creation of new, uncontrolled hazardous waste sites. (USEPA, 2007c)

Response Action A response action is a short-term removal action or a long-term remedial response, authorized under CERCLA that is taken at a site to address releases of hazardous substances. (USEPA, 2007c)

Response Change developed in the state or dynamics of an organism, system, or (Harrison and Hoberg, 1994)population in reaction to exposure to an agent. (WHO, 2004)

Response The proportion or absolute size of a population that demonstrates a specific effect. May also refer to the nature of the effect. (SRA, 2007)

Retrospective risk assessment — An evaluation of the causal linkages between observed ecological effects and a stressor in the environment. (USEPA, 2007a) (USEPA, 2007c)

Retrospective study See case-control study. (SRA, 2007)

Robustness – The capacity of a model to perform equally well across the full range of environmental conditions for which it was designed. (Committee on Models in the Regulatory Decision Process, 2007)

Route EPC The EPC, based on either a statistical derivation of measured data or based on modeled data, that was selected to represent the route-specific concentration for the exposure calculations. The Route EPC differs from the Medium EPC in that the Route EPC may consider the transfer of contaminants from one medium to another, where applicable for a particular exposure route. (USEPA, 2007c)

Safety factor Composite (reductive) factor by which an observed or estimated no-observedadverse- effect level (NOAEL) is divided to arrive at a criterion or standard that is considered safe or without appreciable risk. Related terms: Assessment factor, Uncertainty factor (WHO, 2004)

Sample (Environmental) Fraction of a material tested or analyzed; a selection or collection from a larger collection. (USEPA, 2007c)

Sampling and Analysis Plan A sampling and analysis plan (SAP) documents the procedural and analytical requirements for a one-time or time-limited project that involves the collection of samples of water, soil, sediment, or other media to characterize areas of potential environmental contamination. A SAP contains all the elements of a quality assurance project plan (QAPP) and a field sampling plan (FSP) that must be provided to meet the requirements for any project funded by the EPA under which environmental measurements are to be taken. (USEPA, 2007c)

Scenario Timeframe The time period (current and/or future) being considered for the exposure pathway. (USEPA, 2007c)

Scientific/Management Decision Point (SMDP) A point during the risk assessment process when the risk assessor communicates results of the assessment at that stage to a risk manager. At this point the risk manager determines whether the information is sufficient to arrive at a decision regarding risk management strategies and/or the need for additional information to characterize risk. (USEPA, 2007c)

Screening Model A type of model designed to provide a "conservative" or risk-averse answer. Because screening models can be used with limited information and are conservative, they can be used to determine whether more refined models would be useful or whether the screening model results are sufficient to make decisions without proceeding to a refined model. (Committee on Models in the Regulatory Decision Process, 2007)

Secondary effect An effect where the stressor acts on one component of the ecosystem, which in turn has an effect on the component of interest (synonymous with indirect effects; compare with definition for primary effect). (USEPA, 2007a)

Secondary Effect An effect where the stressor acts on supporting components of the ecosystem, which in turn have an effect on the ecological component of interest (synonymous with indirect effects; compare with definition for primary effect). (USEPA, 2007c)

Sensitive Life Stage The life stage (i.e., juvenile, adult, etc.) that exhibits the highest degree of sensitivity (i.e., effects are evident at a lower exposure concentration) to a contaminant in toxicity tests. (USEPA, 2007c)
Sensitivity – The degree to which the model outputs are affected by changes in a selected input parameters. (Committee on Models in the Regulatory Decision Process, 2007)

Sensitivity In relation to toxic substances, organisms that are more sensitive exhibit adverse (toxic) effects at lower exposure levels than organisms that are less sensitive. (USEPA, 2007c)

Short-Term Exposure: Repeated exposure by the oral, dermal, or inhalation route for more than 24 hours, up to 30 days. (USEPA, 2007b)

