

Nuclear Regulation

ISBN 92-64-01051-3

Nuclear Regulatory Decision Making

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NEA No. 5356

NUCLEAR ENERGY AGENCY
ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT

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NUCLEAR ENERGY AGENCY

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The mission of the NEA is:

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- to provide authoritative assessments and to forge common understandings on key issues as input to government decisions on nuclear energy policy and to broader OECD policy analyses in areas such as energy and sustainable development.

Specific areas of competence of the NEA include safety and regulation of nuclear activities, radioactive waste management, radiological protection, nuclear science, economic and technical analyses of the nuclear fuel cycle, nuclear law and liability, and public information. The NEA Data Bank provides nuclear data and computer program services for participating countries.

In these and related tasks, the NEA works in close collaboration with the International Atomic Energy Agency in Vienna, with which it has a Co-operation Agreement, as well as with other international organisations in the nuclear field.

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FOREWORD

The Committee on Nuclear Regulatory Activities (CNRA) of the OECD Nuclear Energy Agency (NEA) is an international body made up of senior representatives from nuclear regulatory bodies. The Committee guides the work of the Agency concerning the regulation, licensing and inspection of nuclear installations with respect to safety. It acts as a forum for the exchange of information and experience, and for the review of developments which could affect regulatory requirements.

Following the Joint* Workshop on Regulatory Decision-making Processes held in October 2002 in Switzerland, the CNRA undertook the production of a definitive report providing an international consensus on the integrated decision-making process for nuclear regulation. To pursue this objective, similar to the work done in recent years on nuclear regulatory challenges and other nuclear safety issues, an expert group was formed with senior-level regulators.

This report discusses some of the basic principles and criteria that a regulatory body should consider in making decisions and describes the elements of an integrated framework for regulatory decision making. It is not, however, a handbook or guide on how to make regulatory decisions. In preparing the report, the task group reviewed and incorporated information from a wide array of documents produced by the NEA, its member countries and other international organisations, such as the International Atomic Energy Agency (IAEA) Safety Series reports.

* The joint organisers were: the Swiss Federal Nuclear Safety Inspectorate (HSK), the International Atomic Energy Agency (IAEA) and the OECD Nuclear Energy Agency (NEA).

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TABLE OF CONTENTS

Foreword	3
1. Introduction	7
2. Types of Regulatory Decisions	11
3. Basic Principles for Regulatory Decision Making	13
4. Criteria for Regulatory Decisions	17
5. Elements of Regulatory Decision-making Process	19
6. Implementing the Elements of Decision-making Process.....	23
7. Communicating Regulatory Decisions.....	31
8. Summary	33

1. INTRODUCTION

As the nuclear programmes in OECD countries have matured over the four decades of commercial nuclear power operation, this maturation has brought many improvements in safety through backfits in technology and programmes and improvements in operational performance of nuclear power plants generally. In parallel with these changes in nuclear plants' performance there has been a maturation in the safety regulation of nuclear power plants, most notably in the use of new safety analysis methods like 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 nuclear 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.^{1,2} 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 Committee on Nuclear Regulatory Activities (CNRA) of the OECD Nuclear Energy Agency has judged that it is an appropriate time to examine the broad issue of regulatory decision making. That judgement is the basis for preparing this report.

This report is not a handbook or guide on how to make regulatory decisions. Each nation's laws, customs and administrative processes are unique, and the range of circumstances potentially facing a regulatory body is so great that a handbook approach is simply not practical. Instead, this report attempts to discuss some basic principles and criteria that a regulatory body should consider

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1. NEA (1999), *The Role of the Nuclear Regulator in Promoting and Evaluating Safety Culture*, OECD, Paris.
 2. NEA (2000), *Regulatory Response Strategies for Safety Culture Problems*, OECD, Paris.

when approaching the wide range of decisions faced in the course of its daily responsibilities.

The fundamental objective of all nuclear safety regulatory bodies is to ensure that nuclear utilities operate their plants at all times in an acceptably safe manner.³ In meeting this objective, the regulatory body should strive to ensure that its regulatory decisions are technically sound, consistent from case to case, and timely. In addition, the regulator must be aware that its decisions and the circumstances surrounding those decisions can affect how its stakeholders, such as government policy makers, the industry it regulates, and the public, view it as an effective and credible regulator. In order to maintain the confidence of those stakeholders, the regulator should make sure that its decisions are transparent, have a clear basis in law and regulations, and are seen by impartial observers to be fair to all parties.

