

Nuclear regulatory decision making

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Nuclear safety regulators are continuously faced with making a wide variety of decisions. Some of these may be made on the regulator's own initiative, for example a regulation on new reporting requirements, but the large majority of decisions are made in response to stimuli from outside the organisation. A new CNRA report¹ has found that in all decision-making scenarios, whether difficult or straightforward, the nuclear regulator will benefit from a structured decision-making framework.

Nuclear power programmes in OECD countries have matured over their four decades of commercial operation; this maturation has brought many improvements in safety through backfits in technology as well as programmes and improvements in operational performance of nuclear power plants generally. In parallel with these changes in nuclear plants' performance, safety regulation of nuclear power plants has matured, most notably in the use of new safety analysis methods such as probabilistic safety analysis (PSA); in the regulatory responses to new information

and insights from operating experience, especially from the accidents at Three Mile Island and Chernobyl; in the consideration of human factor and organisational impacts upon nuclear safety; and in an increased emphasis on quality management systems.

It has been recognised for some years that the nature of the relationship between the regulatory body and the operator can influence the operator's safety culture at a plant, either positively or negatively.^{2,3} An important factor affecting the relationship between the regulator and the operator is the nature of the

regulator's decision-making process. In light of these insights, the NEA Committee on Nuclear Regulatory Activities (CNRA) judged that it was an appropriate time to examine the broad issue of regulatory decision making. That judgement was the basis for deciding to prepare a report providing an international consensus on the integrated decision-making process. To pursue this objective, an expert group was formed with senior-level regulators.



Types of regulatory decisions

Perhaps the bulk of the decision cases that come before a regulator are straightforward issues, but that does not mean that they are unimportant or that the regulator does not

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need to consider them carefully. Rather, it simply means that there are substantial precedents of case histories and adequate time for the regulator to define the issues clearly, to analyse alternative actions and to involve the appropriate stakeholders. In other words, for such issues there is ample opportunity for the regulator to implement its deliberative, structured decision-making process.

Some of these decision issues will be more challenging for the regulator. They are frequently characterised by unexpected circumstances, lack of complete information, uncertain or contradictory information, disagreement among the safety experts, a real or perceived urgency to make a decision, an incomplete understanding of the consequences of a decision, or all of the above. Adding to these difficulties is often the concern in the mind of the regulator that its decision-making actions may have profound effects not only on public safety but on the public's perception and confidence in the regulatory body itself.

Whether a decision issue is straightforward or difficult, a nuclear regulator will benefit by having a structured decision-making framework and by having experience in following its procedures.

Basic principles for regulatory decision making

A fundamental tenet of nuclear safety is that the operator has the responsibility for safely operating its nuclear power plant(s). It is the nuclear regulator's responsibility to oversee the operator's activities in order to ensure that the plant is operated safely. Nothing the regulator does should ever diminish that

fundamental distinction in roles between the operator and regulator. A regulator's decisions must be grounded in the nation's laws and the regulations and standards that implement those laws. But even further, the regulatory body should promote safety by setting a good example in its own performance.

When approaching regulatory decisions several basic principles can be applied such as assessing safety significance, gathering sufficient information to make an informed decision, seeking input from outside stakeholders, maintaining consistency in decisions, and most importantly, acting as a competent, professional, independent body that makes regulatory decisions on the basis of protecting safety, security and the environment.

In making a decision on a difficult issue, the regulator will have to consider how the decision will appear in retrospect if it turns out to be wrong or not to have the desired outcome. In difficult cases there will frequently be pressure on the regulator from many sources, so the regulatory body should ask itself some questions before rendering a final decision:

- Is there a clear safety basis for the decision?
- Is there a clear legal basis for the decision?
- Were normal procedures followed?
- Were all stakeholder views considered?
- Was there due diligence used in gathering the necessary information?
- Is the decision consistent with earlier precedents?
- Has the regulator ensured that the decision was not made prematurely, bypassing some regulatory require-

ments to satisfy the operational needs of the plant operator?

This questioning is not meant to suggest that the regulator should allow itself to become paralysed by concerns that a decision may not turn out well. Rather, it is a reminder that the regulatory body should assure itself that it has approached the decision following its procedures in a structured manner, has considered all relevant input, has used sound safety principles and has not appeared to be unduly pressured in making the decision.

Criteria for regulatory decisions

Current, comprehensive and clear regulations are essential for a good decision-making process, but these cannot cover all the aspects of the issues that a regulator will face. There will always be questions of completeness, differing interpretations and unexpected situations. For these reasons a regulatory body will usually be guided by broad criteria that form the foundation of its safety philosophy.

One of these criteria is the level of safety and environmental protection to be required by the regulator. There are various statements on the basic level of protection criterion in OECD countries, but they all acknowledge that it is not possible to achieve zero risk in nuclear activities. Some of the criteria for the basic level of protection in OECD countries are:

- no unreasonable risk,
- adequate protection of public health and safety,
- risk as low as reasonably practicable,
- safety as high as reasonably achievable,



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Some of the criteria for the basic level of protection in OECD countries include adequate protection of public health and safety, risk as low as reasonably practicable, and safety as high as reasonably achievable.