Short-term Reference Concentration (RfC): An estimate (with uncertainty spanning perhaps an order of magnitude) of a continuous inhalation exposure for short-term duration (up to 30 days) to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime. It can be derived from a NOAEL, LOAEL, or benchmark concentration, with uncertainty factors generally applied to reflect limitations of the data used. Generally used in EPA's noncancer health assessments. (USEPA, 2007b)

Short-term Reference Dose (RfD): An estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure for a short-term duration (up to 30 days) to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime. It can be derived from a NOAEL, LOAEL, or benchmark dose, with uncertainty factors generally applied to reflect limitations of the data used. Generally used in EPA's noncancer health assessments. (USEPA, 2007b)

Significant deterioration Refers to pollution from a new source in previously "clean" areas. Congress has established standards for certain pollutants to prevent significant deterioration from existing conditions thus establishing increments which cannot be exceeded. (SRA, 2007)
Sink A place where pollutants are collected by means of processes such as absorption. The opposite of source. (SRA, 2007)
Slope Factor: An upper bound, approximating a 95% confidence limit, on the increased cancer risk from a lifetime exposure to an agent. This estimate, usually expressed in units of proportion (of a population) affected per mg/kg-day, is generally reserved for use in the low-dose region of the dose-response relationship, that is, for exposures corresponding to risks less than 1 in 100. (USEPA, 2007b)

Smoke The visible aerosol that results from incomplete combustion. (SRA, 2007)

SMR Standardized mortality ratio. (SRA, 2007)

Solubility Solubility is a measure of the amount of solute that will dissolve in a solution. It is the ability or tendency of one substance to dissolve into another at a given temperature and pressure and is generally expressed in terms of the amount of solute that will dissolve in a given amount of solvent to produce a saturated solution. (USEPA, 2007c)

Species A group of organisms that actually or potentially interbreed and are reproductively isolated from all other such groups; a taxonomic grouping of morphologically similar individuals; the category below genus. (USEPA, 2007c)

Standard deviation A measure of dispersion or variation, usually taken as the square root of the variance. (SRA, 2007)

Standard geometric deviation Measure of dispersion of values about a geometric mean; the portion of the frequency distribution that is one standard geometric deviation to either side of the geometric mean; accounts for 68% of the total samples. (SRA, 2007)

Standard normal deviation Measure of dispersion of values about a mean value; the positive square root of the average of the squares of the individual deviations from the mean. (SRA, 2007)

Standard Operating Procedure A standard operating procedure (SOP) is a step-by-step procedure that promotes uniformity in operations to help clarify and augment such operations. SOPs document the way activities are to be performed to facilitate consistent conformance to technical and quality system requirements and to support data quality. The use of SOPs is an integral part of a successful quality system because SOPs provide individuals with the information needed to perform a job properly and facilitate consistency in the quality and integrity of a product or end result. SOPs also provide guidance in areas in which the exercise of professional judgment is necessary and specify procedures that are unique to each task. (USEPA, 2007c)

Standard Tables One of the Standard Tools under the RAGS Part D approach. The Standard Tables have been developed to clearly and consistently document important parameters, data, calculations, and conclusions from all stages of human health risk assessment development. Electronic templates for the Standard Tables have been developed in LOTUS and EXCEL for ease of use by risk assessors. For each site-specific risk assessment, the Standard Tables, related Worksheets, and Supporting Information should first be prepared as Interim Deliverables for EPA risk assessor review, and should later be included in the Draft and Final Baseline Risk Assessment Reports. The Standard Tables may be found in Appendix A and on the electronic media provided with this guidance document. Use of the Standard Tables will standardize the reporting of human health risk assessments. The Standard Table formats can not be altered (i.e., columns can not be added, deleted, or changed); however, rows and footnotes can be added as appropriate. Standardization of the Tables is needed to achieve Superfund program-wide reporting consistency and to accomplish electronic data transfer to the Superfund database. (USEPA, 2007c)

Standard Tools A basic element of the RAGS Part D approach. The Standard Tools have been developed to standardize the planning, reporting, and review of Superfund risk assessments. The three Standard Tools contained in the Part D approach include the Technical Approach for Risk Assessment (TARA), the Standard Tables, and Instructions for the Standard Tables. (USEPA, 2007c)

