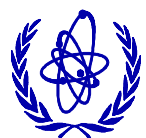


PDRP-4

Assessment of regulatory effectiveness

Peer discussions on regulatory practices



INTERNATIONAL ATOMIC ENERGY AGENCY, 1999

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FOREWORD

This report arises from the seventh series of peer discussions on regulatory practices entitled “Assessment of Regulatory Effectiveness”. The term ‘regulatory effectiveness’ covers the quality of the work and level of performance of a regulatory body. In this sense, regulatory effectiveness applies to regulatory body activities aimed at preventing safety degradation and ensuring that an acceptable level of safety is being maintained by the regulated operating organizations. In addition, regulatory effectiveness encompasses the promotion of safety improvements, the timely and cost effective performance of regulatory functions in a manner which ensures the confidence of the operating organizations, the general public and the government, and striving for continuous improvements to performance.

Senior regulators from 22 Member States participated in two peer group discussions during March and May 1999. The discussions were focused on the elements of an effective regulatory body, possible indicators of regulatory effectiveness and its assessment. This report presents the outcome of these meetings and recommendations of good practices identified by senior regulators, which do not necessarily reflect those of the governments of the nominating Member States, the organizations they belong to, or the International Atomic Energy Agency.

EDITORIAL NOTE

In preparing this publication for press, staff of the IAEA have made up the pages from the original manuscript(s). The views expressed do not necessarily reflect those of the IAEA, the governments of the nominating Member States or the nominating organizations.

Throughout the text names of Member States are retained as they were when the text was compiled.

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1. INTRODUCTION

1.1. BACKGROUND

In 1986, at a Special Session of the IAEA General Conference, it was suggested that the IAEA could play a role in assisting Member States in the enhancement of regulatory practices with the objective of increasing the confidence of the public in the safety of nuclear power. The IAEA subsequently sent out questionnaires on regulatory practices and on inspection and enforcement. Summaries of the replies to these questionnaires were issued as TECDOCs.

In 1988 it was agreed that the most useful way to develop peer review of regulatory practices was for small groups of regulators to meet together, with an IAEA co-ordinator, to discuss selected topics. It was intended that Senior Regulators from different groups of Member States would discuss the same topic in a series of peer group discussion meetings, putting emphasis on identifying beneficial aspects of practices rather than on comparing regimes.

This objective was further enhanced when the Nuclear Safety Standards Advisory Group (NUSSAG) recommended in 1989 that “to promote the sharing of experience through increased professional contacts between nuclear safety regulators, a system should be provided for the identification of commonly accepted good practices and to disseminate them widely among Member States”.

As a result of this recommendation, six series of meetings were held. The first in 1989–1990 discussed “Regulatory Inspection and Enforcement Good Practices”; the second, in 1991–1992, dealt with “Regulatory Good Practices Relating to Monitoring and Assessment of Ageing of Nuclear Power Plants”, and the third, in 1993–1994, addressed “Policy for Setting and Assessing Regulatory Safety Goals”. The third series resulted in the publication in 1995 of IAEA-TECDOC-831, “Policy for Setting and Assessing Regulatory Safety Goals”.

Starting with the fourth series of meetings, the reports of the peer discussions were published in the PDRP special report series. They are PDRP-1 “Development of Measures to Assess the Safety of Existing NPPs and the Effectiveness of Regulations and Regulatory Actions (including ‘Prescriptive’ and ‘Performance Based’ Approaches)”, PDRP-2 “Approaches Relating to Decommissioning of Nuclear Facilities” and PDRP-3 “Regulation of the Life Cycle of Nuclear Installations”.

The present report arises from the seventh series of meetings, held during March and May 1999, which addressed the subject recommended by the Advisory Commission on Safety Standards (ACSS) and which was adopted by the IAEA as “Assessment of Regulatory Effectiveness”.

1.2. OBJECTIVE

In order to protect people and the environment from hazards associated with nuclear facilities, the main objective of a nuclear regulatory body is to ensure that a high level of safety in the nuclear activities under its jurisdiction is achieved, maintained and within the control of operating organizations.

Even if it is possible to directly judge objective safety levels at nuclear facilities, such safety levels would not provide an exclusive indicator of regulatory effectiveness.