In meeting these goals, the regulator should be guided by an integrated framework for making regulatory decisions. The framework can be adapted to different types of decision-making processes but it must be consistent with national laws, customs, international treaties, regulations and internal policies of the regulator. The basic elements of such an approach to decision making 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 workload 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.

Not every issue facing a regulator can be addressed in such a structured manner. There will be unexpected events, urgent situations, lack of information, uncertain information, difficult cases with strong differing opinions, and other challenges. Nonetheless, having recourse to a decision-making framework will benefit the regulator by fostering consistency and efficiency. By now all regulatory bodies have large case histories of past decisions and can rely on those precedents for handling similar issues. The nuclear plant operators will also see the benefits from a stable and consistent regulatory decision-making framework. Other stakeholders may see the benefits and thereby have enhanced confidence in the regulator's decision-making process by knowing that it has a structured framework.

3. NEA (2002), *Improving Versus Maintaining Nuclear Safety*, OECD, Paris.

A prime example of decision making facing a nuclear regulator is whether to require a safety backfit. This subject has been discussed extensively in a previous NEA report.⁴

In view of the background above, the purpose of this report is to describe the basic principles, criteria and elements of nuclear regulatory decision making.

While focused on the regulation of nuclear power plants, the principles in this report apply to the regulation of other nuclear facilities as well, and the principles can be considered by each regulatory body when structuring its unique decision-making framework. It follows, therefore, that the audience for this report is primarily nuclear regulators, although the information and ideas may also be of interest to nuclear operating organisations, other industry organisations and the general public.

Although this report stresses the importance of the regulatory body having a structured decision-making process, we must keep in mind that it cannot substitute for the experience and judgement of the senior managers in a regulatory body gained over many years in facing diverse situations and making regulatory decisions. Likewise, the decision-making framework should not be so rigid that it does not allow room for individual judgement and discretion on the part of inspectors and managers in making regulatory decisions.

4. NEA (2002), *The Regulatory Challenge of Judging Safety Backfits*, OECD, Paris.

2. TYPES OF REGULATORY DECISIONS

A nuclear safety regulator may be faced with making a decision for any number of reasons. 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. The regulatory decision-making framework discussed in this report is meant to apply to the full range of decisions that a nuclear regulator faces.

Examples of the types of decision issues facing a regulator are the following:

- Setting regulatory requirements including consensus standards.
- Granting licenses and permits.
- Reviewing plant modifications in response to operator requests.
- Reviewing fuel design changes and fuel operating limits.
- Reviewing calculation methods.
- Taking enforcement actions in response to inspection findings.
- Responding to stakeholder requests for regulatory action.
- Reviewing decommissioning plans.
- Reviewing new plant designs.
- Responding to serious operating events or accidents.
- Making recommendations for action during emergencies.
- Taking action to deal with perceived adverse operating trends.

- Dealing with perceived safety culture problems at a plant.
- Dealing with safety issues raised by new information.
- Dealing with generic safety issues affecting several plants.
- Deciding on the need for additional safety research.
- Dealing with legal changes to the regulatory framework.
- Dealing with disagreeing opinions within the regulatory staff or its technical safety advisors.
- Dealing with disagreements with the operator or other outside organisations.

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

3. BASIC PRINCIPLES FOR REGULATORY DECISION MAKING

A fundamental tenet of nuclear safety is that the operator has the responsibility for safely operating a nuclear power plant. It is the nuclear regulator's responsibility to oversee the operator's activities in order to assure that the plant is operated safely. Nothing the regulator does should ever diminish that fundamental distinction in roles between the operator and regulator.

