

Consultancy Specifications

NCP Project on 'Regulatory Styles'

Background and Issues

Performance-based regulation is the opposite of the prescriptive or command and control type regulations. Instead of prescribing both the objectives and the rules, regulations would only specify the desired outcomes. Performance-based approaches may provide greater flexibility and encourage innovation. Government agencies may spend fewer resources to write and update detailed rules. The over-generalisation of risks sometimes found in prescriptive regulations aimed to capture a wide range of situations and activities may be avoided.

However, performance-based approaches involve risk management by the industry. This can add costs to small businesses, which usually have limited resources to address flexible approaches or to conduct risk analysis. This may lead to decisions based on inadequate analysis or information.

For larger organisations such as major industrial users, national laboratories, teaching hospitals etc., which support their own radiation protection infrastructure, there is more room to manoeuvre and it could be argued that those who “own” the risk should “own” the responsibility to define the processes to achieve the performance outcomes. However, it could also be argued that performance-based approaches may be inappropriate for the activities of even large firms or corporations, which can afford to conduct their own risk assessment and management, if their activities require high levels of safety and may cause externalities that can adversely affect public health and safety.

In some cases, monitoring costs for government agencies may be higher than monitoring and enforcement systems employed in a prescriptive approach. This could be due to the lack of established standards or disagreements on whether the compliance model demonstrated by an industry participant is sufficient to achieve the outcomes specified in the legislation.

There is still a general reluctance in Australia to accept performance-based approaches for radiation protection. Submissions made to the NCP Review Team argued that businesses are profit motivated and would select low cost control systems and compromise safety standards. Respondents felt that defining acceptable levels of exposure and putting in place legislation to ensure that such levels are not exceeded might be a safer approach.

However, the Council of Australian Governments (COAG) calls on regulators to move away from overly prescriptive standards towards performance-based standards¹. According to COAG, regulations could reference standards or a number of standards and there should be no restriction on the use of other standards as long as objectives of the legislation are met. Nevertheless, COAG also cautions regulators that prescriptive requirements may be needed to ensure public health and safety in high-risk activities.

It is evident that any shift to performance-based approaches to achieve radiation protection objectives has to be approached very cautiously. Even if a performance-based approach is to be adopted for particular activities in radiation safety administration, this has to be gradual and only after a thorough analysis to determine which activities may be regulated through an outcome-based approach.

¹ *Principles and Guidelines for National Standard Setting and Regulatory Action by Ministerial Councils and Standards-Setting Bodies*, Council of Australian Governments, November 1997.

Where performance-based approaches are to be adopted, the implementation has to be accompanied by substantial efforts to educate the industry on risk analysis and management. A well-defined transition plan may be required to overcome the resistance to performance-based approaches. The transition to a performance-based approach could be aided by using a “dual track” method with either “safe harbour” or “waiver/variance” provisions in regulations².

“Safe harbour” provisions in performance-based regulations enable persons or businesses that do not have the resources to comply with the outcomes-based approach to elect to use certain rules or standards prescribed or referenced in the regulations. This enables those that prefer to comply with prescribed rules to have the option to do so while others use the performance-based approach. Alternately, regulations can continue to be prescriptive but may contain provisions that empower agencies to grant waivers or variances on a case-by-case basis to firms that demonstrate compliance through alternative means.

It is also possible for performance-based approaches to be mitigated in some circumstances by imposing prescriptive conditions in licences for the conduct of activities for which the applicant has not sufficiently demonstrated an ability to deal with all the risks of the activities that are to be licensed.

The NCP Review Team concluded that the analysis of activities that may be suitable for regulation by outcomes-based approaches might be done in a nationally uniform manner within the framework of the National Directory for Radiation Protection.

A related issue is the question of risk management. The NCP review considered a paper released by the Legislation Reform Working Group (LRWG) of the National Public Health Partnership (NPHP)³. The paper made certain recommendations on how public health legislation can be written to ensure that risk management is undertaken. Many of the recommended approaches are already present in existing radiation protection legislation. These include, licensing provisions, obligations to report mishaps, powers to inspect premises, powers to conduct inquiries, the use of standards and codes of practice and the defence of due diligence. The NPHP paper recommends that risk management principles should be entrenched in public health legislation to ensure that regulators and the regulated are compelled to analyse risks and hazards from policy formulation through to legislative action.

The NCP review concluded there was scope for radiation protection legislation to be improved through the application of risk management principles.

Supported NCP Review Recommendations

Recommendation 5: “Jurisdictions are to consider using performance-based approaches where appropriate (that is, description of outcomes rather than the prescription of required action) based on risk management principles and all applicable quality and process standards”.

² See *Improving the Cost Effectiveness of Government: Alternatives to Command and Control Regulation*, by Brian Mannix, OECD, May 1994 (as reproduced in *From Red Tape to Results*, NSW Cabinet Office, February 1995).

³ *The Application of Risk Management Principles in Public Health Legislation*, Legislation Reform Working Group, National Public Health Partnership, June 2000.

Recommendation 6: “Jurisdictions are to incorporate risk management principles in the National Directory for Radiation Protection”.

Planned outcome

Lower costs to industry and regulators through outcome-based regulations and standards where appropriate.

Required outputs from consultant

The consultant is expected to identify all the risks that existing radiation protection legislation standards and codes of practice aim to treat and identify those risks that can be treated more efficiently with an outcomes-based approach. The consultant will develop principles for regulatory authorities to apply in reviewing their legislation to move towards an outcomes-based approach based on regulatory best practice.

As a move towards an outcome-based approach for certain identified risks will provide the industry with greater flexibility to comply with outcome-based regulations, there is a need for the industry to be provided with the necessary risk management tools to ensure that they can comply with outcome-based regulations. Bearing in mind that risk management standards and methodology are already commercially available to the industry, the consultant is expected to develop broad and generic risk management principles that are focussed on the radiation risks identified as suitable for treatment through an outcomes-based approach.

Expected start and end dates of consultancy

Start date: Date of execution of contract.

End date: To be proposed by tenderer.

Selection Criteria

- Extensive knowledge and experience in the area of radiation health and protection.
- Extensive experience in undertaking regulatory review projects for government departments or agencies.
- Experience in risk management and its practical application.
- Ability to complete short-term public sector projects within tight deadlines.

Closing date for expressions of interest:

28 February 2003