

# The Characteristics of an Effective Nuclear Regulator





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# **The Characteristics of an Effective Nuclear Regulator**

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NUCLEAR ENERGY AGENCY  
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- to assist its member countries in maintaining and further developing, through international co-operation, the scientific, technological and legal bases required for a safe, environmentally friendly and economical use of nuclear energy for peaceful purposes, as well as
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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 authorities. The committee guides the NEA programme concerning the regulation, licensing and inspection of nuclear installations with respect to safety. It acts as a forum for exchange of information and experience, and for review of developments which could affect regulatory requirements.

The CNRA has produced a series of regulatory guidance reports, known as “green booklets”, which are prepared and reviewed by senior regulators and provide a unique resource on key nuclear regulatory issues. The booklets examine various regulatory challenges and address the major elements and contemporary issues of a nuclear safety regime.

Following a special topical discussion held on the characteristics of an effective regulator at the 27<sup>th</sup> CNRA meeting on 4-5 June 2012 [1] and subsequent discussions at the 28<sup>th</sup> CNRA meeting on 3-4 December 2012 [2], the CNRA decided that a “green booklet” on *The Characteristics of an Effective Nuclear Regulator* would be a timely and appropriate addition to this resource on key contemporary nuclear regulatory issues. A senior-level task group (STG) was therefore established with the remit to prepare a regulatory guidance report on the characteristics of an effective nuclear regulator.

Although the audience for this report is primarily nuclear regulatory bodies, the information is also expected to be of interest to other stakeholders and to the nuclear industry. The CNRA believes it should also be of use to countries that are looking to begin a nuclear energy programme but have yet to develop well-established regulatory regimes. The CNRA encourages established regulatory bodies to use this report as a benchmark, and to continually strive to enhance their effectiveness as they fulfil their mission to protect public health and ensure nuclear safety.

This report has been prepared by the CNRA STG on the Characteristics of an Effective Regulator and is based on discussions and input from members of the group as well as information from a wide array of documents produced by the NEA, its member countries and other international organisations.

Michael Cheok (United States) chaired the meetings and the work of the STG. The members of the group were An Wertelaers (Belgium), Robert Lojk (Canada), Miguel Santini (Canada), Kirsi Alm-Lytz (Finland), Anne-Cécile Rigail (France), Kai-Jochen Weidenbruck (Germany), Gisela Stoppa (Germany), Roberto Rainieri (Italy), Masahiro Aoki (Japan), Victor M. Gonzalez-Mercado (Mexico),

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## 1. Executive summary

Both national and international organisations agree that the fundamental objective of all nuclear safety regulatory bodies – the regulator’s prime purpose – is to ensure that nuclear licensees operate their facilities at all times in a safe manner. In order to effectively achieve this objective, the nuclear safety regulator requires specific characteristics that will allow it “to do the right thing well and efficiently”.

Much has been written about ways to improve regulatory processes or to improve the effectiveness of a regulatory body, including in previous NEA regulatory guidance booklets [3] or in International Atomic Energy Agency (IAEA) publications [4]. However, since no report has been dedicated to the topic of the characteristics of an effective nuclear safety regulator, the CNRA decided that a “green booklet” on the subject would be a timely and appropriate addition to the series. (See Appendix 2 for a full list of NEA regulatory guidance booklets.)

Effective organisations are those that have good leadership and are able to transform strategic direction into operational programmes. Effectiveness is about how well the organisation is achieving its fundamental purpose – in the case of a nuclear safety regulator, ensuring that licensees operate their facilities and discharge their obligations in a safe manner.

This report describes the characteristics of an effective nuclear safety regulator in terms of roles and responsibilities, principles and attributes. For the purpose of this report, the following definitions are used:

- Principles
  - Fundamental primary and accepted rules or the basis of conduct from which all actions are derived.
- Attributes
  - Qualities that identify or describe an organisation that results from the actions of the organisation.