To meet its responsibility, the regulatory body will have in place a set of regulations that the operator must follow in order to operate the plant safely, to assure the security of nuclear materials, to manage safely radioactive waste and spent nuclear fuel, and to protect the environment. The regulatory body will make regular inspections at a plant site to assure that plant activities are conducted in a safe manner and, in case they are not, will act to see that the operator takes corrective actions to bring the plant into compliance with regulations and the plant's safety envelope. In the course of its normal activities, the regulatory body will be faced with the need to make frequent decisions of the types discussed in the previous section. In making these decisions, the regulator should be guided by the basic principles embodied in an integrated framework for making regulatory decisions. Having such a structural process will foster consistency and efficiency as well as provide enhanced stakeholder confidence in the decisions.

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. This means, for example, the regulatory body should be technically competent, set high safety standards for itself, conduct its dealings with operators in a professional manner, have clear guidelines for its safety reviews and inspections, have clear acceptance criteria, and show good judgement in its regulatory decisions. In the spirit of improving regulatory performance, the regulatory body may consider conducting periodic self-assessments or requesting external assessments of its performance.

When approaching regulatory decisions, the regulator must make an early assessment of the safety significance of the issues. This action is necessary to give priority attention to the most serious risks and to guide the proportionality of the regulatory action to be commensurate to the risks involved.⁵ Most regulators find that assessing the safety significance of an issue can be improved through the use of PSA insights. This topic will be discussed later in this report.

Once a judgement has been reached on the safety significance of an issue, the regulator should gather sufficient information to make an informed decision. This activity may be limited by the time available. In some cases, regulatory decisions must be made urgently with little time for extensive data gathering, for instance when making protective action recommendations to local authorities during emergencies at a nuclear plant. In most cases, however, there will be sufficient time to collect adequate information on the issue. The regulatory body should not let itself be rushed into a premature decision by pressures from interests that may conflict with safety.

A regulator may find it useful to have internal policy guidelines on when to seek input from outside stakeholders. The operator's input should be sought on decisions affecting the operator's plant, if it has not already been volunteered, and in many cases it may be appropriate to seek public input as well. On broader generic issues, like changes to radiation protection requirements, the regulator should obtain the views of other government agencies and national and international experts, in addition to the interested public. When the regulator is seen to consider a broad range of views, the regulator's ultimate decision will generally have enhanced credibility and acceptance by its stakeholders.

The regulator should be particularly sensitive to the need to maintain consistency in its decisions. That is, when faced with similar safety issues and similar circumstances, the regulator should render similar decisions or clearly explain why a different decision was made. If operators consistently see that they are treated differently on similar issues, they may view the regulator as arbitrary and may lose respect for the professionalism of the regulatory body. A good way to promote consistency is to maintain transparency in decision making – that is, being open in how decisions were arrived at and what their implications are. This can best be done by promptly producing a clear written basis for the decision.

5. HSE (2001), *Reducing Risks, Protecting People* – HSE's decision-making process, United Kingdom.

The credibility of the regulator in the eyes of the public depends, in part, upon the independence of the regulator to make decisions without pressure from interests that may conflict with safety. Within the government, the regulatory body should have a clear separation of responsibilities from those organisations responsible for generating electricity and for developing nuclear technologies. That is, the regulatory body should be seen by the public 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 pressures 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 assured that it was not hurried into bypassing some regulatory requirements 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.

4. CRITERIA FOR REGULATORY DECISIONS

It is axiomatic that the decisions of a nuclear safety regulator must be grounded in its national laws, regulations, codes, standards and policies. Current, comprehensive and clear regulations are essential for a good decision-making process, but these cannot cover all 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 of the basic level of protection criterion among OECD countries, but they all acknowledge that it is not possible to achieve zero risk in nuclear activities. Some of these criteria for 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”.
- “Limit risk 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 level of assurance among OECD countries, but they all recognise that absolute assurance cannot be achieved. Most countries have some variation of a “reasonable assurance” criterion.

These are seen to be qualitative aspirational criteria rather than quantitative safety requirements that must be met. In practice these criteria 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 protection of 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. Rather, 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.

Nuclear safety regulators generally require that their basic level of protection criterion (e.g., “no unreasonable risk”) must be met regardless of cost or other considerations. When considering safety improvements beyond that level, there may come a point where a safety improvement may not be rationally justified after evaluating offsetting factors such as costs, worker radiation exposure, worker safety and equipment degradation through excessive testing. For this reason, the regulatory body’s integrated framework for decision making may include provision for considering these types of trade-offs. Whether this provision includes a formal quantitative cost-benefit methodology or a qualitative consideration of trade-offs is a policy matter for each regulatory body.

