

NUCLEAR REGULATORY DECISION MAKING

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ABSTRACT

The scientific considerations upon which the nuclear regulations are based provide objective criteria for decisions on nuclear safety matters. However, the decisions that a regulatory agency takes go far beyond granting or not an operating license based on assessment of compliance. It may involve decisions about hiring experts or research, appeals, responses to other government agencies, international agreements, etc.. In all cases, top management of the regulatory agency should hear and decide the best balance between the benefits of regulatory action and undue risks and other associated impacts that may arise, including issues of credibility and reputation.

The establishment of a decision framework based on well established principles and criteria ensures performance stability and consistency, preventing individual subjectivity.

This article analyzes the challenges to the decision-making by regulatory agencies to ensure coherence and consistency in decisions, even in situations where there is uncertainty, lack of reliable information and even divergence of opinions among experts. The article explores the basic elements for a framework for regulatory decision-making.

1. INTRODUCTION

Rationally, the decisions are made based on a study of alternatives, expectations and preferences. Any decision rule is applied to choose among the alternatives, one whose values present the most favorable consequences. However, in reality, there is great uncertainty in the probability of each possible consequence and not all the relevant information are available, for example, the probability of a natural disaster or fraud. There is a tendency not to take decisions based on probabilities calculated mathematically, but on the subjective choice of "good enough" or "best." In practice it is rare for a manager to apply a probabilistic method to choose options and make decisions. Probably, the manager has exercised any time, at least academically, the calculation of the probability of future events with the decision tree of possible outcomes. However, it is capable of making decisions based on memory to know how often an event has occurred.

This subjectivity in decision-making depends on behavioral factors that lead to risk taking the decision [1]. The acceptance of risk aversion or depend on their estimate of risk, risk propensity and the context in which decision making occurs.

Unlike the industrial and commercial sectors, in regulatory agencies, security and credibility are important factors in decision making and not profitability. The impact of one bad decision can include loss of credibility and confidence in government's ability to legislate and protect the interests of the population to guarantee on the quality of life

2. TYPES OF DECISION

As part of his duties, a nuclear regulatory agency should take routine decisions on various aspects related to facilities and activities of the nuclear area. In general, decisions may be related to the following types:

- a) Standard-setting: Establishment of mandatory technical regulations and standards agreed;
- b) Licensor: issuing licenses and permits for installations radioactive, nuclear, radioactive waste disposal sites, mining and industrial facilities with associated uranium or thorium, and transport of radioactive materials;
- c) Inspector and controller: execution of audits and inspections and enforcement actions in response to results of inspections and audits;
- d) Certification for physical goods and processes, certification and packaging material in a particular way to transport;
- e) Certification for individuals: certification of technical skills of people;
- f) Certification of institutions, certification bodies for independent technical assessments;
- g) Preventive and mitigating: temporary implementation of specific controls due to accidents (for example, to monitor food and people from places where accidents occur with contamination of large urban and rural areas) or providing services to nuclear or radiological emergencies;
- h) Reviewer: Trial of appeals or resources in response to coercive actions.

They could also include decisions regarding the monitoring and prioritization of actions based on analysis of the demands of society and stakeholders in the process of regulation, which may be operating companies, users of services in the area, or even Government itself.

For this, the nuclear regulatory agency must perform a series of procedures and internal actions such as the evaluation of sites, new projects and the review of methods of calculation and validation of computer codes and the review of modifications (in projects, power levels in operational arrangements, and others) licensed premises, evaluation of decommissioning plans, evaluation of operational trends that could lead to incidents. Furthermore, when necessary, take steps such as hiring experts to evaluate safety or hire specialized research to clarify technical points of uncertainty in decision-making areas.

Also it is the technical regulator role to participate in the negotiation of international agreements in the area and arrangements for cooperation with other regulatory agencies on issues of common regulation. There are still decisions on internal managerial character, for example, training programs, allocation of staff and the reconciliation of divergent views on technical issues such as safety assessment.

3. CHALLENGES TO DECISION-MAKING

In many situations, decision making is characterized by unexpected situations, lack of complete information, uncertain or conflicting information, disagreement among experts, real or perceived urgency to make a decision, and / or an incomplete understanding of the consequences of a decision. In addition, the regulator must be aware that their actions have effects not only on safety and protection of the public, but also in perception and confidence of the public and their representatives, as well as present and future behavior of licensed and regulated professionals.