Each of the characteristics discussed in this report is a necessary feature of an effective nuclear safety regulator but no one characteristic is sufficient on its own. It is the combination of these characteristics – the roles and responsibilities, the principles and the attributes – that leads to the effectiveness of a nuclear regulatory body.

In summary, an effective nuclear regulator:

- is clear about its regulatory roles and responsibilities, its purpose, mandate and functions;

- has public safety as its primary focus;
- has independence in regulatory decision making from any undue influence on the part of the nuclear industry and those sectors of government that sponsor this industry;
- has technical competence at its core, with other competencies built upon this fundamental and essential requirement;
- is open and transparent in its regulations and decisions;
- has a regulatory framework and requirements that are clear and easily understood by all stakeholders;
- makes clear, balanced and unbiased decisions, and is accountable for those decisions;
- has a strong organisational capability in terms of adequate resources, strong leadership and robust management systems;
- performs its regulatory functions in a timely and efficient manner;
- has and encourages a continuous self-improvement and learning culture, including the willingness to subject itself to independent peer reviews.

A regulator with the above characteristics should be effective in ensuring that nuclear facilities are operated at all times in a safe manner, in accordance with international safety principles and with full respect of the environment.

This regulatory guidance booklet on the characteristics of an effective nuclear regulator provides a unique resource to countries with existing, mature regulators and can be used for benchmarking as well as training and developing staff. It will also be useful for new entrant countries in the process of developing and maintaining an effective nuclear safety regulator.

## 2. Nuclear regulatory roles and responsibilities

Individuals working within an effective regulatory body need to have clarity of purpose and a consistent view of what the organisation is focused on achieving and why.

### **Purpose of the regulator**

The fundamental objective of all national nuclear safety regulatory bodies is to ensure that, within their countries, activities related to the peaceful use of nuclear energy are carried out in a safe manner, in accordance with international safety principles and with full respect of the environment.

This is reflected in the mission statements of regulators around the world, which generally promote their roles in protecting workers, patients, the public and the environment against the risks to safety and security related to nuclear activities and in respecting international accords.

It is important to emphasise that, although the mission of the regulatory body is to provide oversight on nuclear safety, the prime responsibility for the safety of a nuclear installation has to remain with the licensee or plant operator.

### **Regulatory framework and mandate**

National parliaments or governments provide the overarching legislation creating and mandating regulatory bodies to discharge their responsibilities in ensuring that the health and safety of people and the environment are protected.

The scope and the kind of facilities and activities under the regulator's supervision vary from one country to another, according to the mandate given by the national regulations.

Within this mandate, regulators have key roles in the development of a regulatory framework, overseeing nuclear safety and radiological protection, and in emergency management.

Regarding emergency management, regulatory bodies may have the responsibility for helping to co-ordinate national and international emergency management programmes, as well as ensuring that licensees/operators have adequate plans, training, programmes and resources in place to deal with postulated and potential emergencies and events.

## Regulatory activities and functions

In order to ensure that the licensees properly discharge their responsibility, the regulators must carry out the following activities [3]:

- define safety objectives;
- develop or propose and promulgate regulations;
- set standards and issue regulatory guides;
- issue or advise on the issuing of licences and amendments;
- carry out inspections;
- undertake regulatory reviews;
- enforce regulatory requirements;
- review operating experience;
- observe attitudes to safety;
- carry out independent safety analyses;
- sponsor safety research;
- contribute to emergency preparedness and response;
- interact with stakeholders and inform the public on radiation protection and nuclear safety;
- interact with the international community.

Regulatory bodies should have an integrated management system that ensures that the above activities are carried out efficiently.

## Implementation strategy

The activities of a regulatory body must be carried out in accordance with national laws and through a robust regulatory framework. In order to ensure that regulatory activities are commensurate with the importance of the safety issues, a graded approach should be applied. This should be a consistent, transparent and objective process which is understood by stakeholders. Such regulatory processes require the insight from experienced staff who have an understanding of nuclear safety (including radiological protection). The regulatory body should consider the opinions of stakeholders and have an understanding of the impact of the regulatory activities on society.