The way the regulatory body ensures the safety of workers and the public and the way it discharges its responsibilities also determine its effectiveness. Hence the regulatory approaches of the regulatory body and its organization are important factors.

Whilst regulatory effectiveness cannot easily be measured directly, there are various characteristics which can be attributed to an effective regulatory body. These characteristics can be used as indicators. They can also provide guidance on the assessment of regulatory effectiveness. They may also indicate possible fields of enhancement of the effectiveness of a regulatory body.

In order to assist Member States in achieving and maintaining a high level of regulatory effectiveness, the IAEA convened the seventh series of peer discussions on “Assessment of Regulatory Effectiveness”. The results and findings of these discussions are summarized in this report which concentrates on common findings and good practices identified during the discussions. Its intention is primarily to disseminate information on existing experience and to identify beneficial aspects of practices in order to provide guidance to Member States.

1.3. STRUCTURE AND SCOPE

This report is structured so that it covers the subject matter under the main headings of:

- elements of an effective regulatory body
- possible indicators of regulatory effectiveness
- assessment and suggestions for good practices to enhance effectiveness.

It is important to note that recommendations of good practice are included if they have been identified by at least one of the groups. It does not follow that all of the groups or individual Member States would necessarily endorse all of the recommendations. However, it is considered that if a single group of senior regulators judge that a particular practice is worthy of recommendation, it needs to receive serious consideration. In some cases the same recommendations arise from all of the groups. These are considered to be particularly meritorious.

1.4. THE MEETINGS

Two meetings were held, in the months of March and May 1999. The list of participants at these meetings is given at the end of this report. In the interests of continuity and consistency, the same consultant was invited by the Agency to chair both meetings. Each meeting was independent, with no details of the discussions at previous meetings being disclosed. The meetings proceeded in the same way with each participating member describing his or her national regulatory regime and practices in turn, with the subsequent discussion examining points of similarity and their merits.

The IAEA organizers set the stage for the discussions by asking participants to start their discussions with the following five questions:

1. What are the major elements that make an effective regulatory body?
2. In what areas should effectiveness be assessed and how?
3. What kind of operating organization performance can be used to evaluate regulatory effectiveness and how?
4. Are there any indicators for regulatory effectiveness?
5. How to enhance regulatory effectiveness?

Both meetings were substantially larger than those at the preceding series of peer discussions. So for each of the meetings the participants divided into two groups and produced reports. It turned out that for each of the meetings the size of the groups was small enough to enable efficient group work yet large enough to foster in-depth discussion, particularly in the plenary sessions.

There were thus four deliverables that were consolidated into this report by a small consultancy group.

The very complexity of the topic — assessing the effectiveness of a regulatory body — means that this report probably does not fully develop all the ideas that are presented within it. The difficulties for fully developing these ideas and providing a working framework of unambiguous assessment tools are acknowledged. Further discussions will be necessary, and are encouraged, to continue and fine tune the recommendations of good practices that are presented in the report.

2. MAJOR ELEMENTS THAT MAKE AN EFFECTIVE REGULATORY BODY

The elements that make an effective regulatory body can be considered in two groups — elements which are provided by government or lawmakers, depending on national legal systems, and elements which are under the control of the regulatory body.

2.1. ELEMENTS PROVIDED BY GOVERNMENT OR LAWMAKERS

Government needs to provide the legal framework for nuclear activities in its country, establishing the overall duties and responsibilities.

A regulatory body needs to be provided with a legal basis with powers to set standards and powers to perform licensing, inspection, review and assessment, and enforcement functions as well as to regulate these processes. Access to installations, to safety related documentation and to relevant safety information is important and needs to be supported by law.

To be effective, a regulatory body needs to be institutionally independent. It needs to be independent of the industries which it regulates, independent of considerations of energy policy particularly of any consideration of the need to maintain electrical supplies to consumers, and independent of government departments which sponsor or fund nuclear facilities.

Government needs to set the mission to be accomplished by the regulatory body. The mission — which needs to indicate that safety is important — can be set annually or otherwise, for example in the laws which provide the legal basis for the regulatory body.