5. ELEMENTS OF REGULATORY DECISION-MAKING PROCESS

The basic principles and criteria for regulatory decision making discussed in the previous chapters 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 internal policies of the regulator. The basic elements of an integrated framework are discussed below.

1. Clearly define the issue

In most cases the regulatory issue will be straightforward, but in some difficult cases the issue will be more complicated. An example might be to determine which governmental agency has jurisdiction when an operator proposes to dispose of mixed waste containing both radioactive and chemically toxic materials. In such cases it is important that the issues are clearly defined before making a decision that may be inappropriate.

2. Assess the safety significance

In most cases the regulator's experience will tell it the safety significance of the issue, but in some cases further analyses will have to be done. An example might be an operator's request to delay the repair of service water pipe corrosion until the next refuelling outage. In such a case the regulator would have to decide whether the risk is serious enough to require an early shutdown or whether the plant can safely continue operating until the next refuelling outage to repair the service water pipe. Clearly the most safety significant issues should receive the regulator's priority attention.

3. Determine the laws, regulations, or criteria to be applied

An experienced regulator will generally know which criteria will govern the issue being faced. There may be situations, such as an apparent weak safety culture at a plant that is affecting performance, where the criteria do not explicitly cover the circumstances being considered. In these cases the regulator may need legal advice to be sure it is on a sound legal footing before taking

regulatory action. In all cases the regulator should review past case histories on similar issues and use these precedents to ensure consistent decision making. There may be instances where the regulator may deviate from its current criteria where new criteria based on new information are in preparation. In such cases the regulator should follow its established procedures for granting deviations.

4. Collect data and information

An early activity for the regulator is to assemble all of the relevant information pertaining to the decision. This may, for example, involve the operating history of the plant, recent event reports, and case histories of similar situations it has faced at other plants it regulates. The regulator might also want to contact other regulatory bodies for information and consider international sources and other industry organisations that may have relevant information. The regulator will have to judge the adequacy of the information available and, if there is an information gap, how best to proceed toward a regulatory decision. One possible conclusion by the regulator could be that more safety research is needed.

5. Judge the expertise and resources needed

For most of the decision cases that come before a regulator the expertise and resources needed will be well known from past experience. There may be more complex issues from time to time, for example an operator's request for approval to install a modern digital instrumentation and control system to replace an older analog system. If the regulator has not faced a similar situation before, it will be necessary to analyse carefully the skills and resources needed for the review, including expert resources outside the regulatory staff. It is important that such complex reviews be carefully planned in order to avoid disruptions to other regulatory decision schedules.

6. Agree on the analyses to be performed

After the safety issue and the regulatory criteria have been defined, the regulator must agree on the analyses to be performed. An example would be an operator's request to extend the fuel burnup limits. In such cases the regulator must be in agreement with the validity of the computer codes, the data, the acceptance criteria to be used in the analyses, and the operator's quality programmes. The regulator may choose to conduct an independent analysis, particularly in first of a kind situations.

7. Assign priority to the issue among the other workload of the agency

It can be expected that there will be many competing interests for a regulator's decision-making attention. A good regulatory practice would be to have an established set of work priority categories that may be publicly available for all stakeholders to see. Obviously, the most safety significant issues should have the regulator's highest priority. But all issues, particularly requests for action from outside organisations, deserve a timely decision. If the regulatory body finds that it has a chronic and growing work backlog, it may find it necessary to approach the government authorities and the legislature for additional resources.

8. Make the decision

Prior to reaching a final decision on an issue the regulator should be sure that it has sought appropriate stakeholder input. These stakeholders may include nuclear plant operators, nuclear organisations, national and local government authorities, public interest groups and the general public. In some urgent or highly technical situations it may not be practical to obtain broad stakeholder input, but it is a good regulatory practice to seek as broad an input to the decision-making process as practical. After reviewing the stakeholder input and analysing the facts against the relevant criteria the regulator must reach a decision. Clearly, where the issue involves safety, the regulator must assure that its basic protection criteria are met, above all other considerations. When considering safety improvement beyond the basic level of safety criteria, there may come a point where a safety improvement may not be rationally justified by the costs involved. The regulatory body's decision-making framework may include provisions for considering these types of trade-offs. Whether this provision includes a formal cost-benefit methodology or a qualitative consideration of trade-offs is a policy matter for each regulatory body.