The regulator may consider the use of various regulatory approaches [5]. These include prescriptive, case and facility based, outcome based, risk and hazard informed, process based, self-assessment based and education/influence-based. Appendix 1 to this document provides a summary description of these approaches.

Regulatory supervision is an iterative and dynamic process that uses combinations of approaches as tools to address the inherent complexity of the facilities being regulated. The effectiveness and efficiency of any approach are tied to its suitability to the specific features of the case. Therefore, the regulator should consider the appropriate approaches to be used depending on the specific case, including the safety significance of the issue, characteristics of the industry, the use of contractors, the level of trust in the licensee/regulator relationship, the type of communication or interaction between the regulatory body and licensee and the experience and competence of the licensee and the regulator.



### 3. Principles for an effective nuclear regulator

The following principles are the fundamental primary and accepted rules or the basis of conduct from which all regulatory body actions should be derived.

#### **Safety focus and safety culture**

A regulatory body must have public safety as its primary focus. In addition, a robust and strong safety culture is important for regulatory bodies. This culture must encompass individual staff members, leaders and the organisation as a whole [3a]. INSAG-4 [6] was originally written for operators but the concepts apply equally well to regulatory bodies. It defines safety culture as follows: “Safety culture is that assembly of characteristics and attitudes in organisations and individuals which establishes that, as an overriding priority, nuclear plant safety issues receive the attention warranted by their significance”.

The regulatory body’s safety culture starts at the highest level in the organisation and includes the following individual and organisational characteristics (summarised from [3a, 6] and various safety culture charters from existing regulatory bodies, e.g. [7], and other organisations):

- The expected safety culture within the regulator is clear and promotes the highest level of safety consciousness in the organisation.
- Leaders demonstrate a commitment to safety in their decisions and behaviours.
- All individuals take personal responsibility for safety, hold themselves personally accountable and demonstrate strong values and ethics. Their personal accountabilities are clear.
- Issues potentially impacting safety are identified, evaluated, and addressed in a timely manner.
- Continuous learning opportunities to ensure safety are sought out and implemented.
- Individuals feel free to raise safety concerns without fear of retaliation, intimidation, harassment, or discrimination.
- Communications are effective and maintain a focus on safety.
- Trust and respect permeate the organisation.
- Individuals have a questioning attitude and avoid complacency with respect to existing conditions and activities.

## Independence

The basic requirements for regulatory body independence are set out in GSR-Part 1 Requirement 4 [8] and in Article 8 of the Convention on Nuclear Safety [9]. According to these texts, the function of the regulatory body shall be effectively separated from those of any other body or organisation concerned with the promotion or utilisation of nuclear energy or having other interests. Functional separation forms the background and the conditions for independent regulatory decision making without undue influence. This includes making and being seen to make independent, clear, balanced and unbiased regulatory decisions.

Due to the ultimate responsibility for nuclear safety on the part of the government in each member country, the regulatory body is not entirely separate from the government [10, 11]. Based on its constitution and organisation of government, each country sets up the regulatory and legislative framework recognising that the regulatory body needs sufficient authority. Within this framework it is fundamental to ensure that the regulatory body is able to perform its functions for ensuring safety. Sufficient authority is needed to avoid any conflict of interests regardless of the regulatory body's functional separation from government or parts of the government. Such independence enables a regulator to take, when appropriate, strong decisions, such as requiring the closure of an unsafe facility. This independence requires a strong supporting legal framework, including decision making and enforcement capabilities, as well as transparent and active relations with government, parliament and stakeholders.

Independence does not mean isolation – the regulator needs to have frequent open discussions with all of its stakeholders at all times and remain accountable to them for its actions and its decisions.

In order to ensure that the regulatory body is effectively independent from undue influence in its decision making, several elements are of utmost importance. These elements include:

- Political independence
  - Authorised and being able to make independent regulatory judgments and regulatory decisions within their field of competence for routine work and in crisis situations.
  - Ability to take regulatory decisions and enforcement measures founded on objective safety-related requirements.
  - Empowered to give independent advice to government departments and governmental bodies on matters relating to the safety of facilities and activities.
- Financial independence
  - Provided with sufficient financial resources, reliable funding and staffing for the proper and timely discharge of its assigned responsibilities.
  - Provided with a clearly defined financing mechanism and budget allocation process within the national framework.



