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Quality management of the nuclear regulatory body

Peer discussions on regulatory practices

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Safety Co-ordination Section
International Atomic Energy Agency
Wagramerstrasse 5
P.O. Box 100
A-1400 Vienna, Austria

QUALITY MANAGEMENT OF THE NUCLEAR REGULATORY BODY
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FOREWORD

This report is the outcome of the ninth series of peer discussions on regulatory practices entitled Nuclear Regulatory Body Quality Management, held in March and May 2001, and which involved the participation of senior nuclear regulators from 23 IAEA Member States.

This report conveys the essence of two peer group discussions and highlights some good practices identified by the participating senior regulators. The shared experiences and good practices presented in the report, however, do not necessarily reflect the views of and good practices endorsed by the governments of the nominating Member States, the organizations to which the regulators belong, or the International Atomic Energy Agency.

EDITORIAL NOTE

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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 a 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, seven 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 culminated in the publication of Policy for Setting and Assessing Regulatory Safety Goals in 1995 (IAEA-TECDOC-831).

Starting with the fourth series of meetings, the reports of the peer discussions were published in the PDRP reports 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; PDRP-3, Regulation of the Life Cycle of Nuclear Installations; PDRP-4, Assessment of Regulatory Effectiveness, and PDRP-5, Regulatory Control of the Use of Contractors by Operating Organizations.

The present report arises from the ninth series of meetings, held in March 2001 and May 2001, which addressed the subject recommended by the Commission on Safety Standards (CSS) and which was adopted by the IAEA as: Quality Management of the Nuclear Regulatory Body.

The application of quality assurance requirements to the operating organization has long been common practice in the Member States. This is one of the effective ways used by the regulator to ensure the safety of the nuclear industry.

A quality management system or a quality assurance programme generally consists of a high level policy statement, which reflects the commitment of senior management to the attainment and continuous improvement of quality. It also states the objectives of the

organization and designates the functional responsibilities. The next level is the description of the management processes to be performed. This is followed by the implementation level procedures for staff performing the work. The effectiveness of management processes and work performance are evaluated by performing assessments and audits.

The necessity for adopting a similar approach to quality assurance in a regulatory body has been considered for some time. Some Member States now have a formal quality management or quality assurance system in place and it has been proven to be very useful in improving the accountability of the regulatory work. Some Member States, learning from the successful experience of the forerunners, are in the process of upgrading their internal management arrangements to a more systematic quality approach. Nonetheless, some other Member States consider that the quality assurance requirements should be applied to the operating organization but have not taken steps to introduce a system for their own activities. However, even in those cases the management practices in the regulatory bodies do have implicit QA features.

It is important for this series of peer discussions to exchange experience between regulators in developing and implementing the application of systematic approaches for quality management (QM) within their own organizations.

1.2. OBJECTIVE

In order to assist Member States in developing and implementing a QM system for regulatory work, the IAEA convened the ninth series of peer discussions on Quality Management of the Nuclear Regulatory Body.

The objective of the discussions was to share experiences of regulatory bodies in implementing QM systems in their own work so as to ensure that the regulatory control over the licensees is effective and efficient and is commensurate with the mandate assigned by their governments.

The results and findings of these discussions are summarized in this report which sets out shared experiences 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

The report sets down the peer group's experience in developing, implementing and evaluating QM within their regulatory bodies and identifies points to bear in mind when introducing such a system.

This report is structured so that it covers the subject matter under the main headings of:
- application of quality management to regulatory work
- development and implementation of quality management
- assessment and improvement of performance
- good practices.

It is important to note that some good practices 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 good practices. 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 many cases the same good practices arise from all of the groups.

1.4. THE MEETINGS

Two meetings were held in March and May 2001. The list of participants at these meetings is given at the end of this report. For the sake of continuity and consistency, the same consultant was invited by the IAEA 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 questions that can be grouped in the following four areas:

(1)   What is the necessity for a quality management approach to regulatory work?
(2)   What approaches are necessary and available to manage the quality of regulatory work?
(3)   What methods can be used to evaluate the quality of regulatory work?
(4)   What good practices can be identified for the QM of regulatory work?

At each of the meetings the participants divided into working groups and produced reports. It turned out that for each of the meetings the size of the working groups was small enough to enable efficient group work and in-depth discussion, the plenary session was large enough for extensive exchange of experience. The results of the working groups were consolidated into this final report by a small consultancy group.

2. APPLICATION OF QUALITY MANAGEMENT TO REGULATORY WORK

2.1. GENERAL

Owing to different definitions in different publications the terms quality assurance and quality management may cause confusion. The term 'quality assurance' used by the IAEA in its Safety Standards and 'quality management' used in the series of ISO 9000 standards have essentially the same meaning. However, the term 'quality assurance' in the ISO 9000 terminology is just a part of the quality management. In the context of this report QM includes quality assurance, assessment and continuous improvement.