Government needs to provide sufficient funding for the regulatory body in such a way that the regulatory body can deliver its mission. Stability for the regulatory body is important, but an annual budgetary bidding process is likely to exist in practice.

Government needs to agree on the division of responsibilities between the regulatory body and other regulatory or governmental agencies, such as those responsible for radiation protection, environmental matters and transport, so as to prevent overlaps or gaps. Co-operation and co-ordination between all parties is important.

Government needs to set out its policy as regards the degree to which the regulatory body should publish the results of its work or generally be open.

2.2. ELEMENTS PROVIDED BY THE REGULATORY BODY ITSELF

(a) Policies, objectives and strategies

To be effective, a regulatory body needs to have clear policies, objectives and strategies related to safety. A typical policy statement would be one which states that the operating organizations are responsible for safety. In general, policies need to:

- aim to target high risk situations;
- be proportionate in such a way that resources are applied to matters of high safety concern or that enforcement actions are commensurate with the offence;
- ensure consistent decisions over time, across national nuclear industries and with international practice; and
- be transparent by being understandable and accessible.

Typical objectives which are effective would be those which aim to reduce risks so far as is reasonably practicable, those which aim to ensure that periodic reviews of plants are carried out at regular intervals by operating organizations against modern standards and those which aim to ensure that operating organizations update old plants as far as is reasonably practicable.

Examples of regulatory strategies are those that are prescriptive, performance based, process based or goal based with self-evaluation by the operating organizations.

(b) Organization, functions and competencies to meet the mission and mandate of the regulatory body

To be effective, a regulatory body needs to have an organization and processes to deliver licensing, inspection, review and assessment, and enforcement functions including the withdrawal of previous authorizations. The organization will specify roles, responsibilities and accountabilities of staff members, allocate staffing levels and provide a flexible approach to adjust resources according to priorities. The processes will allow for a timely response by the regulatory body to operating organizations activities, events and incidents, an assessment function that is independent of the operating organizations and the designer, manufacturer architect engineer and an inspection function which provides a capability for both proactive and reactive inspections. It is important that a regulatory body have the capability to follow up its regulatory decisions and requirements to ensure that these are met in a timely and correct manner.

The regulatory body needs to be appropriately structured to carry out its functions. There are several ways to achieve this successfully. For example, organizational units can correspond to each basic function of the regulatory body. Alternatively, organizational units can cover both inspection, review and assessment and enforcement functions leaving licensing and other more specialist functions in separate organizational units. Whatever organizational structure is chosen, responsibilities of each unit and staff member need to be clear, good communication needs to exist between relevant units and staff members on common items of interest and the overall organizational structure needs to be sufficiently flexible to respond to actual priorities. The regulatory body can be structured in a number of ways according to the legal system of the Member State. The IAEA Safety Series publications provide information on this topic. A typical overall framework is illustrated in Figure 1.

To be effective, a regulatory body also needs to have regulatory standards, regulatory guides and internal guidance for use by the regulatory staff. This suite of documentation not only needs to exist but it needs to be reviewed regularly and updated according to need. The aim should be to provide a clear, predictable and logical regulatory process for dealing with safety issues.

The regulatory body needs to have sufficient staff who are highly competent with sufficient knowledge, experience, training and motivation to perform the work of the regulatory body and to make independent regulatory decisions.