9. Write a clear decision and publish it

In the interest of assuring transparency and future consistency in its decision-making process, the regulator should write a clear description of its final decision and its basis and may make it publicly available.

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. The rigor 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.

In the spirit of continuous regulatory improvement the regulator may want to add an element on lessons learned to its decision-making process. For issues of high regulatory significance, the regulator could conduct a self-assessment to consider the quality of how the decision-making process was conducted, the effect of the decision on safety, and the impact of the decision on stakeholders.

6. IMPLEMENTING THE ELEMENTS OF DECISION-MAKING PROCESS

The regulatory body can use the elements above to develop a regulatory decision-making framework and 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 or that do not fit neatly into the framework outlined above. The following discussions focus on some of those difficult decision-making situations that regulators may face from time to time.

Decision making in the face of uncertainties

Some of the most challenging decision-making situations for a regulator are when it is faced with an issue that is surrounded by uncertainties or lack of data or time pressures. A characteristic of these situations is that one may not be able to rely on a detailed safety analysis for the decision, and that is what makes them so difficult. There may be a number of reasons for these situations, for example:

- Operating experience leads to discovery of a new phenomenon that is not well studied but that appears to pose a serious safety problem.
- Analyses uncover a completely new issue where there are no governing regulatory criteria.
- Technical issues may arise that pose questions beyond normal engineering experience and where data is sparse.
- There may be signs of potential degradation of plant equipment or components that are difficult to inspect.

- Emergency situations may arise that pose time pressure for a regulatory decision and where information may be lacking or not reliable or contradictory.

When faced with situations like these, the regulator must first do its best to collect and assess the available information. Since the plant operators are usually the ones closest to the issue, the regulator should request their information and their assessment of the issue. There may be other sources of information and data as well. After gathering and assessing the information, the next step for the regulator is to assess where there are information gaps and what are the implications of proceeding without filling those gaps. It may be possible to use conservative bounding analyses to cover data uncertainties until better data are available. The regulator may also decide that additional research is needed.

In parallel with the information gathering effort, the regulator may begin to consider alternate resolutions of the issue. If there are time pressures, this effort to evaluate alternatives may be constrained, but generally there will be time to evaluate the pros and cons of alternate resolutions. An early step is to request the operator's recommended solution to the issue. The regulator may develop its own approach to resolution, perhaps with advice and consultation with outside experts. The regulator may consider requiring compensatory measures at the plant while more data is gathered and a permanent resolution can be found.

Sooner or later the regulator will have to make a decision on the issue, even in light of continuing uncertainties and lack of full information. This is where the regulatory body's conservative tradition of using the defence in depth principle and safety margins will be an important guide. Of equal importance will be the experience and judgement of the experts and senior members of the regulatory staff.

As in other significant regulatory decisions, the regulator should consider carefully how the decision is communicated to its stakeholders and the public. Special attention should be given to any discussion of how conservative decision making was used to compensate for uncertainties or lack of data.

Safety culture issues

When assessing the operational safety of a nuclear power plant it is important for the regulator to consider all the information concerning the plant that could affect its safe operation. A special challenge for the regulator is how to assess and evaluate conditions at a plant that may not be covered by specific regulations such as safety culture problems. By now there can be no doubt that

safety culture problems at a nuclear plant can lead to safety risks that a regulator must be prepared to recognise and deal with. An earlier OECD report⁶ discussed how a regulatory body can assess and recognise early signs of declining performance caused by safety culture problems.

When a nuclear power plant shows signs of declining performance, a possible root cause may be that the operator's organisation has elements of a weak safety culture. This situation poses a difficult challenge for a regulator because it is not really possible to measure quantitatively the safety culture of an operating organisation and it is seldom clear from the early signs of declining safety performance just what the root causes may be. Nonetheless, the regulatory body should be alert to potential safety culture problems at a nuclear plant and should include that information in the framework for making regulatory decisions concerning that plant. A follow-on OECD report⁷ discussed a graduated regulatory strategy for assessing possible safety culture problems. This strategy includes enhanced inspection oversight, regular meetings with operator management, and systematic assessments of all aspects of the plant's performance.