The requirement for nuclear facilities to have a QM system has long been a licence condition in the Member States. However, the application of QM to the activities of the regulator may not to date have been afforded the same degree of formality.

This is not to say that regulators without a QM system have not controlled their activities or that they have not undertaken their responsibilities in a serious manner. Most of them already have the elements of QM such as an organization, procedures, guidelines for regulatory tasks, document control, training programmes, etc. Where this differs from the formal QM system is that it is not as systematic or formalized as a QM system demands. Most regulatory staff were highly experienced and the development of nuclear technology was interconnected and relatively limited in scope. This situation made it easier to allocate and control activities through direct contact with the technical areas of licensee activities and used a more 'hands on' approach to regulatory work.

Over time many factors have evolved and challenged the regulatory situation causing regulators to reassess the way they are organized, controlled and to question how their performance can be improved. This may have also led to the realization that regulators may have been anticipating in their outlook and therefore needed to be more pro-active to meet potential problem scenarios. Examples from other industries in successfully applying QM to their way of doing business and managing change has been seen as having merit by some regulators and has led to the realization that QM is worthy of adoption.

This is further endorsed by the international perspective on the need for QM as required in IAEA Safety Standards Series No. GS-R-1 [1] on Legal and Governmental Infrastructure for Nuclear, Radiation, Radioactive Waste and Transport Safety which requires that "The regulatory body shall establish and implement appropriate arrangements for a systematic approach to quality management which extend throughout the range of responsibilities and functions undertaken" (para. 4.5.).

2.2. STAKEHOLDER EXPECTATIONS

The identification of stakeholders (customers, in many QA references [2, 3]) is an essential prerequisite for the QM system. However, in some Member States the term stakeholder is not fully understood and not easy to translate. Stakeholders are all those who have interest in an organization, its activities and its achievements. These may include the public, government, licensees, employees and other regulators. Stakeholder expectations and requirements constitute the main reasons for assessment of regulatory performance.

Some of the factors which may influence the regulator to apply formal QM to its work include:

- New expectations, without commensurate increases in resources and requirements from the public, government and the international community. The public seeks increased reassurance on nuclear safety and protection, new revised legislation requires action, whilst pressures from environmental groups place new demands on regulators.

- New or increased reporting requirements from regulators for public, governmental and statutory agencies. In some cases certain international financial bodies also require QM system features to be put in place at the regulator before releasing funds for nuclear investment or upgrading.

- Transparency, openness and the consequences of poor nuclear safety performance reflecting on regulatory credibility due to incidents, accidents and the associated liability of perceived failure to regulate.

- Increases in the scale, scope and complexity of regulatory work coupled with the diversification of technology, requiring greater competence, expertise and attention from a regulatory perspective.

- Justification of cost effectiveness in those cases where licence fees or costs are invoiced for regulatory work, including the substantiation of time and resources incurred by the regulator.

- Many regulators are experiencing a loss of experience as a consequence of an ageing workforce and have to develop comprehensive training and development programmes for newer staff to maintain competence and acceptable safety culture levels.

- Progress in information technology, development of improved communications systems provide better means of planning, communicating, controlling and recording than ever before.

- The regulator needs to achieve full coverage and implementation of all regulatory tasks in an optimum and effective manner, to receive adequate feedback on the outcome of its operations, to effectively and timely define its own improvement actions.

- Safety decisions and their bases need to be traceable through a secure and formal system.

- Necessary human resources and competencies are available without diminution of regulatory effectiveness, taking into account movement and replacement of personnel and the developments of the nuclear programme.

- Limited resources are justified and used effectively.

- Opportunities now exist to obtain certification or accreditation through recognized external agencies, this can assist a regulator to gain credibility and recognition through approval of its QM system.

- Liaison and co-ordination with other regulatory agencies such as those which have jurisdiction over water, mining and environment related activities, may require interfacing with their QM and communication and reporting systems.

- International assessment and recognition by peer reviews such as IRRT or peer exchanges at the regulator level provide independent and valuable feedback on the regulator's status against accepted international regulatory practices.

Reorganization can provide the opportunity, if properly managed, to introduce the formal structure of QM into the regulatory organization and can act as a catalyst to promote the desired change from the past to the future by introducing the concepts of continuous improvement, enhancement of safety culture and of becoming a learning organization.

2.3. ATTRIBUTES OF QUALITY MANAGEMENT

As well as having a proper foundation and framework, the QM system needs to provide support for dynamic learning and improvement. The target is to be an effective and efficient regulator with continuous improvement in performance. Studies have demonstrated some features of QM that are common to all successful organizations. Examples of these features are presented for instance in the ISO 9000:2000 standard [2] under Quality Management Principles and in the European Foundation for Quality Management Excellence Model (EFQM EM) [3] under Fundamental Concepts of Excellence. Applicability of these documents to the public sector and especially to the nuclear safety authorities has been demonstrated by some Member States, with good results.