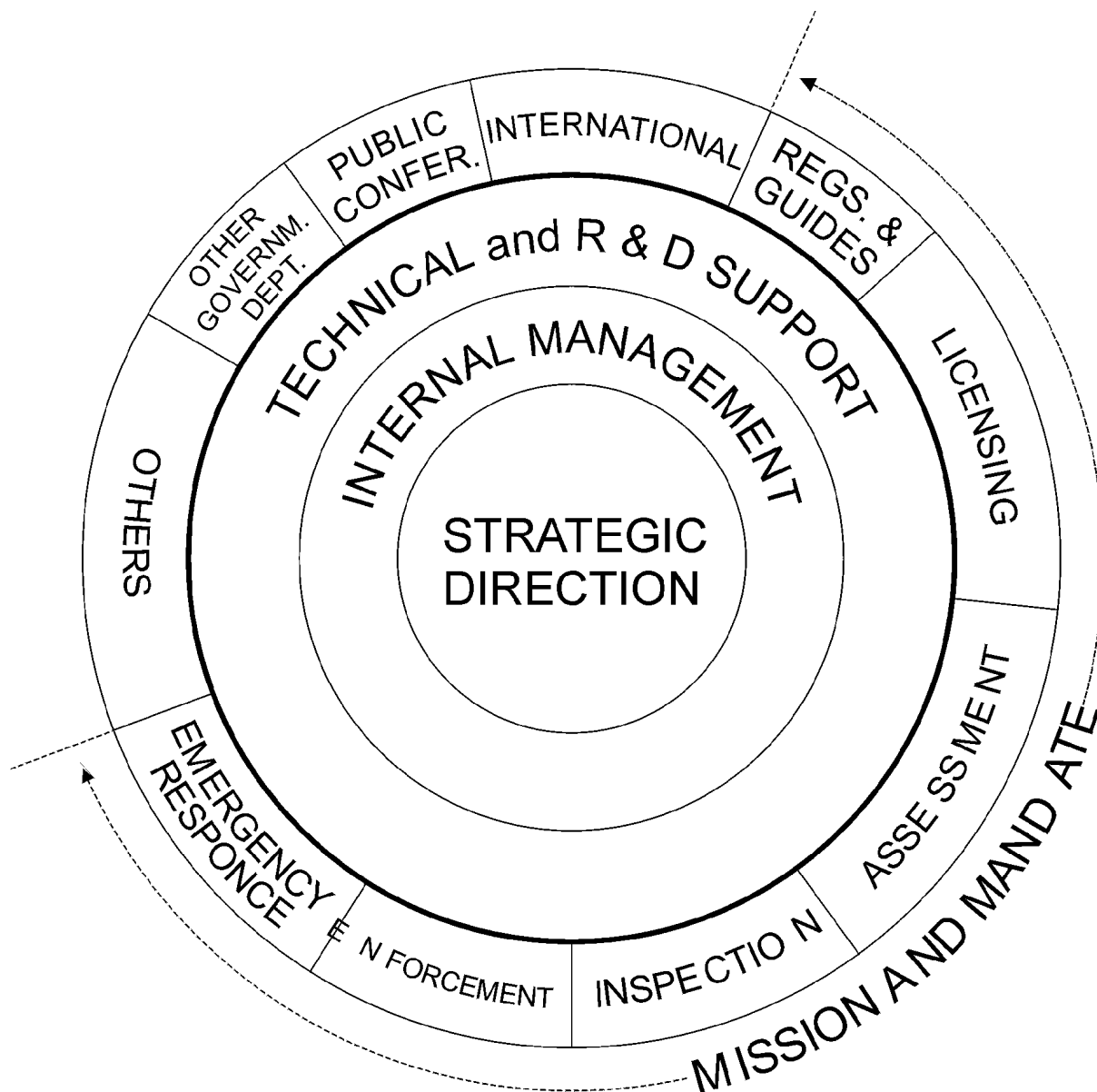
Depending on the national system, size and competence of the regulatory body, the regulatory body should have access to external technical support including Advisory Committees. However, such access does not relieve the regulatory body from discharging its responsibilities.

The regulatory body needs to have an internal quality assurance system to cover such items as internal rules, planning, budgeting, delivery of work to an acceptable level, audit and review. The aim should be to ensure consistent and timely actions for both proactive and reactive situations.

The regulatory body needs to ensure that adequate emergency planning and preparedness exists and be prepared to participate in national decision-making and communication in relation to significant events, wherever they occur.

The regulatory body needs to have the capability to fund and manage or to perform research activities in support of its work. It also needs to be able to fund and manage work which it is unable to carry out itself because it does not have the expertise. In all cases the regulatory body needs to be able to judge whether the outcome of the contracted work is adequate and whether it can be adopted by the regulatory body.

The regulatory body needs to have international contact with other regulatory bodies in order to assist in standard making, to facilitate benchmarking of national practices and to exchange information on operating experience and safety issues. International contact in respect of experience feedback is very important. It is also helpful to exchange personnel between countries to enhance training and to give and receive technical support from other countries.