- risk limited by use of best technologies at acceptable economic costs.

A related question is what criterion should be used for the level of assurance that the required safety criteria are met? Here again, there are various formulations of the criterion for the level of assurance in OECD countries, but they all recognise that absolute assurance cannot be achieved. Most countries have some variation of a “reasonable assurance” criterion.

These criteria are seen to be qualitative aspirational criteria rather than quantitative safety requirements that must be met. In practice, they are what some may call “revealed standards”. That is, the sum of perhaps hundreds of case history decisions and case law over several years will yield a working definition of what these criteria mean.

Beyond these qualitative aspirational criteria a regulatory body may adopt quantitative safety goals – for example, numerical goals for protecting

the health and safety of people living near nuclear power plants. In order to be more useful in practical decision making, the health goals are often supplemented by numerical goals for core damage frequency (CDF) and large, early radioactive release frequency (LERF). Clearly the use of these latter safety goals requires the production and maintenance of high-quality, plant-specific PSAs as well as operator and regulatory staffs proficient in PSA methodology. Although the promulgation and use of quantitative safety goals is fairly common among OECD regulatory bodies, these criteria are generally regarded as not appropriate for use as the sole basis for making regulatory decisions. Instead, the quantitative safety goals are best used as guidelines by the regulator to supplement other regulatory criteria.

A fundamental principle for safety regulators is the practice of conservative decision making. This is exemplified by the traditional defence-in-depth safety philosophy. Since the

earliest days of commercial nuclear power, regulators have embraced defence in depth to require multiple layers of protection to prevent accidents and to mitigate their consequences. The use of defence-in-depth principles and safety margins have been, and continue to be, effective ways to account for uncertainties in equipment and human performance. As more operating experience and improved safety analysis methods give us a deeper understanding of nuclear plant safety, safety margins and their uncertainties, it may be possible to reduce overly conservative margins or to add margins where needed.

Elements of the regulatory decision-making process

The basic principles and criteria for regulatory decision making should be embodied in a practical, integrated framework that regulators can use in their daily activities. The framework need not be rigid but must be consistent with national

laws, customs, international treaties, regulations and the internal policies of the regulator. The basic elements of an integrated framework are to (a) clearly define the issue, (b) assess the safety significance, (c) determine the laws, regulations or criteria to be applied, (d) collect the relevant information and data, (e) judge the expertise and the resources needed, (f) agree on the analyses to be performed, (g) assign priority to the issue among the other tasks of the agency, (h) make a well-informed decision, and finally (i) write a clear decision and its basis, and publish the decision when needed.

The elements above are not meant to be followed in sequential order; in fact, several of them can be conducted in parallel and some could even be omitted in certain situations. The rigour and depth with which the elements are followed should generally be proportionate to the safety and regulatory significance of the issue being considered.

The regulator's responsibility does not end with the decision and its publication. Clearly, there are follow-up actions a regulator should take to ensure that its decision is implemented. Likewise, the decision and its basis must be stored in the regulatory body's established document control system. This will enable effective follow-up actions and will facilitate retrieval of the information to assist in future decision making.

Implementing the elements of the decision-making process

The regulatory body can use the elements above to develop a regulatory decision-making framework and to integrate it into its overall management

system, similar to its planning and budgeting processes, taking into account the national laws, customs and internal policies of the regulator. In this way the decision-making process will over time become part of the culture of the regulatory body's organisation.

The integrated decision-making framework will cover the great majority of decisions faced by a regulatory body. But every regulator will encounter special situations that are unique in some aspect or that do not fit neatly into the framework outlined above. The CNRA report on *Nuclear Regulatory Decision Making* provides advice on how best to approach a number of these types of situations, notably: decision making in the face of uncertainties, handling safety culture issues, facing differing opinions, considering information from safety advisory bodies and using risk information in regulatory decisions.

Communicating regulatory decisions

In any discussion of the basic principles and criteria that a safety regulatory body should consider when making a decision that can affect a wide range of stakeholders, it is necessary to keep in mind how those stakeholders might view the decision and its rationale. In this regard, it is important for the regulatory body to consider how its decisions are communicated to its stakeholders.

For many of the difficult issues facing the regulator, the outside party most directly affected will be the plant operator. In some complex or contentious cases, the regulator may want to explain the written decision in a meeting with the operator, perhaps in a meeting open to the public.

Conclusion

There is no guide or handbook that will tell a regulator how to make a proper decision, especially for difficult cases where the issues may be contentious and the circumstances unique. That is the value of having a decision-making framework to fall back on. Beyond that, the regulator will have to rely on its experience and good judgment, keeping in mind that safety, and, to some degree at least, the credibility of the regulatory body may be at stake in the regulatory decision and the way it is made. ■

Notes

1. The CNRA booklet on *Nuclear Regulatory Decision Making* was published this spring and is available on the NEA website at www.nea.fr and upon request from the NEA Secretariat. Its contents formed the basis for this article.
2. NEA (1999), *The Role of the Nuclear Regulator in Promoting and Evaluating Safety Culture*, OECD/NEA, Paris.
3. NEA (2000), *Regulatory Response Strategies for Safety Culture Problems*, OECD/NEA, Paris.