Therefore, it is important to note that within the accepted worldwide nuclear safety philosophy, reflected in legal instruments, the primary responsibility for safety and security of facilities and activities rest with the operation professionals. It is the regulatory agency role to verify if the operator is complying with safety standards and criteria and agreed requirements. Nothing the regulator does will reduce the regulatory responsibility for the safety of the operation of a facility.

By way of clarification and transparency, the regulator must be able to justify their decisions. As part of their assessments and judgments, the regulatory agency must inform about the objectives, principles and criteria related to safety requirements and in which their decisions are based. Considering the consequences of poor decisions, it is necessary to set some lines of behavior in decision making at the regulatory agency.

3.1. Coherence

A premature decision because of pressure from interests may conflict with safety. The regulator should be particularly sensitive to the need to maintain consistency in their decisions. That is, when confronted with issues of safety and similar circumstances, the regulator must give similar decisions or explain clearly why a decision was different. The lack of coherence leads to loss of credibility.

3.2. Consistency

In making a decision on a difficult issue, the regulator will need to consider how the decision will appear in retrospect, if it is inappropriate or does not have the desired result. In difficult cases, there will be pressure on the regulator from various sources. Therefore, some questions should be asked before making a final decision consistent.

- a) There is a clear basis of safety for the decision?
- b) There is a clear legal basis for the decision?
- c) We followed the normal procedures?
- d) We considered all the views of stakeholders?
- e) The required information is reliable?
- f) The decision is consistent with earlier precedents?
- g) The governor tried to circumvent some regulatory requirements by political, economic, operational or technical pressure?

Often this questioning is seen as being exaggerated and the decision may be premature. On the other hand, without a framework to test consistency, the regulatory agency may postpone the decision for too long, in understanding that maybe still there are missing elements for a reliable assessment. This "checklist" should be made to ensure that the agency used a

structured procedure, considering the relevant entries, safety principles used and was not pressured by stakeholders.

3.3. Suitable Information Treatment for Decision

Even with all the information available in bulky administrative processes, there are problems of communication to, in a short time to make decisions, share and analyze often complex information, and from other areas of the organization.

For decision making, information required to be understood. To this end, the decision maker must have the explicit and tacit knowledge needed and be able to form inferences about the causal connections of events and on the relevant characteristics of the environment. Often the information is relevant, but in a given context, the controller can not realize its importance, or fails to make inferences of different information to form a real interpretation of the outcome of a decision. On the other hand, it can be given an improper value to irrelevant information [1].

The limited information available in a regulatory environment comes primarily from incomplete or unverified nuclear safety analysis reports, inconclusive or ambiguous technical advice or inspection reports, difficult to assess or to communicate relevant information, modification of items important to safety in the installation regulated, and so on.

One of the most difficult decision-making is when the manager is faced with an issue that is surrounded by uncertainties in the information or lack thereof. A study conducted by TCU (Union Audit Office) in conjunction with *Fundação Getulio Vargas*, from 2005 to 2007, mapped and classified the risks of regulatory agencies for infrastructure, in terms of materiality, likelihood and relevance. The study results show that among 164 actions that caused positive or negative impacts on a strategic objective, the absence, delay, inaccuracy or problem in the treatment of information received was responsible for 26% of occurrences [2].

When it comes to nuclear safety, the regulator requires a detailed risk assessment, but some data are scarce (meteorological, operational experience of a new technology, development of an emergency situation with multiple risk factors) or when signs of potential degradation of the facilities similar, the regulator must take a decision on the matter. The operation of a facility with conditions that do not compromise the safety benefits that may outweigh the risks, for example, in medical facilities that will benefit patients so far unattended.

3.4. Technical Knowledge

A fundamental principle for regulating nuclear safety is the practice of "conservative" decision-making, always favoring safety. In case of doubt, the regulator tends to make more restrictive, especially in new situations. Thus, the higher the operational experience and understanding of safety of nuclear installations that the regulator has, the greater the possibility that the safety margins are established in a more coherent, avoiding excessive safety margins and accelerating the process of making decision.

3.5. Suitable Treatment for Divergent Opinions

It is not unusual for a regulatory agency faces differing opinions when considering complex issues. In fact, one can expect that any operator to see the issues differently, simply because of their different responsibilities and perspectives. These types of differences can be dealt

with in meetings associated with the regulatory decision-making, maintaining the dominance of the agency's authorization. Differences with other governmental agencies should be reduced to a set of technical issues can be resolved through additional data, analysis and, where necessary, with commitments of understanding.