Outer Ring: Front-line Functions

Internal Management: Efficient Practices

Technical and R&D Support : Skill;
Knowledge;
Experience

Strategic Direction: Resources;
Priority

FIG. 1. Model for assessment of a regulatory body.

(c) Relations with operating organizations and others

The regulatory body, while recognizing its role as a regulator should have an open relationship with operating organizations and other agencies on regulatory and safety issues. Good and efficient communication is very important. It is particularly important that the regulatory body ensures that operating organizations report safety issues to the regulatory body.

The regulatory body needs to deliver the government's policy in relation to openness. For example, it is helpful to have regular and open communication with the public through press releases, press conferences, seminars, published reports and provision of information on the Internet about safety issues, regulatory decisions and significant events.

3. POSSIBLE INDICATORS OF REGULATORY EFFECTIVENESS

Section 2 describes the major elements of an effective regulatory body as defined by a legal framework, authority, mandate and mission. It also describes suitable organizational structures to provide outputs for effective control of nuclear safety. The challenge now is to identify possible indicators that can be used for assessment of regulatory effectiveness.

3.1. POSSIBLE INDICATORS OF REGULATORY EFFECTIVENESS IN RESPECT OF LEGAL AND GOVERNMENT PROVISIONS

- (a) An adequate legal basis exists for the regulatory body and the processes which it regulates.
- (b) Legal responsibilities for safety are clearly stated.
- (c) The mission of the regulatory body is clear and is delivered in practice.
- (d) The regulatory body is institutionally independent of the industries which it regulates, independent of energy policy considerations particularly of any consideration of the need to maintain electrical supplies to consumers and independent of government departments which sponsor or fund nuclear facilities.
- (e) Sufficient funding is ensured to enable the regulatory body to carry out necessary work and provide funding for research and any expertise it does not have within its organization and to enable the regulatory body to deliver its mission.

3.2. POSSIBLE INDICATORS OF REGULATORY EFFECTIVENESS IN RESPECT OF REGULATORY BODY ORGANIZATION

- (a) The regulatory body targets high risk areas, enforces serious matters and not trivia, provides consistent decisions in similar circumstances and is accessible and transparent to the public.
- (b) The regulatory body issues statements on safety philosophy and regulatory strategies which are clear to its staff, to operating organizations and to the public.
- (c) Clear roles and responsibilities exist within the regulatory body for licensing, inspection, review and assessment (including periodic review) and enforcement. These processes are documented.
- (d) The ratio of time spent on planned inspections to time spent on reactive inspections is high.

- (e) The regulatory body has the capability to carry out reviews and assessments independently of the operating organizations, designers, manufacturers and architect engineers.
- (f) Good communication, interchange of views and co-operation exists within the regulatory body between inspectors and assessors.
- (g) The regulatory body plans and prioritizes its work. But flexibility exists to change regulatory priorities according to safety needs to enable high safety risks to receive the highest priority.
- (h) The frequency of new regulatory requirements. Too many changes indicate a lack of forethought by the regulatory body.
- (i) The period of delay between the identification of the need for a new regulatory requirement and its introduction.
- (j) The regulatory standards, regulatory guides and internal guidance for use by the staff or the regulatory body are clear, complete and have been regularly reviewed and suitably amended.
- (k) Operating organizations and other agencies are consulted before regulatory standards and guides are issued or amended.
- (l) Competent staff with the right knowledge, experience, and number exist to perform the processes of the regulatory body, including the provision of independent assessments.
- (m) The ratio of the number of staff leaving the regulatory body each year is low when compared with that of the cadre level.
- (n) Good internal quality assurance.
- (o) Effective internal management exists to ensure that policies, strategies and practices are followed in a consistent manner.
- (p) The regulatory body is forward looking to spot future regulatory challenges in sufficient time to have workable strategies and resources in place before the challenges occur.
- (q) A capability exists to fund and manage research and any work carried out by others because the regulatory body does not have the expertise within its organization.
- (r) Good international contact exists for standard making, benchmarking of national practices and international exchange of information and people.
- (s) The regulatory body displays a willingness to learn and improve and a willingness to accept a peer review such as an IRRT mission from IAEA or some other review organization.
- (t) Regulatory decisions are taken quickly in situations when high safety risks actually exist.
- (u) The regulatory body has the capability to enhance safety culture.
- (v) Planned work is completed within budget and on schedule.
- (w) The regulatory body consults operating organizations and other stakeholders about its work, particularly for aspects such as the timeliness, quality and consistency of its actions, including regulatory decisions.
- (x) The regulatory body makes good use of office management and human resources; document control and records; service standards and monitoring; finance; and human resource planning, human resource development and training.
- (y) The existence at the regulatory body of effective systems for operational experience feedback and incident assessment.
- (z) The reaction time of the regulatory body is short between its discovery of an unsafe practice and the taking of regulatory or enforcement action.