Standardized mortality ratio (SMR) The ratio of observed deaths in a population to the expected number of deaths as derived from rates in a standard population with adjustment of age and possibly other factors such as sex or race. (SRA, 2007)
Standardized Mortality Ratio (SMR): This is the relative measure of the difference in risk between the exposed and unexposed populations in a cohort study. The SMR is similar to the relative risk in both definition and interpretation. This measure is usually standardized to control for any differences in age, sex, and/or race between the exposed and reference populations. It is frequently converted to a percent by multiplying the ratio by 100. (USEPA, 2007b)

Stationary source A pollution location that is fixed rather than moving. (SRA, 2007)

Statistic A computed or estimated statistical quantity such as the mean, the standard deviation, or the correlation coefficient. (USEPA, 2007c)

Statistical significance The statistical significance determined by using appropriate standard techniques of statistical analysis with results interpreted at the stated confidence level and based on data relating species which are present in sufficient numbers at control areas to permit a valid statistical comparison with the areas being tested. (SRA, 2007)

Statistical Significance: The probability that a result is not likely to be due to chance alone. By convention, a difference between two groups is usually considered statistically significant if chance could explain it only 5% of the time or less. Study design considerations may influence the a priori choice of a different level of statistical significance. (USEPA, 2007b)

Steady state exposure Exposure to an environmental pollutant whose concentration remains constant for a period of time. (SRA, 2007)

Stochastic Model A model that includes variability (see definition) in model parameters. This variability is a function of (SRA, 2007) changing environmental conditions, (Committee on Models in the Regulatory Decision Process, 2007) spatial and temporal aggregation within the model framework, and (NATIONAL RESEARCH COUNCIL, 1994) random variability. The solutions obtained by the model or output is therefore a function of model components and random variability. (Committee on Models in the Regulatory Decision Process, 2007)

Stress Regime The term "stress regime" has been used in at least three distinct ways: (SRA, 2007) to characterize exposure to multiple chemicals or to both chemical and nonchemical stressors (more clearly described as multiple exposure, complex exposure, or exposure to mixtures), (Committee on Models in the Regulatory Decision Process, 2007) as a synonym for exposure that is intended to avoid overemphasis on chemical exposures, and (NATIONAL RESEARCH COUNCIL, 1994) to describe the series of interactions of exposures and effects resulting in secondary exposures, secondary effects and, finally, ultimate effects (also known as risk cascade [Lipton et al., 1993]), or causal chain, pathway, or network (Andrewartha and Birch, 1984). (USEPA, 2007c)

Stressor-response profile A summary of data on the effects of a stressor and the relationship of the data to the assessment endpoint. (USEPA, 2007a)
Stressor-Response Profile The product of characterization of ecological effects in the analysis phase of ecological risk assessment. The stressor-response profile summarizes the data on the effects of a stressor and the relationship of the data to the assessment endpoint. (USEPA, 2007c)

Subchronic Exposure: Repeated exposure by the oral, dermal, or inhalation route for more than 30 days, up to approximately 10% of the life span in humans (more than 30 days up to approximately 90 days in typically used laboratory animal species). [See also longer-term exposure.] (USEPA, 2007b)

Subchronic Reference Concentration (RfC): An estimate (with uncertainty spanning perhaps an order of magnitude) of a continuous inhalation exposure for a subchronic duration (up to 10% of average lifespan) to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime. It can be derived from a NOAEL, LOAEL, or benchmark concentration, with uncertainty factors generally applied to reflect limitations of the data used. Generally used in EPA's noncancer health assessments. (USEPA, 2007b)
Subchronic Reference Dose (RfD): An estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure for a subchronic duration (up to 10% of average lifespan) to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime. It can be derived from a NOAEL, LOAEL, or benchmark dose, with uncertainty factors generally applied to reflect limitations of the data used. Generally used in EPA's noncancer health assessments. (USEPA, 2007b)

