Management of uncertainty in safety cases and the role of risk

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Deep geological repositories aim to protect humans and the environment from the hazards associated with long-lived radioactive waste over timescales often up to several thousand or even a million years. Radioactive waste management thus involves a unique consideration of the evolution of the waste and engineered barriers, and the interactions between these components and geological barriers over very long periods of time. Over long enough timescales, however, even the most stable engineered materials and geological environments are subject to perturbing events and changes that are subject to uncertainties. The uncertainties associated with the evolution of the disposal system have to be appropriately considered and managed throughout a repository development programme.

At each stage of a stepwise development programme, decisions should be based on appropriate levels of confidence about the achievability of long-term safety, with the current level of technical understanding established through uncertainty analysis. A safety case[1] is a key input to support the decision to move to the next stage in repository development. A key output of the safety case is the identification of uncertainties that have the potential to undermine safety. The connection therefore needs to be made between key uncertainties that have been identified and the specific measures or actions that will be taken to address them, especially with regard to the R&D programme, in order to eventually arrive at a safety case that is adequate for licensing. Explicit treatment of uncertainties is thus an essential part of building confidence in the safety case. Confidence in the safety case is supported by a reliable safety assessment with a clear statement on data quality, clear justifications of assumptions and discussion of the sensitivities of the system performance to uncertainties. The uncertainties and the potential for reducing them in subsequent development phases should therefore be described in the safety case at each stage.

There is a clear consensus among all national programmes on the importance of managing uncertainties in a safety case. Managing uncertainties and establishing levels of confidence can be approached in different ways. This requires a clear classification of the uncertainties since a large range of uncertainties are to be handled. Various classifications of uncertainty exist – such as epistemic uncertainties, uncertainties due to natural variability, and randomness – and the concept of uncertainty classification is both widely used and judged as necessary for performing uncertainty analyses. One part of the overall uncertainty management process is the evaluation of quantifiable uncertainties in a quantitative assessment of system performance. However, since not all uncertainties can be quantified, the use of other elements of information making up a safety case, such as complementary, qualitative lines of evidence, will also contribute to the uncertainty management

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process (NEA, 2004). Uncertainty management consists of understanding the potential implications of uncertainties, and in some cases planning to minimise these potential effects through the site selection process and design adaptations. Other issues, including policy, social context, availability of resources and decision-making timetables, also affect choices.

The presentation of a safety case will place most emphasis on the evaluation and argumentation of the expected performance of a waste management facility. However, making the case for the expected performance requires an illustration of performance in its uncertainty context while taking into account the current stage of system development.

Previous NEA activities on uncertainty issues

One of the earliest NEA activities on uncertainty issues was a meeting in Seattle in 1987 at which the importance of treating uncertainties in assessments of post-closure performance of disposal facilities was highlighted. This early recognition of the issue was developed through a series of NEA meetings and workshops in subsequent years. The Probabilistic Safety Analysis Group (PSAG) played an important role in encouraging debate of different approaches, and also organised a series of code inter-comparison exercises (NEA, 1997a). Other key activities include initiatives by the Integrated Performance Assessment Group (IPAG) (NEA, 1997b, 2002a); workshops on confidence building (NEA, 1999) and the handling of timescales (NEA, 2002b); and the ongoing development of the Safety Case Brochure (NEA, 2004).

These activities have led to some broad conclusions about how uncertainties should be treated in a safety case:

- The safety case informs decisions at each stage of a step-by-step decision-making process. There is therefore a trend towards safety cases providing a statement on why there is confidence in the results presented, and on the sufficiency of the safety case for the decision at hand. With that perspective, such a statement should acknowledge the existing uncertainties, their significance at the present stage of assessment, and the future steps required to reduce uncertainty.
- Uncertainties should be recognised as an inevitable aspect of radioactive waste management systems, and these uncertainties will increase with the timescale considered.
- Uncertainties should be treated explicitly, and a systematic approach will aid understanding.
- A combination of deterministic and probabilistic approaches may be appropriate. Decision making is not based on a numerical value for uncertainty, and there is a need to clarify the role of each approach in the safety case.
- A range of scenarios needs to be considered in order to explore uncertainties. The issue of human intrusion has a special place within the scenarios considered.
- A range of arguments is important in treating uncertainties and developing a safety case. In particular a mixture of quantitative and qualitative arguments will engender confidence in both the provider and the reviewer. Overall, the safety case can best fulfil the requirements of decision making by including a statement on why there should be confidence in the analysis of performance and associated uncertainties.

The 2004 workshop on the management of uncertainty

To build upon the lessons learnt from the earlier activities and workshops and to provide a forum for a focused discussion on the handling of uncertainty and risk, the Integration Group for the Safety Case (IGSC) decided to organise a workshop on the Management of Uncertainty in Safety Cases and the Role of Risk. The workshop was held in Stockholm on 2-4 February 2004 and hosted by the Swedish Institute for Radiation Protection (SSI). The overall aim of the workshop was to create a platform in order to better understand different approaches to managing uncertainty in post-closure safety cases and regulatory approaches in different national waste management programmes. The aims of the workshop were:

- to identify common elements in different approaches to managing uncertainty;
- to discuss different approaches to setting regulatory standards for regulatory review;
- to facilitate information exchange and to promote discussion on different technical approaches to the management and characterisation of uncertainty and on the role of risk;
- to explore the merits of alternative approaches to risk-informed decision making; and
- to identify the potential for further developments of methods or strategies to support the management of uncertainties.

The NEA prepared a synthesis of the workshop, which was published in proceedings (NEA, 2005). The main findings may be summarised as follows.

What is risk?