It also needs to be realized that establishment and maintenance of the QM system is a never-ending process that requires additional resources. From a resource management point of view, short term benefits may be difficult to quantify or justify. The quality of key regulatory work may also suffer due to increased attention to formal administrative matters in order to comply with the QM requirements. However, benefits of a sound QM system always compensate for costs in the long term, and such a QM system will help focus resources on regulatory work.

Some of the attributes of a QM system include:

- receiving inputs from all staff and, once approved at the appropriate level, being communicated to all concerned;
- covering all regulatory work; and identifying all processes;
- identifying responsibilities, accountabilities and reporting lines;
- taking into account internal factors (human, motivation, cultural, financial etc.);
- taking into consideration external factors, national and international, and the available technology;
- covering training and career development;
- being extended to cover the work and documents, whenever technical support organizations or consultants are employed on regulatory work;
- identifying, producing and monitoring performance indicators.

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3. DEVELOPMENT AND IMPLEMENTATION OF QUALITY MANAGEMENT

3.1. MAIN FEATURES

Top management has to commit itself to the total purpose of the QM system and to the specific goals that are defined to make it a reality. The overall goal is to establish the QM system and implement it. In order to make sure that the scope of the QM system is complete, the jurisdictional boundaries (i.e. with other agencies) and the intended application scope of the system within the regulatory body need to be identified. It is necessary that the QM system be applied to all regulatory staff wherever they perform their regulatory work.

Care is exercised to ensure that the system is applied only to an extent and manner that is appropriate to the importance and nature of the activity being carried out. In other words, the QM system is seen to be sensible by the staff and the definition of the QM system and its detailed scope of application reflects this.

A particular goal is to foster the creation of a quality culture within the regulatory organization whereby the staff carry out their regulatory duties with a continuous and instinctive regard for the need to do them in accordance with the mission of the regulator.

A schedule needs to be developed and agreed to cover all the basic stages or phases of development and implementation of the QM system. This entails breaking the work into identifiable and manageable sections, defining responsibilities for managing the work and setting check points or milestones to track progress. In essence, this is not different from planning and controlling any other project, although the scale and interfaces may be more complex and wider ranging for QM.

Essential areas that need to be included in the schedule are the definition of training associated with the various phases and the prioritization of critical activities that may warrant special attention or precautions. The detail of schedules may vary according to the competence and experience of the relevant managers and staff and will need to be tailored to suit the available resources.

Communicating to the personnel the schedules, milestones and written reports associated with the project for developing a QM system is an important area for management to address. Contingency plans to cope with schedule overruns and unforeseen obstacles to progress should be accommodated and allowed for in the time-scales. Regular progress checks and rescheduling enables disruptions to be absorbed without major backtracking and loss of motivation by the staff.

The aim should be to set realistic targets for each schedule phase linked to a master schedule which tracks the progress towards overall project achievement. This in itself is a QM exercise that can promote the discipline needed throughout the entire QM process. Figure 1 depicts the main steps in scheduling the establishment and implementation of the QM system.

It may be appropriate to apply a pilot project approach to certain parts of the organization, with other parts using a staged approach. This would mean that QM is applied to only a few processes initially, then that core experience is gradually involved and resources are optimized so that QM may extend over the entire organization.

Senior management commitment

Evaluate existing practices

Select QM model(s)

Fix general implementation schedule

Establish centralized control arrangements

Define scope of application & work to be done to establish* QM systems (Goals)

Design overall implementation strategy including: detailed schedule; decision on certification; adequacy of resources; collaboration with other agencies; communications plan; overcoming resistance to change; training; arrangements (short & long term) for feedback & adjustment

Establish QM system

QM system full documented (established)

Implementation

Carry out final evaluation and confirmation that implemented QM system complies with goals

Certification as required

Feedback & adjustment phase

QM system established and implemented

* establish = design, consult & document

FIG. 1. Outline of the steps for the establishment and implementation of a QM system.

3.2. PREREQUISITES FOR A QUALITY MANAGEMENT SYSTEM

Before a decision is made to embark on a formal QM system it is necessary to determine whether the essential prerequisites are in place for effective regulatory functioning. These include:

Legal basis

The regulator has the legal authority to regulate the siting, design, construction, commissioning, operation and decommissioning of all nuclear installations under its jurisdiction. This regulation comprises the establishment of requirements, standards, criteria, guidelines etc., the granting (or refusal/withdrawal) of licences, the inspection and enforcement activities, etc.

Governmental infrastructure

The regulator can only perform at a high quality level if a proper governmental infrastructure is in place. This may comprise the support structure of the working environment, the basic education schemes for the employees, decision making, communications and co-operative arrangements between government authorities, etc.