Subchronic Study: A toxicity study designed to measure effects from subchronic exposure to a chemical. (USEPA, 2007b)

Sublethal Below the concentration that directly causes death. Exposure to sublethal concentrations of a substance can produce less obvious effects on behavior, biochemical and/or physiological functions, and the structure of cells and tissues in organisms. (USEPA, 2007c)

Sufficient Evidence: A term used in evaluating study data for the classification of a carcinogen under the 1986 U.S. EPA guidelines for carcinogen risk assessment. This classification indicates that there is a causal relationship between the agent or agents and human cancer. (USEPA, 2007b)

Supporting Information Information submissions that substantiate or summarize detailed data analysis, calculations, or modeling and associated parameters and assumptions. Examples of recommended Supporting Information include: derivations of background values, exposure point concentrations, modeled intakes, and chemical-specific parameters. Supporting Information should be provided as Interim Deliverables for EPA risk assessor review prior to the development of the Draft Baseline Risk Assessment Report. (USEPA, 2007c)

Supporting Studies: Studies that contain information useful for providing insight and support for conclusions. (USEPA, 2007b)

Surface water All bodies of water on the surface of the earth. (SRA, 2007)

Surrogate Something that serves as a substitute. In risk analysis, surrogates are often used when data on the item of interest (a chemical, an industry, an exposure, etc.) is lacking. As an example, underground mining of coal and hardrock minerals can be used as a surrogate for underground oil shale mining. (SRA, 2007)

Susceptibility – Increased likelihood of an adverse effect, often discussed in terms of relationship to a factor that can be used to describe a human subpopulation (e.g., life stage, demographic feature, and genetic characteristic). (Committee on Models in the Regulatory Decision Process, 2007) (USEPA, 2007b) Susceptible Subgroups – May refer to life stages (e.g., children and the elderly) or to other segments of the population (e.g., people who have asthma or who are immune compromised), but are likely to be chemical-specific and may not be consistently defined in all cases. (Committee on Models in the Regulatory Decision Process, 2007)

Susceptible Subgroups: May refer to life stages, for example, children or the elderly, or to other segments of the population, for example, asthmatics or the immune-compromised, but are likely to be somewhat chemical-specific and may not be consistently defined in all cases. (USEPA, 2007b)

Synergetic Working together; an agent that works synergistically with one or more other agents. (SRA, 2007)

Synergism An interaction between two substances that results in a greater effect than both of the substances could have had acting independently. (SRA, 2007)

Synergistic effects Joint effects of two or more agents, such as drugs that increase each other's effectiveness when taken together. (SRA, 2007)

Systematic error A reproducible inaccuracy introduced by faulty equipment, calibration, or technique. (SRA, 2007)

Systematic Planning Systematic planning is a planning process that is based on the scientific method. It is a common-sense approach designed to ensure that the level of detail in planning is commensurate with the importance and intended use of the data, as well as the available resources. Systematic planning is important to the successful execution of all activities at hazardous waste sites, but it is particularly important to dynamic field activities because those activities rely on rapid decision-making. The data quality objective (DQO) process is one formalized process of systematic planning. All dynamic field

activities must be designed through the use of systematic planning, whether using DQO steps or some other system. (USEPA, 2007c)

Target Organ: The biological organ(s) most adversely affected by exposure to a chemical, physical, or biological agent. (USEPA, 2007b)

Technical Approach for Risk Assessment (TARA) One of the Standard Tools under the RAGS Part D approach. The TARA is a road map for incorporating continuous involvement of the EPA risk assessor throughout the CERCLA remedial process. Risk-related activities, beginning with scoping and problem formulation, extending through collection and analysis of risk-related data, and supporting risk management decision making and remedial design/remedial action issues are addressed. The TARA should be customized for each site and the requirements identified should be included in project workplans so that risk assessment requirements and approaches are clearly defined. Chapters 2 through 5 of Part D present the TARA. Worksheets Formats for documenting assumptions, input parameters, and conclusions regarding complex risk assessment issues. The Data Useability Worksheet (found in Exhibit 3-3) should be an Interim Deliverable for all sites. Worksheets addressing Lead and Radionuclides are under development and will be provided in a revision to RAGS Part D. (USEPA, 2007c)