The specific conditions at a plant with safety culture problems are certain to be unique to that plant. This difficulty should not deter the regulator from facing the issue and taking the necessary actions, because safety culture problems are likely to recur from time to time. With experience in dealing with safety culture issues, the regulatory body can use those case history precedents to include some general guidelines in its integrated decision-making framework. There are experts in several countries working to understand the influence of safety culture on a plant's safety performance. As these efforts bear fruit over time, the regulatory body may choose to include this information in its decision-making process. In this regard, it would be a special benefit for OECD regulatory bodies to share their experiences in dealing with specific safety culture issues.

Differing opinions

It is not uncommon for a regulatory body to be faced with strong differing opinions when considering complex safety issues. In fact, it may be expected that plant operators and nuclear industry organisations will view issues

6. NEA (1999), *The Role of the Nuclear Regulator in Promoting and Evaluating Safety Culture*, OECD, Paris.

7. NEA (2000), *Regulatory Response Strategies for Safety Culture Problems*, OECD, Paris.

differently from the regulator simply because of their different responsibilities and perspectives. These types of differences can be handled in the normal interactions associated with regulatory decision making. From time to time, the nuclear regulatory body may encounter disagreements with other government agencies. Insofar as possible, these disagreements should be reduced to a set of technical questions that can be resolved through additional data, analysis and perhaps compromise. When the disagreements with other government agencies are philosophical or political, the resolution is much more difficult and in any case is beyond the scope of this report.

Particularly challenging are those cases of differing professional opinions within the regulatory body itself. Senior regulatory managers should pay careful attention to differing professional opinions within the regulatory staff because of the potential to harm the credibility of the regulatory body if not handled properly. If a differing view has not been considered seriously or has been peremptorily dismissed, it can lead to lingering animosity within the staff or even a source of public controversy. Thus, it is clearly important for the regulatory body to respectfully consider dissenting views within its own organisation. To a large degree, this issue is a function of management style of individual managers. Some regulatory bodies have found that they can deal with these situations by having a procedure for resolving differing professional opinions within the decision-making framework. The elements of a procedure for resolving differing professional opinions might include: (a) having the differing professional clearly state the issue at stake and the areas of disagreement, (b) having an independent technical review of the issue, (c) having the decision made by a senior manager in the regulatory body, and (d) perhaps allowing for an appeal process. Clearly the resolution of a differing professional view should be done in an expeditious manner.

The regulatory decision maker might not always know that there are differing opinions among the staff when preparing to make a decision. Therefore, the decision maker may want to make it a practice in complicated or difficult issues to find out if there are differing opinions among the staff.

In all cases of differing opinions, whether from inside or outside the regulatory body, the regulator should observe some basic principles in dealing with them. First and foremost is a serious, respectful consideration of the differing opinions. A second principle is to deal with the differing opinion promptly according to established procedures, once it becomes clear that the issue is not coming to closure through the regular management processes. Finally, there should be a clear record of the decision and its basis.

Safety advisory bodies

Many nuclear regulatory bodies have established advisory bodies to give advice on technical safety matters. These bodies are generally composed of independent, outside experts in various technical disciplines of relevance to nuclear engineering and safety. Although the functions of safety advisory bodies are unique to each country where they have been established, the safety advisory bodies should generally be viewed as a part of the regulatory decision-making process. The views of advisory bodies must be seriously considered (and may sometimes be adopted), but it should always be clear that the regulatory body is the decision maker. It should be a basic regulatory principle that the role of advisory bodies is to provide the regulator with technical information and insights that may be used for regulatory decisions but not to propose decisions.

Using risk information in regulatory decisions

Most of the safety regulations of OECD regulatory bodies were established before the methods of probabilistic safety analysis was well developed. The regulations were developed using engineering judgement and analyses to specify rules about design features, operations and quality assurance. This deterministic approach, using conservative assumptions in analyses and supplemented by following the defence in depth safety philosophy, has generally resulted in substantial safety margins that have served the interests of safety well over the years.