Statutory independence

The regulator needs to be effectively independent of governmental or private organizations that promote the use of nuclear technology or are in charge of the operation of nuclear installations. The QM system needs to reinforce the regulator's independence.

Mission/mandate

These terms generally describe the 'purpose' of an organization. The reason for existence of a nuclear regulator is to ensure that the health and safety of the public, of the workers in a nuclear installation and the environment are adequately protected.

The definition of the regulatory mission is important for understanding the mandate of the regulator. The mission statement needs to be expressed in a short and understandable manner. It may be clearly defined in the legislation which establishes the regulator and is to be used as the ultimate goal of the QM system.

Quality policy

The quality policy is a broad statement from top management (head of the regulator or equivalent) setting out the way the organization should accomplish its mission, and communicating its expectations and means for managing the quality of the work of the regulator.

The quality policy statement is usually prepared in consultation with managers and often involves consultation with the staff. Once finalized, the quality policy statement is officially promulgated and made known to all the staff. This can be done by several methods, including placards, murals, circular letters, Internet and the regulatory body home page. Internal discussions or seminars can be organized to ensure that all staff fully understand the policy.

In addition to issuing the policy statement, top management should demonstrate a real commitment to developing and supporting the QM system. However, it needs to be emphasized that the QM system is not a goal in itself, but one of the essential tools to facilitate the attainment and retention of the regulatory mission.

Strategy

Strategy needs to be planned to cover the setting of long term objectives and to define how to achieve them. The strategic plan is developed on the basis of current conditions and needs to be periodically assessed and updated. It should also include the strategy for QM.

Vision

The development of a 'vision statement' is the task of top management and forms part of the QM system documentation. It should present in a few clear words the aspirations of the regulator and should be communicated to all concerned.

Values

Values and ethical rules need to be developed through consultation between the top management and staff. The necessity to develop values and ethical rules for the regulator is considered as very important in setting out the ground rules and acceptable behaviours. These include such things as honesty, professionalism, independence, etc.

Human and financial resources

The regulator needs to be provided with the financial means and human resources in a manner that is commensurate with its duties and responsibilities. This involves having a sufficient number of personnel with adequate qualifications, experience and expertise, training and retraining programmes and facilities. Adequate funding of the regulator is also essential. According to the legal and administrative system of the Member State, these funds may be provided by a public budget or through fees or a recovery of costs from the operator(s)/licensees(s) or through a combination of these options. Quality also has costs but the consequences of not having a QM system may be far more expensive for the Member State if regulatory credibility and performance are allowed to drop below an acceptable level. An efficient QM system can also provide the data and reports to justify expenditure and requests for additional funding.

Cultural aspects

The culture of a Member State comprises a variety of human activities, values, attitudes, legal aspects, understanding of concepts, meanings of words, etc., that are interactive and that develop with time. The culture of a regulator is impacted by the Member State's culture but also contains elements that are specific for the mission it has to accomplish. IAEA-TECDOC-1090 [4], Annex 3: shows 'An example of a set of values that a Member State's regulatory staff is obliged to follow'.

The QM system usually does not have any impact on the Member States culture, but has a definite positive impact on the culture of the regulator. In order for this impact to be effective, it is necessary for incoming documents (e.g. from the IAEA, the consultant, ISO) to be translated or interpreted into the existing cultural environment of the regulator, without

changing their basic content and message (it should be noted that IAEA documents are 'culture neutral'). The main aim is to make these documents perfectly understandable by the staff, taking due account of their specific cultural environment and background.

In particular, it is advisable to adapt the application of general QM principles to incorporate the national regulatory practice and regulatory framework, as far as is feasible and necessary.

Working processes and functions

Current quality standards apply mainly to process management. However, most organizations have some form of matrix management. This is a combination of both process management and line (functional) management. The specific combination of process and line management depends upon the complexity of processes, historical experience, size of the organization, need for the creation of temporary teams for complex tasks, etc. What is important is to cover all the processes and functions and incorporate them into the QM system according to their priority and importance. A clear definition of responsibilities of all participants is also necessary. Process management has some strengths but matrix management may also cause some concerns.

If matrix management is used, the clear definition of responsibilities among all participants needs to be drawn up, including timing. The formal creation of temporary teams for complex tasks is used in some Member States. The decision to use process management or line management depends on the complexity of processes, historical experience, size of the organization, number of staff, etc. What is important is to cover all the processes and functions and incorporate them into the QM system according to their priority and importance.

The quality of documentation prepared as an output of regulatory activities (regulations, decisions, protocols, etc.) and the results of different processes (assessment, inspection, etc.) as well as supporting documents (internal outputs) need all to be in such a form that they can be used for public information and scrutiny if requested.