3.3. POSSIBLE INDICATORS OF REGULATORY EFFECTIVENESS FROM THE PERFORMANCE OF OPERATING ORGANIZATIONS

There is usually interaction between operating organizations and regulatory bodies such as:

- (a) during licensing when the operating organization makes an application for an installation and the regulatory body assesses the application and issues the licence;
- (b) for significant plant modifications when the operating organization makes safety analyses and the regulatory body assesses the safety analyses and authorizes implementation of the modifications;
- (c) for regulatory standards and guides where the regulatory body usually consults operating organizations and other bodies prior to issuing the regulatory standards and guides;
- (d) for operational feedback and incident and accident assessment when the operating organization performs this work with regulatory body oversight, inspection and interaction according to national practices;
- (e) during inspections when the regulatory body forms a view about the subject area being inspected by discussion with the staff of the operating organization and examination of documentation and practices;
- (f) during regulation when the regulatory body seeks by persuasion or enforcement to change operating organization practices;
- (g) during non-confrontational discussions when the regulatory body and the operating organization discuss technical, regulatory or regulatory process issues.

Because of the interaction between operating organizations and the regulatory body it is possible to draw some conclusions about regulatory effectiveness; nonetheless this is a difficult proposition and care needs to be taken. For example, if an operating organization has a consistently good safety performance over time does it mean that the regulatory body is being effective? The answer could be yes, but only if the regulatory body has had to regulate, persuade or use enforcement to ensure that the operator's safety performance is high. It may well be that the operating organization achieves acceptable safety despite the regulatory body. However, there is probably a closer correlation between a consistently poor safety performance of an operating organization over time and a poor effectiveness of a regulatory body.

Possible indicators of the performance of operating organizations which may reflect on the performance of the regulatory body are:

Safety assessment and plant upgrades

- the extent to which operating organizations comply with regulatory standards and guides and with the state of the art;
- the extent to which the regulatory body ensures that operating organizations upgrade their plants to modern standards, lessons learned and stay in step with changing technology;
- the time taken by the regulatory body to agree to operating organizations' proposals either because of inadequate safety submissions by the operator or delays by the regulatory body;
- number of safety issues not discovered by the utility but by the regulatory body.

Incidents and accidents

- the number of internal corrective actions to be taken after an incident or accident;
- the number of changes to regulatory requirements after an incident or accident.

General

- the reduction of occupational radiation exposure;
- the reduction of radioactive releases;
- the reduction in the number of significant events;
- the time which is taken by an operating organization to respond to reasonable demands of the regulatory body.

4. FIELDS FOR ENHANCING EFFECTIVENESS OF REGULATORY BODIES

The working groups considered this to be a difficult question but nevertheless concluded that the effectiveness of regulatory bodies could be improved by:

- establishing a systematic approach to manage people and processes;
- involving staff members in continuous improvement of the regulatory body's processes;
- preferring process-oriented management;
- developing leadership skills of line managers and senior managers;
- developing data management and associated classification systems to aid in future analyses and decision-making;
- establishing a systematic approach for annual planning and its implementation;
- developing an appropriate approach to salaries, awards and bonuses for the regulatory body staff;
- reviewing the appropriateness of the regulatory regime on a regular basis and the topics of regulatory control;
- discussing the values, mission, vision and strategy to be applied in regulatory work;
- collecting feedback from the main stakeholders of the regulatory body to provide ideas for improving regulatory body performance;
- establishing a systematic approach for:
 - the day-to-day monitoring of work
 - self-assessment at all organizational levels
 - the measurement of performance and outcomes
 - external independent assessments of the regulatory body;
- maintaining good communication with government decision-makers to aid in strategic forward planning by the regulatory body and in drawing up annual budgets which are consistent with the work to be done. An annual report to government highlighting the outcomes for the elapsed year may be helpful;
- within the regulatory body, making necessary staff changes in such a way that the work output of the regulatory body at worst only suffers lightly and the effects on staff motivation are minimized;
- ensuring that regulatory standards, guides, internal guidance and internal quality assurance are clear, complete and up to date;