Diversity definitions are sometimes adopted for terms such as "risk". The word "risk" could be interpreted as having different meanings for different

end-users (nuclear power plants, waste management organisations...), and a set of characteristics for which alternative approaches or viewpoints exist: objectivist/realist (regards risks as real) vs. constructionist (regards risk as a mental construct); quantitative vs. qualitative; and different mathematical formulations [e.g. probability times consequence; expected (negative) utility; and open formulations]. For technical experts, "risk" often means the product of probability and consequence. In public discussion risk may mean only the probability (of a negative consequence), although the consequences may be of most interest to the public. Both "constructed" (perceived) risk and "realist" risk do matter and the public may be concerned about both. As an example, in Andra's usage, "risk" is defined as the characterisation of a potential danger in terms of both probability and importance. The product of both is rarely considered. Therefore, such expressions as "the probability of a risk" or "the importance of a risk" refer to two independent variables. "Risk", in such expressions as "risk analysis", refers to the methods used in the field of both nuclear and non-nuclear industry, to identify potential sources of danger and rank them in terms of importance.

The following additional definitions were suggested:

- risk-based approach: "regulatory decision making solely based on the numerical results of a risk assessment";
- risk-informed approach: "risk insights considered with other factors";
- deterministic approach: "the use of fixed values in modelling for characterisation of uncertainty";
- probabilistic approach: "characterisation of uncertainty with probabilistic distribution functions as input to modelling";
- risk: "consequence times probability of occurrence".

A general observation from the workshop discussions was that differences in the interpretation of key terms and concepts may hamper a good discussion and understanding of the national regulatory and assessment approaches. Hence, it was concluded that clear definitions, when making a safety case, are key to a successful dialogue with various stakeholders.

Regulatory approaches

There is no simple distinction to be made between regulations with risk or dose criteria. In particular, regulations requiring the calculation of dose for the normal or expected evolution may require an assessment of risk for less likely scenarios. Also, regulatory guidance requiring the calculation of risk for natural events and processes may not require an assessment of probabilities for human intrusion scenarios. Regulators have similar expectations regarding the importance of treating uncertainty whatever the regulatory end-point. Although expectations regarding the evaluation and presentation of uncertainties do vary depending on the end-point used, there are similar expectations regarding the use of supporting arguments, transparency and traceability, justification of assumptions and other qualitative aspects of treating uncertainties, whether the end-point is dose or risk.

Regulators see interactions with implementers ahead of the licensing process as an opportunity to identify critical issues, to resolve differences in approach and to reduce the resources and time required for review of a license application. Overall, regulatory expectations are for safety cases that are risk-informed rather than risk-based.

Assessment of uncertainty and risk

All assessments must address the components of the risk triplet: What can happen? What are the consequences? and What is the likelihood? Approaches differ in the extent to which probabilities are assigned explicitly (e.g., as probability density functions) or implicitly (e.g., through the selection of likely and less likely scenarios). The explicit use of probabilities to characterise uncertainty is not restricted to calculations of risk. Overall, there is a role for deterministic and probabilistic calculations in both risk- and non-risk-oriented assessments.

A key difference between the alternative approaches to the treatment of uncertainty is the extent to which uncertainties are aggregated or disaggregated. Disaggregated analyses are of value for developing detailed system understanding and providing information for design choices and research

priorities. Aggregated analyses may be of value in assessing scenarios that have a similar effect on safety functions, and are required under some regulatory approaches.

All types of uncertainty assessment require the use of expert judgements. There is consensus as to the need for a formal process for documenting and using such judgements. The use of experts to quantify information is favoured in situations where there are conflicting sources, laboratory-scale data but field-scale uncertainties, limited evidence or information on uncertainties, and unverified models and procedures. Expert judgements attempt to record the information available at a particular time, and as with other approaches, may need to be updated as more information becomes available. The selection of experts is important, and the selection process may receive as much scrutiny as the judgements themselves. Perhaps the most unacknowledged difficulty in obtaining expert judgements is the specification of the explicit issues to be addressed.

Risk dilution, or risk dispersion, is recognised as a potential issue in some assessments depending on the methodology used and on the regulatory context. Risk dilution may under certain conditions lead to an apparent lowering of the calculated risk, for example, in connection with the evaluation of high consequence events with a large uncertainty as to their time of occurrence. There is no simple mathematical solution to this issue, which is related in part to regulatory philosophy as to who should be protected and the definition of the exposed group. The overall consensus at the workshop was that the proponent should explore potential risk dilution effects, and that regulators need to be aware of such effects and consider developing guidance as to acceptable approaches.

Risk management and decision making

The decision-making process differs between countries, reflecting different legal frameworks and cultural traditions. The role of stakeholders in decision making also differ between countries. In all cases, early dialogue, together with transparency and openness, are recognised as important. Different end-users of information from a safety case may attach different meanings to the term risk. Results of risk assessments should therefore be set in a broad perspective so as to inform as wide a range of end-users as possible. Risk assessment is the initial stage of a sequence that also includes decision making and risk management. In the context of the safety of radioactive waste disposal facilities, the extent to which risks can be affected after repository closure is debatable. Potential risk management approaches include stepwise decision making, reversibility/retrievability and monitoring. No consensus was reached among workshop participants as to the role of these approaches, but it was concluded that an iterative coupling of risk assessment and risk management options would be of value.

A continued dialogue

A continuation of international dialogue between regulators and implementers in the area of uncertainty and risk management may be envisaged to further explore alternative regulatory approaches and to share experiences with different assessment tools and approaches. Risk assessment methodologies for disposal facilities are converging as programmes mature, but a continued dialogue would help in developing an understanding of the different approaches, with their associated strengths and drawbacks. Such an understanding would also help to provide assurance to stakeholders and decision makers that any particular approach is fit for its intended purpose. ■

Note

1. A safety case is a collection of arguments, at a given stage of repository development, in support of the long-term safety of the repository.

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