Technology Forcing The establishment by a regulatory agency of a requirement to achieve an emissions limit, within a specified time frame, that can be reached through use of unspecified technology or technologies that have not yet been developed for widespread commercial applications and have been shown to be feasible on an experimental or pilot-demonstration basis. (Committee on Models in the Regulatory Decision Process, 2007)

Technology-Based Standards – A type of standard that dictates polluters use specific techniques (e.g., a particular type of pollution abatement equipment) or follow a specific set of operating procedures and practices. (Committee on Models in the Regulatory Decision Process, 2007)

Threshold limit value (TLV) Refers to airborne concentrations of substances and represents conditions under which it is believed that nearly all workers are protected while repeatedly exposed for an 8-hr day, 5 days a week (expressed as parts per million (ppm) for gases and vapors and as milligrams per cubic meter (mg/m3) for fumes, mists, and dusts). (SRA, 2007)
Threshold Limit Value (TLV): Recommended guidelines for occupational exposure to airborne contaminants published by the American Conference of Governmental Industrial Hygienists (ACGIH). TLVs represent the average concentration in mg/m3 for an 8-hour workday and a 40-hour work week to which nearly all workers may be repeatedly exposed, day after day, without adverse effect. (USEPA, 2007b)

Tolerable daily intake Analogous to Acceptable daily intake. The term “tolerable” is used for agents that are not deliberately added, such as contaminants in food. (WHO, 2004)
Tolerable intake Estimated maximum amount of an agent, expressed on a body mass basis, to which each individual in a (Harrison and Hoberg, 1994)population may be exposed over a specified period without appreciable risk. (WHO, 2004)
Toxic Mechanism of Action The mechanism by which chemicals produce their toxic effects, i.e., the mechanism by which a chemical alters normal cellular biochemistry and physiology. Mechanisms can include; interference with normal receptor-ligand interactions, interference with membrane functions, interference with cellular energy production, and binding to biomolecules. (USEPA, 2007c)
Toxic substance A chemical or mixture that may present an unreasonable risk of injury to health or the environment. (SRA, 2007)
Toxic Substance A toxic substance is a chemical or mixture that may present an unreasonable risk of injury to health or the environment. Toxic Substances Control Act (TSCA) TSCA was enacted in 1976 to test, regulate, and screen all chemicals produced or imported into the U.S. TSCA requires that any chemical that reaches the consumer marketplace be tested for possible toxic effects prior to commercial

manufacture. Any existing chemical that poses health and environmental hazards is tracked and reported under TSCA. (USEPA, 2007c)

Toxic Substance: A chemical, physical, or biological agent that may cause an adverse effect or effects to biological systems. (USEPA, 2007b)

Toxicant A poisonous substance. (USEPA, 2007c)
Toxicant A substance that kills or injures an organism through chemical or physical action or by altering the organism's environment; for example, cyanides, phenols, pesticides, or heavy metals; especially used for insect control. (SRA, 2007)

Toxicity Assessment Review of literature, results in toxicity tests, and data from field surveys regarding the toxicity of any given material to an appropriate receptor. (USEPA, 2007c)
Toxicity EPA's Integrated Risk Information System (USEPA, 2007b) defines toxicity as "The degree to which a chemical substance (or physical agent) elicits a deleterious or adverse effect upon the biological system of an organism exposed to the substance over a designated time period." (USEPA, 2007c)

Toxicity Inherent property of an agent to cause an adverse biological effect. (WHO, 2004)
Toxicity The degree of danger posed by a substance to animal or plant life. (SRA, 2007)
Toxicity: Deleterious or adverse biological effects elicited by a chemical, physical, or biological agent. (USEPA, 2007b)

Toxicity Test The means by which the toxicity of a chemical or other test material is determined. A toxicity test is used to measure the degree of response produced by exposure to a specific level of stimulus (or concentration of chemical) compared with an unexposed control. (USEPA, 2007c)