- Technical independence
  - Possess technical and scientific competence and the capacity to make independent decisions.
  - Has access to independent scientific and technical support.

## **Competence**

Core technical competency and experience are the basis of an effective regulatory body. As discussed in other sections of this report, competence is the foundation of many of the other characteristics of an effective regulator such as independence, transparency, credibility and trust.

The organisation's technical competency is a necessary and fundamental condition but not sufficient in itself. Other complementary competencies need to be built upon it. Relevant competencies include knowledge of organisational and human factors, legal competence and core regulatory competence. The competency and skills for effectively exercising legal enforcement are also key elements for the decisions of the regulatory body so that these decisions have the intended impact on the level of safety.

In order to be an effective, credible and trusted regulatory body, the regulator must be able to explain its requirements and expectations to the licensees and other stakeholders in a clear and understandable manner. The regulator must also be able to independently justify or verify technical, regulatory and legal information when there is a need to do so.

The regulatory body must have available facilities and the means to maintain and develop the technical and regulatory skills of both new and present staff. The training programmes must cover relevant areas so that technical, organisational and human factors and regulatory competencies can be maintained and improved.

## **Openness and transparency**

Openness and transparency means adopting a policy of disclosure of information and of stakeholder involvement and ensuring the public are informed about the regulatory processes.

Appropriate stakeholder involvement within decision-making processes provides the opportunity to obtain a broader basis for decisions which can also contribute to the regulatory body's improved credibility in society. In considering stakeholder input, the regulatory body should be seen by the public as a competent, professional and independent body that makes timely decisions ensuring the required level of safety and protection of the environment.

Key outputs of the policy on disclosure of information are publishing safety information and the appropriate annual reports and results that would be of interest to stakeholders. Information concerning incidents and events at nuclear facilities, their safety relevance and regulatory measures should be made

publically available. Communications should be clear to the public and other competent authorities.

Availability of information and transparency of regulatory activities and reporting on regulatory decisions can lead to increased public confidence that decisions are underpinned by robust criteria and processes.

## 4. Attributes of an effective nuclear regulator

Attributes are the qualities that identify or describe an organisation that result from or are caused by the actions of the organisation.

### Clear and consistent regulation

Laws, regulations, guides and licence conditions provide the framework for regulatory requirements. These requirements need to be kept clear, consistent, and comprehensive with predictable implications.

Regulations vary among member countries depending on the regulatory approach and national practices and requirements. However, most regulators recognise the value and importance of issuing regulatory guides to provide more detail to explain the regulatory objectives, and thus the expectations for different facilities, phases of operation, etc. The legal status of such regulatory guides must be clear and the extent to which they will be used to measure safety achievements should be made clear to all stakeholders, especially the operators.

Moreover, to maintain the regulations up-to-date, technological advances, research and development, relevant operational lessons learnt and institutional knowledge, in addition to well-established standards and endorsed practices, are valuable in reviewing and revising the regulations and guides.

In summary, regulatory requirements and guides should:

- have a clear legal/legislative basis and status;
- be readily understood, coherent and logical;
- have a clear connection with the regulatory body's goals and objectives;
- be benchmarked against the state of the art in science and technology, for example, internationally and regionally recognised expectations and requirements (e.g. OECD/NEA guidance, IAEA Nuclear Safety Fundamentals and Standards, WENRA reference levels).

### Consistent and balanced decision making

Effective regulatory processes ensure the stability and consistency of regulatory control and prevent subjectivity in decision making by the individual staff members of the regulatory body. The regulatory body should strive to ensure that its regulatory decisions are technically sound, consistent from case to case, pragmatic and commensurate with the risk, and timely and just. The regulator

should make sure that its decisions are balanced and transparent, have a clear basis in law and regulations, are based on facts and scientific grounds, and are viewed by impartial observers as being fair to all parties. It is very important that the regulatory body be able to justify its decisions.