Applicability of available models

Preparation of a QM system consists of defining the different processes and activities which have to be taken into account. One of the first tasks is to decide which model could be used to identify and manage numerous linked activities and could create an acceptable QM system.

It is considered that conventional quality standards and criteria such as ISO 9000:2000 for the establishment and assessment and the EFQM EM for assessment may be applicable for the regulator's QM system.

The advantages of using an established QM model include:
- It facilitates communication with stakeholders and thus increases understanding and transparency (the model can be used in public information).
- It may reduce the probability of misinterpretation of instructions or directions. Usually a guide is provided together with the model to assist the user.

- Although a QM model may contain a process logic that is fairly complete and adaptable to regulatory work, each regulator may modify the model to suit its own environment and purposes.
- It acts as a type of reference standard in the QM system development and implementation process.

Choosing a QM model does not mean that all activities in the model may be applicable to the regulator. It has to be understood that successful application of any model is dependent on appropriately trained staff and their in depth familiarization with the regulatory activities.

Certification

Certification, as part of the end result, is not strictly necessary. However, certification serves as an independent and clear signal that the QM implementation as a 'specific project' has been completed to a certain reference standard. Formal certification is also a psychological tool for the staff as it provides a visible goal to strive for, and the regular certification audits reaffirm the status of the QM system. The commitment of recertification demands that the QM system be continuously kept up to standard and provides a valid reason for it to be maintained and improved.

Formal certification is associated with a QM standard such as ISO 9001. However, such a standard may need some amendment ('customizing the rules') to make it applicable to the regulator. Certification costs money but a recognized certification may make the QM system more readily accepted by the staff and other parties.

Use of consultants

Many Member States consider that the regulator should make use of an independent QM expert (e.g. external consultants) in order to get professional guidance on QM, if it is not available within the organization. However, it is essential to select a consultant who can demonstrate capability, competence and experience in the QM field, preferably in other organizations with work comparable to the activities of the regulator.

The tasks of the consultant need to be carefully determined and documented to specify what the consultant is to deliver. The management and staff need to realize that the consultant acts as an adviser but not as the controller of the QM system.

A consultant can provide certain advantages such as having access to a higher level of decision making, rethinking what has been done, bringing in new ideas and training/mentoring regulatory staff. However, the factors of possible loss of management control to the consultant and external interference need to be kept in mind. Consultants do provide expertise for a specified period and can be contracted to deliver specific tasks. This means that the regulatory staff can learn from the consultant and, with appropriate training, become competent to take over the project of developing a QM system once the consultant has fulfilled the contract and departed.

Interface with other agencies

There is a need to take into consideration the position and role of other regulatory authorities which might impact the nuclear regulator's functions and activities. This may

require some involvement in the development of regulations to take into account the position and role of other agencies in the process of licensing or it may involve participation in joint inspection activities and event investigation or even enforcement.

It is essential that the top management of all involved agencies have a mutual understanding of the interface issues, and where possible and feasible, corresponding QM system elements of these other agencies ought to be co-ordinated into the QM system.

3.3. DEPLOYMENT

Prerequisites for deployment

Deployment is one of the most challenging phases of developing the QM system. After and even in the process of the preparation of QM system and procedures, it is necessary that the top management of the regulator implement appropriate arrangements to deploy the QM into practice.

The regulator needs to identify and determine the functional responsibilities, the reporting relationships and the levels of authority of individuals and organizational units as well as clearly define the accountability of all staff and where, within the organization, the regulatory decisions are to be made.

Staff need to be involved from the outset in the QM activities as this creates a sense of ownership and can promote a positive attitude to quality.

An owner or custodian needs to be assigned to each procedure in terms of the responsibilities of the staff and the processes concerned. All the necessary documentation has to be readily available to staff and it may help to put the quality policy, schedule, programme and procedures on the internal communication net or system.

It is also essential that the regulator organizes a series of training activities to make staff familiar with the QM system and procedures. General training is to be arranged for all staff on quality assurance principles and approaches and specific training courses are to be given to the relevant personnel on the use of administrative and technical working procedures and in the development of the QM system. A practice in a Member State for introducing QM is the concept of a 'quality day'. Activities concerning quality, such as presentations of projects and quality achievements are organized and celebrated on this 'quality day'. This further aids the promotion and awareness of quality and raises the profile of QM and the organization.

Deployment status of QM system

Deployment of formal QM practices depends upon the state of the current QM system, and it is important for regulators to identify the entry level of the new QM practices. This means identifying:

- QM practices which are considered already acceptable for inclusion in the first version of the institution-wide, formal QM system.
- QM practices which need to be modified before being included.

- QM practices which are missing and which need to be established in order to complete the institution-wide, formal QM system. This information will result from a comparison between what the regulator has in place initially and what is prescribed for a complete QM system by a selected reference or model.