Toxicity Value A numerical expression of a substance's exposure-response relationship that is used in risk assessments. (USEPA, 2007c)

Toxicology – The study of the harmful effects of substances on living organisms. (Committee on Models in the Regulatory Decision Process, 2007)

Toxicology The study of the adverse effects of chemicals on living organisms. (SRA, 2007)
Toxicology: The study of harmful interactions between chemical, physical, or biological agents and biological systems. (USEPA, 2007b)

Trace A very small amount of a material. Usually used in reference to concentrations which are on the order of or less than 1-10 parts per million. (SRA, 2007)

Transparency – The clarity and completeness with which data, assumptions and methods of analysis are documented. (Committee on Models in the Regulatory Decision Process, 2007)

Trophic Level A functional classification of taxa within a community that is based on feeding relationships (e.g., aquatic and terrestrial plants make up the first trophic level, and herbivores make up the second). (USEPA, 2007c) (USEPA, 2007a)

Type I Error Rejection of a true null hypothesis. (USEPA, 2007c)

Type II Error Acceptance of a false null hypothesis. (USEPA, 2007c)

Uncertainty factor Reductive factor by which an observed or estimated no-observed-adverseeffect level (NOAEL) is divided to arrive at a criterion or standard that is considered safe or without appreciable risk. Related terms: Assessment factor, Safety factor (WHO, 2004)

Uncertainty/Variability Factor (UFs): One of several, generally 10-fold, default factors used in operationally deriving the RfD and RfC from experimental data. The factors are intended to account for (SRA, 2007) variation in susceptibility among the members of the human population (i.e., inter-individual or intraspecies variability); (Committee on Models in the Regulatory Decision Process, 2007) uncertainty in extrapolating animal data to humans (i.e., interspecies uncertainty); (NATIONAL RESEARCH COUNCIL, 1994) uncertainty in extrapolating from data obtained in a study with less-than-lifetime exposure (i.e., extrapolating from subchronic to chronic exposure); (USEPA, 2007c) uncertainty in extrapolating from a LOAEL rather than from a NOAEL; and (WHO, 2004) uncertainty associated with extrapolation when the database is incomplete. (USEPA, 2007b)

Unit Risk: The upper-bound excess lifetime cancer risk estimated to result from continuous exposure to an agent at a concentration of 1 µg/L in water, or 1 µg/m3 in air. The interpretation of unit risk would be as follows: if unit risk = 2 x 10-6 per µg/L, 2 excess cancer cases (upper bound estimate) are expected to develop per 1,000,000 people if exposed daily for a lifetime to 1 µg of the chemical in 1 liter of drinking water. (USEPA, 2007b)

Upper bound: A plausible upper limit to the true value of a quantity. This is usually not a true statistical confidence limit. (USEPA, 2007b)

Uptake A process by which materials are transferred into or onto an organism. (USEPA, 2007c)

Vadose Zone The vadose zone is the area between the surface of the land and the surface of the water table in which the moisture content is less than the saturation point and the pressure is less than atmospheric. The openings (pore spaces) also typically contain air or other gases. (USEPA, 2007c)

Vital Capacity (VC): The maximum volume that can be exhaled in a single breath (TLC-RC). (USEPA, 2007b)

Water pollution The addition of sewage, industrial wastes, or other harmful or objectionable material to water in concentrations or in sufficient quantities to result in measurable degradation of water quality. (SRA, 2007)

Water quality criteria Levels of pollutants in bodies of water that are consistent with various uses of water, i.e. drinking water, sport fishing, industrial use. (SRA, 2007)

Work injuries Those which arise out of and in the course of gainful employment regardless of where the accident occurs. Excluded are work injuries to domestic servants and injuries occurring in connection with farm chores which are classified as home injuries. (SRA, 2007)

Workers All persons gainfully employed, including owners, managers, other paid employees, the self-employed, and unpaid family workers, but excluding domestic servants. (SRA, 2007)