To some extent, safety regulations have always been risk informed, in the sense that there was an attempt from the earliest times to design a plant's safety systems and accident mitigation systems with capabilities commensurate with the risk significance of design basis accidents thought to pose the most risk to public health and safety. These qualitative risk insights were sometimes augmented by quantitative risk analyses, for example in the requirements for safety train redundancy.

Since the introduction of a complete probabilistic safety assessment framework in 1975, PSA methodology has matured and found widespread usage in OECD countries. By now there is a vast literature on the technology and uses of PSA, and it is generally accepted among OECD regulatory bodies that PSA methods can be used to augment the traditional deterministic methods for regulatory decision making. In many cases, PSA provides deeper insights and a more balanced picture of the actual risks posed by operation of nuclear plants than the largely conservative deterministic analyses. At the same time, it is recognised that a PSA, like all other methodologies, has limitations in

portraying the total risk at a plant. For example, a PSA cannot model safety culture and is therefore unable to quantify the risk impact of a poor safety culture at the plant. For this reason, regulators are generally cautious in using PSA bottom line estimates of risk (such as core damage frequency) as the sole basis for making regulatory safety decisions for a plant. But a PSA does not have to be perfect to be of value to the regulator and the operator. Therefore, recognising the strengths and weaknesses of probabilistic safety analyses, the regulator is faced with the question of how extensively to use risk information in its regulatory decision-making process.

In some countries the regulatory body has the explicit policy to use PSA wherever practical in its decision-making process as a complement to deterministic approaches. Other regulatory bodies rely largely on deterministic regulations and methods, with only a limited use of PSA information. Within this spectrum among OECD countries there is nonetheless a general consensus that PSA, if properly used, can be an effective tool for supporting the regulatory decision-making process. Some of the areas where it is generally agreed that PSA can be most useful are:

- Identification of plant vulnerabilities.
- Ranking accident sequences according to their relative contribution to risk.
- Ranking the relative risk importance of different systems, components, and operator actions.
- Specifying equipment allowed outage times and surveillance intervals.
- Scheduling maintenance and outage activities.
- Analysing operating events for lessons learned.

In the final analysis there is no single approach to using risk information in decision making that is correct for all regulatory bodies. Each regulator must judge for itself how much weight should be given to risk information and at what pace to introduce risk informed judgements into its decision-making process. There are some basic guidelines that the regulator can use to assist in its judgements on the use of risk information:

1. The regulator needs to ensure that a PSA used to generate risk information for decision making is of high quality.

2. The operator's staff should have a depth of competence and experience in using PSA methodology.
3. The regulatory staff itself should be knowledgeable of PSA methodology and its limitations.
4. The risk information from PSAs should not be used to replace the defence in depth safety philosophy.
5. PSA results should be judiciously interpreted and used with consideration of their limitations and uncertainties.

7. 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 most decisions of the type discussed in Section 2, the regulator will have procedures, such as a letter to the operator or a press release that will be sufficient communication of the decision. For the more difficult issues, particularly those that are complicated or publicly contentious, the regulator should consider a careful written explanation of its decision. After all, the published decision by the regulatory body is the major product of the decision-making process that the general public will see. For this reason, the regulator should strive to make sure its written decisions are transparent and will be seen by impartial observers to be fair to all parties.

There are some special circumstances, such as during emergencies, where a regulator may have special communication policies to be followed. For important public policy decision of special interest to the public the regulator may augment its regular communication procedures with meetings with local government authorities and the public to discuss the decision and its basis.

In preparing the written decision, the regulator should consider some of the questions from Section 3.

- Were normal procedures followed?
- Is there a clear legal basis for the decision?
- Is there a clear safety basis for the decision?
- Were all stakeholder views considered?
- Was there due diligence used in gathering the necessary information?

- Is the decision consistent with earlier precedents?

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.

8. SUMMARY

This report has described some basic principles and criteria that a regulatory body should consider when approaching the wide range of decisions faced in the course of its daily responsibilities. In addition to these basic principles and criteria, it was emphasised that the regulatory body should have internal procedures for an integrated framework for making regulatory decisions. The basic elements of such an integrated framework were outlined in this report.

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 judgement, 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.

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