The regulator should be 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. A good way to promote balanced and consistent decision making is to have clear criteria and to maintain transparency – that is, being open in publishing the decisions in terms of how these decisions were arrived at and their implications.

### **Accountability**

National regulatory bodies are accountable to national parliaments/governments and the public. The regulatory body must have the capacity, ability and willingness to make considerate and well-informed decisions that are supported by evidence. The regulator should be able to explain their decisions and actions, either to licensees or to other stakeholders, and be able to withstand challenges to those decisions.

### **Strong organisational capability**

The regulatory body should be structured in a way so that good practices are employed, and that the managers have appropriate spans of control, with appropriate authority and responsibility at the various levels of the organisation. Attributes that characterise a capable and strong organisation include sufficient financial resources, competence in all areas of importance for nuclear safety and radiation protection and an effective management system.

### **Management system**

The regulatory body's management system should [8]:

- ensure that the responsibilities assigned to it are properly discharged;
- maintain and improve its performance;
- foster and support a safety culture in the regulatory body.

The management system should consist of processes and internal guides that support staff when they execute their regulatory work. These include inspections, reviews and assessments, licensing, enforcement and developing or proposing regulations. The internal guides should be followed to ensure a systematic and consistent approach to regulatory processes while allowing sufficient flexibility for staff to take the initiative when dealing with new concerns that arise. The management system should also have provision to monitor and improve the processes.

## **Leadership**

A vital role of all regulatory body's senior leaders is to give the organisation and the staff clarity of purpose i.e. a clear and consistent view of what the organisation is trying to achieve and why. That purpose is generally agreed by the international nuclear safety community to be about ensuring that nuclear activities are carried out in a safe manner.

All leaders within the regulatory body should serve as role models for the activities of the regulator, both internally and externally. Leaders should demonstrate a commitment to safety and safety culture in their decisions and behaviours and be capable of dealing with issues from the licensees, with demands from the general public and communicating with media. The leaders are also responsible for ensuring that activities are conducted effectively, efficiently and in alignment with the mission and objectives of the regulatory body.

In addition to these aspects, they should be good supervisors who are not only expected to manage the operations, but to improve them as well. Training programmes for supervisors should be available so that supervisors can provide staff with the assistance and support needed to deal with complicated issues.

## **Staffing**

The regulatory body needs sufficient and qualified staff in all areas, and access to suitable technical and scientific support. A technical support organisation (TSO) can provide technical and scientific support. The regulator should maintain supervision over assistance from external experts and be an intelligent customer capable of properly understanding and independently evaluating the expert advice.

## **Continuous improvement, peer review and international involvement**

The regulatory body should establish appropriate governance within the management system to monitor performance and effectiveness of regulatory strategies and to embrace a culture of continuous improvement. Such arrangements should include processes for self-assessments, management reviews, internal audits and independent reviews. Data should be evaluated to determine the robustness of regulatory activities and decisions. Appropriate operational experience feedback should be used to inform and improve the regulatory strategy. Examples of frameworks developed for evaluating performance within regulatory bodies can be found in projects led by the CNRA [3a].

Peer reviews are important to enhance the effectiveness and the independence of a regulatory body and to promote continuous improvement. These should be performed at appropriate intervals. In conducting these reviews, the peers accept a joint mandate for review in order to identify good practices and areas for improvement, and the hosting country sets up an action plan to respond to the findings.

A commitment of the NEA member countries to implement peer review processes of their own activities as well as to engage in international peer reviews

is an important step forward to ensure continuous improvement of nuclear safety and improvement of the effectiveness of regulatory bodies.

The NEA CNRA acts as a forum for exchange of information and experience, and for review of developments which could affect regulatory requirements. Closer global harmonisation of approaches to the application and implementation of safety requirements through peer evaluations and discussions is a goal that many organisations are actively pursuing.