- ensuring that good communication exists between individuals and groups working on the same issue within the regulatory body so that inspection and assessment work is appropriately integrated and that a consistent feedback can be provided to the operating organizations;
- ensuring that the regulatory body discusses issues with the operating organizations before taking regulatory action so as to provide an opportunity for the operating organizations to explain to the regulatory body why such an action may be counterproductive.

5. CONCLUSIONS

This seventh series of peer discussions has shared the established policies and practices of the regulatory bodies of Member States as well as the personal knowledge and experience of the attending senior regulators in order to identify elements of regulatory effectiveness, possible relevant indicators, and ways to assess and — where justified or necessary — to enhance the effectiveness of the regulatory body.

The assessment methods for regulatory effectiveness discussed in this report are of necessity surrogate because it is not possible, in finite time, to calibrate the measurement tools and techniques to statistical data of accidents in nuclear facilities. The accident rate is simply too small because of the high reliability that has been designed into them. It is therefore necessary to be proactive in the choice of methods. In this report the assessment methods are a mix of traditional and new. Traditional methods include audits, internal assessments, reviews of strategic plans, roles and responsibility assignment, QA of work plans and programmes, training programmes, career management, etc. New techniques include the use of proactive safety improvement programmes by the regulatory body and the use of peer reviews, audits and inspections of the regulatory body by external organizations.

The participating senior regulators agreed that regulatory bodies need to:

- accept the value of being learning organizations;
- strive for improvement and enhancement by such means as self-assessment and peer reviews by external organizations;
- maintain and adopt systems for the budgeting, prioritizing, planning and monitoring of their work and processes;
- have good internal quality assurance systems for their work, processes and documentation;
- have good communication with their stakeholders about regulatory body work and processes;
- participate and co-operate with regulatory bodies from other countries and with international organizations in respect of information exchange, peer reviews and international standards, etc.

The IAEA has established a programme of International Regulatory Review Team (IRRT) missions, which, at the request of interested Member States, can perform a review of the national regulatory system.

The key objective of an IRRT mission is to enhance nuclear safety by:

- providing the host country (regulatory body and governmental authorities) with an objective review of their nuclear regulatory practices with respect to international guidelines;
- providing the host regulatory body with recommendations and suggestions for improvement in areas where their organization or performance can be performed or falls short of internationally accepted practices;
- providing key staff at the host regulatory body with an opportunity to discuss their practices with experts who have experience with other practices in the same field;
- providing all Member States with information regarding good practices identified in the course of the review; and
- providing experts from Member States and the IAEA staff with opportunities to broaden their experience and knowledge of their own field.

The participating senior regulators agreed that the IRRT programme is an efficient tool for the assessment and the enhancement of the effectiveness of a regulatory body. They encourage the IAEA to continue this programme and to use the outcome and findings of these peer discussions as an input for their own recommendations, suggestions or identification of good practices.

The experts participating in this seventh series of peer discussions on regulatory practices were aware of the fact that there is no universal or generally accepted definition of the term ‘regulatory effectiveness’. The following statement may, however, be considered as the essence of these peer discussions:

The regulatory body is effective when it:

- **ensures that an acceptable level of safety is being maintained by the regulated operating organizations;**
- **takes appropriate actions to prevent degradation of safety and to promote safety improvements;**
- **performs its regulatory functions in a timely and cost effective manner as well as in a manner that ensures the confidence of the operating organizations, the general public and the government; and**
- **strives for continuous improvements to its performance;**

given the necessary authority and resources as prerequisites.

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