Quality management documentation

A decision needs to be taken at an early stage on how many hierarchical levels of documents would be an optimum. Such QM documents would include:

- a policy statement
- a quality manual
- procedures.

The term 'procedures' embraces different types of documents such as regulations, safety guides, internal administrative procedures, process procedures, work instructions, records, etc.

Procedures are to be developed in a unified manner, preferably in accordance with internal rules. The necessity of some procedures needs to be assessed. One Member State uses the cost-benefit analysis as an instrument for decisions on the preparation of certain procedures. Different approaches exist concerning the responsibility for procedures control and updating (procedure owner or process owner). Familiarization with and understanding of procedures should be documented. In one Member State all procedures are signed by the staff to document their familiarization with the procedure. To ensure currency and validity, an updated list of valid procedures needs to be available at all times and this will be a fundamental requirement of the QM system.

Resources

It may be necessary to allocate extra resources for QM implementation. This may also include costs for payment of consultancy services and person-hours. It is usually preferable that the human resources be provided by the regulatory organization, because local organizational knowledge and familiarity with its operations is essential for success. In order to optimize the utilization of limited resources, feasible goals need to be set which consider how much the normal regulatory work is actually affected.

3.4. IMPLEMENTATION OF THE QUALITY MANAGEMENT SYSTEM

The successful implementation of the whole regulatory approach through compliance with a QM system needs to be facilitated by successful implementation of individual procedures and the control of processes and functions.

Every employee is responsible for his/her own work. The activities implemented by each staff member need to be followed up by the responsible line manager. The frequency of such regular follow-up action depends on the complexity and duration of the activities.

It is considered advantageous for the regulator to nominate at least one suitably qualified person to be responsible for monitoring the status of the QM system and for providing advice and assistance concerning its effective implementation.

This nominee may be an experienced QM practitioner who can handle the QM system on a permanent basis or someone who would work with a QM consultant from startup and take over control of QM when the consultant leaves and hands over the QM system.

As an ongoing task the procedure custodian or owner is allocated responsibilities which may include developing procedures where necessary, follow-up of activities under the scope of procedures for which they are responsible, updating of procedures, and the issuance of corrective action requests as a result of regular follow-up action. All the corrective action requests and the non-conformance reports need to be integrated, and the emerging trends of conformity to the QM system manual and working procedures need to be analysed. This analysis needs to be undertaken by the procedure custodian and the process owner in order to evaluate the effectiveness of the QM system and the validity of the QM documentation.

Internal communication and consultation

Communications need to be planned, e.g. periodic QM progress reports to staff that identify needed actions to bring the activities back on track, as well as periodic reporting to top management. No staff member should feel excluded from the process, as this would tend to undermine the positive messages given by management and other staff members. Effective institution-wide communication works in two ways: 'top-down' and 'bottom-up'.

To promote top-down communication, top management clearly communicates its commitment, vision and expectations related to the development and implementation of a QM system. It is also visibly demonstrating its leadership when corrective actions or redirections are needed. The goals of the QM system, as well as the corporate definitions, descriptions and all results of the project for developing the QM system (e.g. flow charts of regulatory process descriptions) are communicated in a clear fashion to staff for comment. It is important to be transparent with respect to colleagues, public, auditors, etc. and to invite staff to participate.

To promote bottom-up communications, top management needs to be informed of progress and intermediate outputs of the activities on a regular basis and in accordance with an established mechanism. This is achieved by the establishment of reports, action lists, detailed work schedules, etc. As a result of staff feedback, top management can motivate staff and gain their support by recognizing staff insecurity, any resistance to change, the current regulatory workload and by assuring staff that all their suggestions, concerns and remarks are duly taken into account and are valued.

Centralized control of implementation

A centralized or project type control system facilitates the regulator's control of the implementation and is a proven way to assure success. The project team report to top management and regularly communicate with all staff. A typical project team could be a single project manager plus assistance dependent upon the prevailing circumstances e.g. staff numbers, scope of coverage, implementation deadlines, etc. The credentials of the project team are vital (e.g. past experience, etc.), and they need to be good communicators, skilled at handling people, approachable and adaptable. It is also important that the project team operate according to strict QM principles and avoid becoming trapped in details or unnecessary debate over trivialities. The skills and attributes of the project leader and the team can have a profound effect on the success or failure of the QM system. It may be prudent to spend some time and effort in their selection and training.

Training

Appropriate training has to be provided to all levels of personnel in the regulatory body organization: Top management, middle management, persons responsible for QM system implementation and control e.g. project managers, task managers, department managers, staff involved in a pilot project, and any other personnel involved. Training for successful implementation of a QM system needs to be planned, designed, implemented and its effectiveness evaluated according to a systematic approach to training. Some of the elements that need to be considered are:

- Training in handling conflict (how to lead/conduct a discussion and let everyone express their own ideas without entering into conflict situations) is mandatory for those staff members who have a leading or co-ordinating role in the whole process.
- Training is relevant, contains the essential elements and is tailored to the different groups (top management, management, project staff, etc.). Where possible and available the assistance of a consultant can be very valuable in providing training with the correct focus.
- Training needs to be directed in support of the organization's mission and quality vision and needs to cover what is expected from staff in their contribution to the development and implementation of the QM system.