Particularly difficult, however, are cases of differing opinions among professionals of the regulator itself. The regulatory agency's top management should pay attention to different professional opinions of staff regulations, the potential to undermine the credibility of the regulator, if not properly treated. In case a different point of view is not considered or has been rejected out of hand can lead to animosity within the team or even a source of public controversy. Some regulators say they can deal with these situations through a procedure that includes:

- (a) clear statement of the issue at hand with different professions and areas of disagreement,
- (b) independent technical review of the issue,
- (c) analysis and decision made by a senior manager of regulatory body, and
- (d) an internal appeal.

The appeal process must be resorted to when there are situations where there is a clear disagreement. Decision-making levels and mechanisms to be used on appeal must be defined. It is clear that solving the dispute should be done in an expeditious manner [3]. It is important, however, that there is a mechanism by which, given the opportunities for solving the dispute and as soon as the decision is adopted by the agency within their hierarchy of responsibilities, the discordant accepts the decision, resulting in no impact on credibility and to the teamwork.

3.6. Independence

The main reason for the independence of the regulator is to ensure that regulatory decisions can be made and control actions taken without pressure from interests that may conflict with safety. Thus, in order to ensure independence in its decisions, the INSAG [4] recommends that the regulator has an effective independence from government units and agencies, industries and interest groups that promote or oppose nuclear technologies. In particular, it should be independent of the organizations that it regulates, whether state or private.

At the same time, it is recognized that a regulator can not be absolutely independent in all aspects of the rest of the government: it is within a national system of laws and under budget constraints, as well as other non-governmental organizations do. However, political support, guidance and supervision should be clearly defined and limited in appropriate legal instruments to ensure a high level of professional independence in the way the regulator operates at its decisions. In this respect, a regulatory body should more resemble the judicial branch than the executive.

Measures to ensure the independence of regulatory decision-making are part of a quality management system, which includes the quality of scientific and technical information used in decision-making, as well as the independence and competence of decision makers. In nuclear safety, independence in regulatory decision making must be ensured by the responsibility and commitment of its decision makers (government and parliament) and the high level regulatory management. Clearly there is a direct relationship between

independence in decision making by the regulator and other aspects of quality of regulatory activities [4].

4. FRAMEWORK FOR DECISION MAKING

There are several formulations of the criterion for the level of safety, but it is recognized that absolute security can not be achieved. Most countries have some variation of the criterion of "reasonable certainty." Some of subjective criteria to achieve the level of protection are:

- a) Adequate protection of public health and safety;
- b) No unreasonable risks;
- c) Risk as low as reasonably achievable;
- d) Security as much as reasonably achievable;
- e) Limit risk through the use of best technologies to acceptable economic costs.

Nuclear regulators generally require that the base level of the criterion of protection, for example, "without unreasonable risks," must be met regardless of cost or other considerations. When considering improvements in the safety beyond that, it can reach a point where improved safety can not be rationally justified, after evaluating the compensation factors such as costs and degradation of equipment due to excessive force. For this reason, an integrated framework for formal decision-making may include a provision for considering these types of compensation or trade-offs. However, the quantitative goals of security are used as guidelines by the regulator to complement other regulatory criteria.

The framework for decision making should include basically the following elements [3]:

- a) Define the issue objectively: In most cases, the regulatory issue is simple and predictable. A more complex example might be to determine which government agency is responsible when an operator proposes the disposal of mixed waste containing radioactive materials and toxic chemicals. In such cases, it is important that the issues are clearly defined before making a decision that may be inappropriate.
- b) Assess the importance of security: In most cases, the experience of the regulator will set the safety level, but further analysis may be made. An example might be requesting an operator to delay the repair of a service pipe cooling until the next break to recharge the reactor core. In this case, the regulator would have to decide whether the risk is serious enough to require immediate stop or if the plant can continue to operate safely until the next reload of the nucleus to repair the pipe. Clearly, the most important safety issues should receive priority attention of the regulator.
- c) Determine the laws, regulations or criteria to be applied: An experienced regulator will generally know what criteria will govern the problem to be faced. There may be situations where the performance is being affected by a culture of safety and management appear weak in a plant, but the licensing regulations do not explicitly cover the circumstances (eg, management actions) to be considered an enforcement action. In these cases, the regulator may require a legal opinion before taking regulatory measures.
- d) Collect data and information: A primary activity is to gather all relevant information regarding the decision. This can, for example, involve the history of licensing, reports of recent events, and case reports of similar situations at other facilities in the country or abroad.
- e) Trial of technical competence and resources: There may be more complex problems, for example, an application for an operator to install a digital instrumentation and control

system to replace an old analog system or replacing a system of personal dosimetry. If the regulator has not faced a similar situation before, you will need to carefully consider the expertise and resources to review, perhaps including the agenda items out of regulation. It is important that such technical advice are well planned to avoid disruption of other routine work of the regulator.