## **Efficiency**

Regulatory effectiveness is about ensuring that nuclear facilities are operated safely. Regulatory efficiency is about doing this work right and with good governance [3b]. Efficient regulators make sound use of their resources.

Regulatory bodies may use various combinations of regulatory approaches and strategies to carry out their responsibilities in the most efficient way possible (Appendix 1).

In general, within the regulatory framework, an efficient and effective regulator would require the operator to provide justified solutions to safety issues. The regulator then checks if these proposed solutions are acceptable, thus ensuring that the prime responsibility for the safety remains with the operator.

As an element of efficiency, regulatory decisions should be made without unnecessary delays. However, in all cases, expediency must not come at the expense of safety and striving for efficiency should not harm the effectiveness objective.

## **Credibility, trust and respect**

Credibility, trust and respect are universally seen to be desirable attributes that a regulatory body should possess. However, unlike some of the other attributes discussed above, credibility, trust and respect are more subjective and are outcomes that can only be achieved if the regulatory body is considered to be effective and possesses the characteristics described in this report. That is, credibility, trust and respect are attributes that result from or are caused by the actions of an effective regulatory body.

## 5. Conclusions and recommendations

Each of the characteristics discussed in this report is a necessary feature of an effective regulator but no one characteristic is sufficient on its own. It is the combination of the characteristics – the roles and responsibilities, the principles and the attributes – that leads to the effectiveness of a regulatory body.

Much of what is discussed in this booklet represents cultural and behavioural aspects of a regulatory body as well as those that are statutory and process-driven. The regulatory body should have an appropriate and deeply established safety culture that supports all aspects of *The Characteristics of an Effective Nuclear Regulator*, a culture that is driven and led from the top of the organisation and reflected and reinforced at all levels within the regulatory body.

Individuals within an effective regulatory body should have clarity of purpose and a clear and consistent view of what the organisation is trying to achieve and why. This purpose is generally agreed by the international nuclear safety community to be about ensuring that nuclear activities are carried out in a safe manner, in accordance with international safety principles on the peaceful use of nuclear energy with full respect of the environment. However, it is important to underline that the licensee or the operator has the prime responsibility for safety at all times.

Independence from any undue influence on the part of the nuclear industry and those sectors of government that sponsor this industry is vital to an effective regulator. This functional separation forms the background and the conditions for independent regulatory decision making. It includes making, and being perceived as making, independent, clear, balanced and unbiased regulatory decisions. Independence does not mean isolation – the regulator needs to have frequent and open discussions with all of its stakeholders and remain accountable to them for its actions and its decisions.

Core technical competency and experience are the basis of an effective regulatory body. The organisation's technical competency is a necessary condition but not sufficient in itself. Other complementary competencies need to be built upon this technical competency, such as knowledge of organisational and human factors, as well as legal and core regulatory competencies.

Openness and transparency are seen as fundamental to a regulatory body in achieving and maintaining credibility, trust and respect.

The organisation should have a regulatory framework and requirements that are clear and easily understood by all stakeholders. These should be coherent and logical and have a clear connection with the regulatory body's goals and objectives.

An effective regulatory body should have strong organisational capacity, demonstrate leadership and have in place management systems, sufficient resources and extensive staffing, as well as access to scientific and technical support.

The organisation should use its resources and make its decisions in an efficient and a timely manner. However, expediency must not come at the expense of safety and striving for efficiency should not harm the effectiveness objective.

Continuous improvements, international activities, co-operation and peer review are closely interlinked and are seen as another set of necessary characteristics of an effective regulator, as is an environment of continuous learning to maintain competence and credibility.

The above technical, cultural and behavioural competencies are necessary for effective regulation. These competencies support balanced and unbiased decision making that is commensurate with the risk and cost to people and to society, and they enable the safe operations of nuclear facilities. Such competencies are reflected in people with experience who can formulate and communicate clear judgments and who can resist any pressure that could compromise safety.