Feedback and adjustment

Feedback of experience, including complaints and recommendations, is a basic requirement in a QM system. Feedback is based upon written evaluation reports, check points, documentation on completion of tasks or comment notes about the process or activities. Verbal statements alone are often not sufficient, although top management could hold staff consultation sessions for comments, suggestions and feedback with suitable arrangements for any confidential feedback. Feedback is an essential source from which to optimize the QM system, or at least to remove its deficiencies and to improve confidence. It needs to be included as a vital element in the process of continuous improvement.

All experience feedback in handling the processes, including possible adjustments of the regulatory work, needs to be executed according to the QM system. This brings the regulatory work in line with external expectations and organizational strategy and keeps the QM system and the regulatory process flexible and directed.

Feedback is vital to progress and ensures the currency of a QM system and, therefore, adequate arrangements and planning need to be put in place to ensure a free flow of information to the system.

Overcoming resistance to change

This problem needs to be recognized from the beginning and measures need to be taken to address it. Resistance to new methods and opposition to the introduction of new ideas is not new and is to be expected. Therefore, it is advisable to design the implementation strategy to account for 'real' difficulties (staff acceptance, resources, etc.) and to identify and discuss with the staff what the benefits can be for them by co-operating.

Management has to lead in order to show its determination to achieve the set objectives, but it has also to provide time and opportunity for consultation with the staff, to facilitate a common understanding and acceptance of the goals. It is also useful to identify 'believers' or promoters from the staff to participate in the initial phase, as they will support the ongoing activities and form a core of motivated people to which others will more easily adhere. Staff members will more readily accept the change if their peers convince them that change is needed.

As previously mentioned it may be the policy to create a QM group to handle implementation. However, they could be regarded as hostile or unconnected with real regulatory work, e.g. they might be considered by other staff members as the only ones involved in QM system. To overcome these perceptions, the QM team should work alongside regulatory technical staff, thereby gaining their confidence and sharing the credit for successes in quality system progress. To achieve this, it is desirable to plan for early tangible and modest success rather than spectacular achievements which may take excessive time to realize and may not reflect on individual staff members.

4. ASSESSMENT AND IMPROVEMENT OF PERFORMANCE

4.1. ASSESSMENT

The reasons for which regulatory bodies embark on the development and implementation of a QM system for their activities are peculiar to each Member State. Examples of possible initiators are described in the discussion on stakeholder expectations in this report (Section 2.2.). Whatever the reasons, regulators will need to define what it is they want to achieve through QM and develop a strategy to make this happen. Having defined the objectives of a QM system and being clear on the mission of the regulator are major steps in identifying later whether the objectives have been achieved or not.

Setting out the current status of the regulator and comparing that with the desired end state enables a gap analysis to be made. However, the identification of the desired state also demands that a clear and achievable target be set and agreed. This desired state could be in the form of a QM model, such as ISO 9000, IAEA QM recommendations and guidelines, IRRT review conditions, external consultant models or a combination of these to suit the individual requirement of the regulator.

What is important is the initial identification and agreement on what the desirable end state will be. Once this target has been defined, the process of working towards its achievement can commence. This will entail the production of realistic, measurable milestones to gauge progress and indicate performance to date.

Comparison of the mission, objectives and outputs of the evolving QM system provides measures and indicators of the current state of the QM system. Certification can be an efficient and unambiguous method of confirming the adequacy and acceptance of the complete QM system.

Attainment of the desired end state i.e. a full QM system covering all the processes and functions of the regulator, would be merely an academic exercise if the outcomes of the QM system did not meet the regulator's overall mission and objectives.

Assessment of the successful achievement of the desired objectives requires that the following areas be addressed: those under the direct control of the regulator and those which do not but nonetheless bear upon the accomplishment of the mission. Each stakeholder: the public, government, licensee, etc. has a different perspective of and legitimate expectation from the regulator and if the regulator is to attempt to satisfy these expectations, the regulator must recognize and integrate them into the inputs and outputs of the QM system. This will facilitate the creation of indicators based upon what the stakeholders expect and what the QM system can deliver. How these indicators are to be derived will depend upon the individual situations pertaining to the Member State and the external and internal factors affecting the regulator.

Some Member States have been successful in defining indicators whilst others are still considering the best options to adopt; this section discusses possible ways of evaluating the effectiveness of the QM system. Performance assessment and evaluation is essential to close the QM cycle. The principle of independence of the evaluators from the area assessed needs to be observed. It is noted that confirmation of the end state is also the starting point for the maintenance and improvement process even though elements of improvement are introduced in the last stages of the implementation of the QM system.