- f) Compliance with the analysis to be performed: After the regulatory criteria were defined, the regulator should agree the analysis to be performed. An example would be the request for an operator to extend the use of fuel. In such cases, the regulator must check the validation of computer codes, data, acceptance criteria to be used in the analysis and quality programs of the operator. The regulator may choose to perform an independent analysis, especially in the first type of situation.
- g) a prioritization of the activities of the agency: There are many interests competing for the decision of the regulator. Obviously, the most important issues of safety should be top priorities of the regulator. Requests for all matters, especially to those of other government organizations, deserve special attention. The design of human resources is essential to prevent the regulator becomes the bottleneck in the development of the nuclear area.
- h) Final decision: Before making a final decision on an issue, the regulator must ensure that interested parties were heard. These stakeholders may include plant operators, nuclear organizations, national and local government officials, public interest groups and the general public. In some emergency situations may not be possible to obtain the views of stakeholders, but it is good practice to seek regulatory reviews to make sure the impact of the decision. After reviewing the stakeholder input and analysis of the facts relevant to the criteria the regulator must make a decision. Clearly, when the issue involves safety, the regulator should ensure that the basic protection criteria are met, above all other considerations.
- i) Drafting and publication of the decision: In the interest of ensuring transparency and consistency in their decision-making process, the regulator must write a clear description of its final decision and its basis and make it public. The decision and its basis should be recorded in a control system. This will allow effective monitoring of actions and facilitate the retrieval of information to assist in future decision making.
- j) Evaluation of decision: to ensure that risks are well managed, it is important to review our decisions after an appropriate interval to check whether the measures taken were successful, and if corrections need, what was the impact of the decision and if need be more prepared if a better knowledge and data have helped to make better decision, for example, the methodologies used for risk assessment and cost benefit analysis, or the assumptions made were correct. Assessments are to encourage a system of monitoring and evaluating the progress of the regulator [5].

It is noteworthy that the above steps are not distinct and independent from each other, to the contrary is an iterative process that seeks to base legal and technical decisions and avoid unnecessary impacts and even legal arguments.

The process of decision making in the risk environment is very complex, with a variety of inputs. Judging by the regulator should offer flexibility to operators to meet safety requirements. At the same time, should reflect the values of society at large about the risks that are unacceptable, tolerable or broadly acceptable. As emphasized by the British regulator [5], any discussion raises ethical considerations, social, economic and scientific, for example: how to maximize the benefits to society, taking into account the scientific and technological

advances, ensuring that no undue economic and social impacts or the imposition of unnecessary restrictions.

5. USING RISK INFORMATION ON DECISIONS

Most safety standards were established before the methods of probabilistic safety analysis were well developed. The rules apply technical criteria and requirements analysis to specify the design, operation and quality assurance and licensing after the rite of confirmation of compliance with all regulatory requirements. This deterministic approach, using conservative assumptions and complemented by the defense in depth, resulting in safety margins sometimes exaggerated, but they have served the interests of safety. To some extent, safety standards require risk information, for example, prevention of design basis accidents.

The methodology of probabilistic safety assessment (PSA) has matured since its introduction in 1975 and found use in several countries with nuclear power plants. The literature on technology and the uses of PSA is still not extensive, but the methods are generally accepted among PSA regulators from OECD countries to complement the traditional deterministic methods used in regulatory decision making [3]. In many cases, the PSA provides a more detailed and balanced view of the real risks of nuclear power plants operate than the conservative analysis. At the same time, it is recognized that PSA, like all other methods, has limitations in depicting the overall risk of a plant. For example, the PSA can not shape the safety culture and, therefore, need expert subjective opinions. Recognizing the strengths and weaknesses of probabilistic safety analysis, the regulator is faced with the question of how widely it will use the risk information in the process of regulatory decision making. There is not a unique approach, but there are some basic guidelines that the regulator can use such as: the regulator must ensure that the PSA used is high quality, operators must have experience in using the methodology of PSA and regulators, for in turn, must understand the methodology and its limitations.