A regulator with the above characteristics should be capable of effectively and efficiently discharging its prime purpose of ensuring that the nuclear industry operates its facilities at all times in a safe manner, in accordance with international safety principles and with full respect of the environment.

The NEA Committee on Nuclear Regulatory Activities (CNRA) considers that this regulatory guidance booklet on the characteristics of an effective nuclear regulator provides a unique resource to countries with existing, mature regulators and can be used for benchmarking as well as training and developing staff. It will also be useful for new entrant countries in the process of developing and maintaining an effective nuclear safety regulator.



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## Appendix 1

### Summary description of regulatory approaches and strategies

#### Context

Regulators take different approaches to creating and enforcing safety requirements depending on the mandate provided by the national regulations. In addition to clear and comprehensive regulations and licence conditions, a regulatory body therefore needs to develop strategies by identifying appropriate approaches or combination of different approaches for conducting its regulatory supervision. In order to achieve a regulatory supervision that is effective and appropriate for a particular purpose, approaches and strategies need to be developed for various areas of regulatory supervision and be adapted to the nature of the areas and matters of regulatory supervision, taking into account their importance for safety.

These approaches have an impact on the outcomes for the licensee and other stakeholders and on regulatory supervision. In considering the overarching regulatory framework, regulators should take into account the benefits and difficulties of different approaches for different regulatory functions.

The discussion below is a summary from a study [5] sponsored by the Swedish Radiation Safety Authority (SSM). These regulatory approaches were discussed at the OECD/NEA CNRA Workshop on Regulatory Approaches and the Characteristics of an Effective Regulator which was hosted by SSM in Stockholm, Sweden in October 2013.

#### A summary of the pros and cons of various regulatory approaches

##### *Prescriptive approach*

A prescriptive approach is used by regulators to establish specific requirements for licensees and their activities, including proposed technical or other solutions.

A major benefit of a prescriptive approach is the level of clarity for both the regulator and the licensees. An additional benefit in some situations is that the approach can be used to exert specific regulatory authority. This approach has several difficulties, one of which is the appearance that the regulator is assuming responsibility for plant safety. The approach can also be resource-intensive for regulators and inflexible for licensees and operators.

### **Case- and facility-based approaches**

A case-based or facility-based approach is used by regulators to determine the safety requirements for each licensee through individual assessment of its design and operation, while considering the unique history of each facility.

Case- and facility-based approaches imply benefits of flexibility for the licensees in adapting to regulatory responses to unique situations. Since regulatory requirements are different for different licensees or different situations, potential difficulties of this approach include the regulator being considered arbitrary, inconsistent and unfair. The approach can also be resource-intensive for regulators.

### **Outcome-based approach**

An outcome-based approach is used by regulators to establish specific performance goals or outcomes for licensees to attain, but does not specify how they must be attained. Licensees determine how they will conduct their work activities.

An outcome-based approach is beneficial because it allows licensees to decide on optimal methods to meet safety goals. The approach also encourages licensees to improve plant performance and clearly places the responsibility for safety with the licensee. Potential difficulties for regulators using this approach include identification of good outcome measures.

### **Risk-informed and hazard-informed approaches**

Risk-informed and hazard-informed approaches are used by regulators to determine risk or hazard associated with an issue in order to evaluate the appropriate level of regulatory attention.

- A risk-informed approach uses a specific methodology including probability and potential for harm to identify areas of greatest risk.
- A hazard-informed approach uses specific criteria for the identification of areas of greatest potential for harm.

A major benefit of risk- and hazard-informed approaches includes focusing regulatory attention by prioritising safety issues and allocating resources. Potential difficulties for regulators using these approaches include the possibility of overlooking the limitations of risk and hazard analysis methods, which can therefore result in some regulatory areas receiving inadequate or too much attention.

### **Process-based approach**

A process-based approach is used by regulators to identify specific key processes that lead to safe performance and requires licensees to establish and implement these processes effectively.