Equally important to estimate the probability of an event based on a past incident or accident, one must be careful to check that:

- a) the incident represents a very small sample or limited scope that can be misleading. Scope too broad may result in the inclusion of incidents with different root-cause of the event in question;
- b) Regardless of the term chosen for sampling, the assumption of a constant relationship between the incidents and time must be questioned because of changes in technology and regulatory requirements and the context in general can influence the evolution of the impact of the accident;

The Guidance for Regulations Best Practices [6] suggests the risk assessment to support the decision of the regulator, using for such a structured, systematic process based on ISO Standard 31000:2009 (Figure 1). To reduce subjectivity and balancing risk information, the guide recommends that you make use of structured interviews, focus groups and multidisciplinary use of fault tree and event.

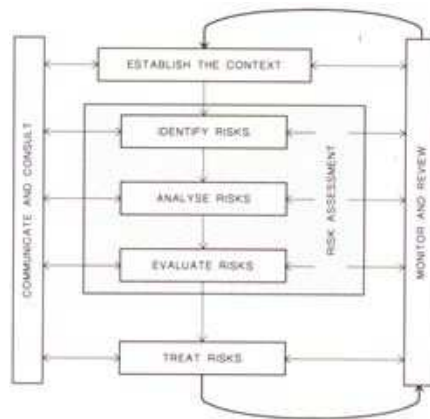


Figure 1 - Risk management structure according to ABNT NBR ISO 31000:2009.

The ideal would be to use methods that consider information from qualitative and quantitative risk (for example, from expert opinion) in fuzzy logic or Bayesian networks. The latter also has the advantage of being easily updated with new information in mind, thus becoming a tool for decision support dynamic and integrated.

6. COMMUNICATION AND INTERACTION WITH SOCIETY

The expert in the regulation of ANVISA, Pedro Ivo Ramalho Sebba [7] states that the establishment of an annual regulatory agenda in each regulatory agency is an example of an initiative to strengthen the autonomy and the role of these organs in the necessary predictability and stability of decision-making rules for business. Transparency and participation of society in the regulatory process ensures greater balance between productive sectors and citizens, encouraging investment and ensuring access, safety and product quality. Ramalho suggests that mitigation of the "regulatory risk" could be achieved through the concomitant expansion of independence, accountability and transparency of the agencies. He recalls that:

- a) The independence of agencies is exercised by its leaders in relation to interest groups, including government agents. Important instruments are the term stable, non-subordination to the ministry supervisor and effective administrative and financial autonomy.
- b) Transparency can be understood as the state's commitment to provide systematic information to the governed. It can be enhanced by knowledge of the rules of decision-making and publicity of the acts.

These mechanisms reduce the uncertainties of the public and serve as control mechanism of the regulators. One expected outcome is the recognition of regulatory authority as trustworthy and ethical. Thus, agencies may become worthy of credit of the population and market agents.

CNEN's website includes a brief report on the activities of licensing and control, instructions for applications with electronic forms for companies and individuals, the regulations, and the channel "contact us". CNEN has implemented in 2008 a systematic public consultation of draft texts to the regulations. The text submitted for consultation is the result of work of a committee composed of representatives of regulators and organizations most directly involved as a matter of the proposed regulation.

Experience shows that the public consultation, entirely over the Internet, has been satisfactory and that the population is interested in participating, presenting technical arguments valid. Thus, the draft regulation is submitted for approval to CNEN'S Deliberative Commission supported by a more profound investigation, giving an opportunity to involve society in regulating nuclear [8]. As part of the interaction with society, promotes the CNEN National Meeting of Regulatory Information (ENIR) to promote communication between CNEN and facilities, associations, researchers and society at large, seeking dynamism, transparency and quality of regulatory activities. The ENIR also provides a unique environment for the establishment of discussions among the participants, in line with the mission of the CNEN to ensure the safe and peaceful use of nuclear energy. In the scope of this meeting, opinion poll is carried out to monitor and evaluate the services provided to society by CNEN, detect the need for improvement actions. In 2009, the survey indicated that 63% of respondents recalls that CNEN should make greater disclosure of its regulatory actions - an improvement, compared with 95% obtained in the 2005 survey [9].

7. CONCLUSIONS

Employing well-established guidelines for decision making will benefit the regulator to seek coherence, consistency and efficiency required [10]. This paper deals with regulatory decision making and emphasizes the use of risk analysis tools and communication with the society. A well planned and decision-making structure, as shown in section 4, facilitates decision making and increases confidence in the decision making process.

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