A major benefit of a process-based approach is that it can provide in depth understanding of the licensees' performance. A difficulty of process-based approaches is the complexity of defining and evaluating processes. A major

drawback of a process-based approach can also be that it is not effective unless the processes are linked to outcomes.

### ***Self-assessment based approach***

A self-assessment based approach is used by regulators to establish requirements for licensees to develop and implement self-assessment programmes for identification of good practices as well as problem areas needing improvement, including internal reviews and follow-ups. The regulator evaluates the licensee self-assessment programme, reviews the results of the licensee assessments, and selectively inspects the licensee's follow-up of self-assessment results.

A self-assessment approach is beneficial because it places the responsibility for safety on the licensee and it promotes continuous improvement by the licensee. Major difficulties of this approach are that it should not be used as a stand-alone approach, that self-assessment programmes need to be closely monitored by the regulator and that the approach often lacks credibility with the general public.

### ***Education/influence-based approach***

An education/influence-based approach is used by regulators to provide information and training opportunities for the industry (including workshops, feedback, research results and other information) in order to improve industry performance.

This approach could potentially be a key tool for regulators when introducing new programmes such as safety culture and in situations when it is important to provide information to the licensees and the public. Potential difficulties of this approach include the requirement of a great deal of regulator experience and the dependence upon licensee acceptance.



## Appendix 2

### Complete list of the CNRA series of regulatory guidance reports (green booklets)

1	1999	<i>The Role of the Regulator in Promoting and Evaluating Safety Culture</i>
2	2000	<i>Regulatory Response Strategies for Safety Culture Problems</i>
3	2001	<i>Nuclear Regulatory Challenges Arising from Competition in Electricity Markets</i>
4	2001	<i>Improving Nuclear Regulatory Effectiveness</i>
5	2002	<i>The Nuclear Regulatory Challenges in Judging Safety Backfits</i>
6	2002	<i>Improving versus Maintaining Nuclear Safety</i>
7	2003	<i>The Regulatory Challenges of Decommissioning Nuclear Reactors</i>
8	2003	<i>Nuclear Regulatory Review of Licensee Self-assessment (LSA)</i>
9	2004	<i>Nuclear Regulatory Challenges Related to Human Performance</i>
10	2004	<i>Direct Indicators of Nuclear Regulatory Efficiency and Effectiveness: Pilot Project Results</i>
11	2005	<i>Nuclear Regulatory Decision Making</i>
12	2006	<i>Regulatory Challenges in Using Nuclear Operating Experience</i>
13	2008	<i>The Regulatory Goal of Assuring Nuclear Safety</i>
14	2011	<i>The Nuclear Regulator's Role in Assessing the Licensee Oversight of Vendor and Other Contracted Services</i>
15	2012	<i>Challenges in Long-term Operation of Nuclear Power Plants: Implications for Regulatory Bodies</i>

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# The Characteristics of an Effective Nuclear Regulator

Both national and international organisations agree that the fundamental objective of all nuclear safety regulatory bodies – the regulator’s prime purpose – is to ensure that nuclear licensees operate their facilities at all times in a safe manner. Much has been written about ways to improve regulatory processes or to improve the effectiveness of a regulatory body, including in previous OECD/NEA regulatory guidance booklets. But until now, none have focused on the characteristics of an effective nuclear safety regulator.

Effective organisations are those that have good leadership and are able to transform strategic direction into operational programmes. Effectiveness is about how well the organisation is achieving its fundamental purpose – in the case of a nuclear safety regulator, ensuring that licensees operate their facilities and discharge their obligations in a safe manner.

This regulatory guidance booklet describes the characteristics of an effective nuclear safety regulator in terms of roles and responsibilities, principles and attributes. Each of the characteristics discussed in this report is a necessary feature of an effective nuclear safety regulator but no one characteristic is sufficient on its own. It is the combination of these characteristics that leads to the effectiveness of a nuclear regulatory body. The report provides a unique resource to countries with existing, mature regulators and can be used for benchmarking as well as training and developing staff. It will also be useful for new entrant countries in the process of developing and maintaining an effective nuclear safety regulator.

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