Because the regulator's mission is primarily related to health and safety of the public and workers as well as the protection of the environment, a measure of the QM process is not equivalent to a measure of regulatory effectiveness. Regulatory effectiveness would include both measures of the regulator's QM process as well as selected performance measures of licensee safety performance. It is therefore not possible to separate completely the regulator's performance from the licensee's safety performance, and similarly the perceptions and requirements of the other stakeholders have a significant impact on the regulatory performance assessment.

To date there has not been a universal or generally accepted measurement of regulatory effectiveness. In its conclusion, the IAEA PDRP-4 Report [5] states that *given the necessary authority and resources as prerequisites, 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.*

It has also been recognized that the IAEA International Regulatory Review Team (IRRT) programme is an efficient tool to assist in the assessment of the effectiveness of the regulator.

It is possible to develop a set of performance indicators which measure the efficiency of a QM system. A list of potential indicators is provided later in this report but would include the general areas of timeliness, productivity, and accomplishment of specific tasks. For evaluation of regulatory effectiveness at different management levels, sets of measurable indicators might be an appropriate tool. The list of such possible indicators was put forward by senior regulators in Section 3 of the IAEA PDRP-4 Report.

It is considered essential that during the assessment process, feedback from stakeholders and other objective performance indicators be gathered from sources such as:
- individual experts
- the regulator's resource utilization data
- licensee sources
- public sources
- governmental and other agencies
- international organizations and institutions.

When considering indicators and performance criteria, it would be useful to consider the perspective of all the stakeholders to assess what they would need to satisfy themselves that their expectations or requirements are being met. This may assist in formulating realistic indicators that meet the specific needs of each stakeholder and of the overall regulatory mission.

When setting up a performance monitoring system, other factors affecting the quality of regulator performance need to be taken into account, including:
- teamwork
- staff competence and training

- staff attitude
- leadership
- quality culture
- safety culture
- adequacy of procedures
- staff access to tools and means needed for the job
- communications (internal and external)
- human resources
- financial resources
- performance assessment methods.

Data from regulator performance is analysed to understand how future plans may be affected. This allows performance assessment to be used as a positive tool to aid future planning. Figure 2 shows an example of a performance monitoring process for planning and budgeting.

While each regulator has its own unique organization, there are generally three categories or levels of management oversight. First, the executive level is responsible for the agency mission and policies, communicating with internal and external stakeholders, and ensuring that the organization has the tools, information and resources necessary to achieve the organization's objectives. The executive level establishes the organizational outcomes and success criteria. Second, the leadership level is responsible to the executive level for identifying the tactics needed to meet the established success criteria and providing access to the tools, information and resources needed by others to plan and execute tactics. Third, the operating level is responsible for directing the line staff in the execution of the established tactics.

All three levels of the organization play important roles in the evaluation of regulatory effectiveness. The organization's mission and expectations are developed by the executive team and are transmitted down to the leadership level where they serve as input for the establishment of more specific and detailed targets and expectations. Similarly, the leadership level's expectations serve as input to the operating level's development of even more specific and detailed targets and expectations.

The evaluation of performance data starts at the operating level and is subsequently used as the basis for performance reports to the leadership level. The leadership level report serves as the basis for developing reports to the executive level. Each management level within the organization understands and operates with consideration for the distinction of the responsibilities and authorities of each level. While the executive team is responsible for the overall mission and its outcome goals are at a high level, the operating team responsibilities and targets are of a much more detailed and specific nature. Similarly, the operating team would assess performance on a nearly continuous (daily) basis, while the leadership team would act on a periodic basis (monthly) and the executive team at even less frequent intervals (quarterly). The frequency and level of detail of performance monitoring varies with the level of organizational management. During the performance evaluation stage, each level of management has the opportunity to make adjustments within their authorities to address performance areas in need of improvement. If the necessary adjustments cannot be authorized at the manager's level, the issue would be raised to the next higher level so that action could be taken to restore performance to the desired level.

Communicate expected outcomes

- Understand the cost of outcomes or results
- Allocate resources based on desired outcomes

Establish performance data collection systems

2. Budgeting

1. Planning

Managing Performance: PBPM

3. Measuring Performance

4. Assessing Performance

- Define outcomes
- Identify work critical to delivering outcomes - effective activities and programmes
- Identify performance measures to help you assess progress towards outcomes

Publicize & Reward Results

Analyze how past performance impacts future plans (outcomes & metrics)
Identify 2-3 critical areas for intensive review (consider return on investment)

Coach & Facilitate

- Collect performance results
- Conduct structured analysis of performance results
- Determine corrective actions where results do not meet expectations
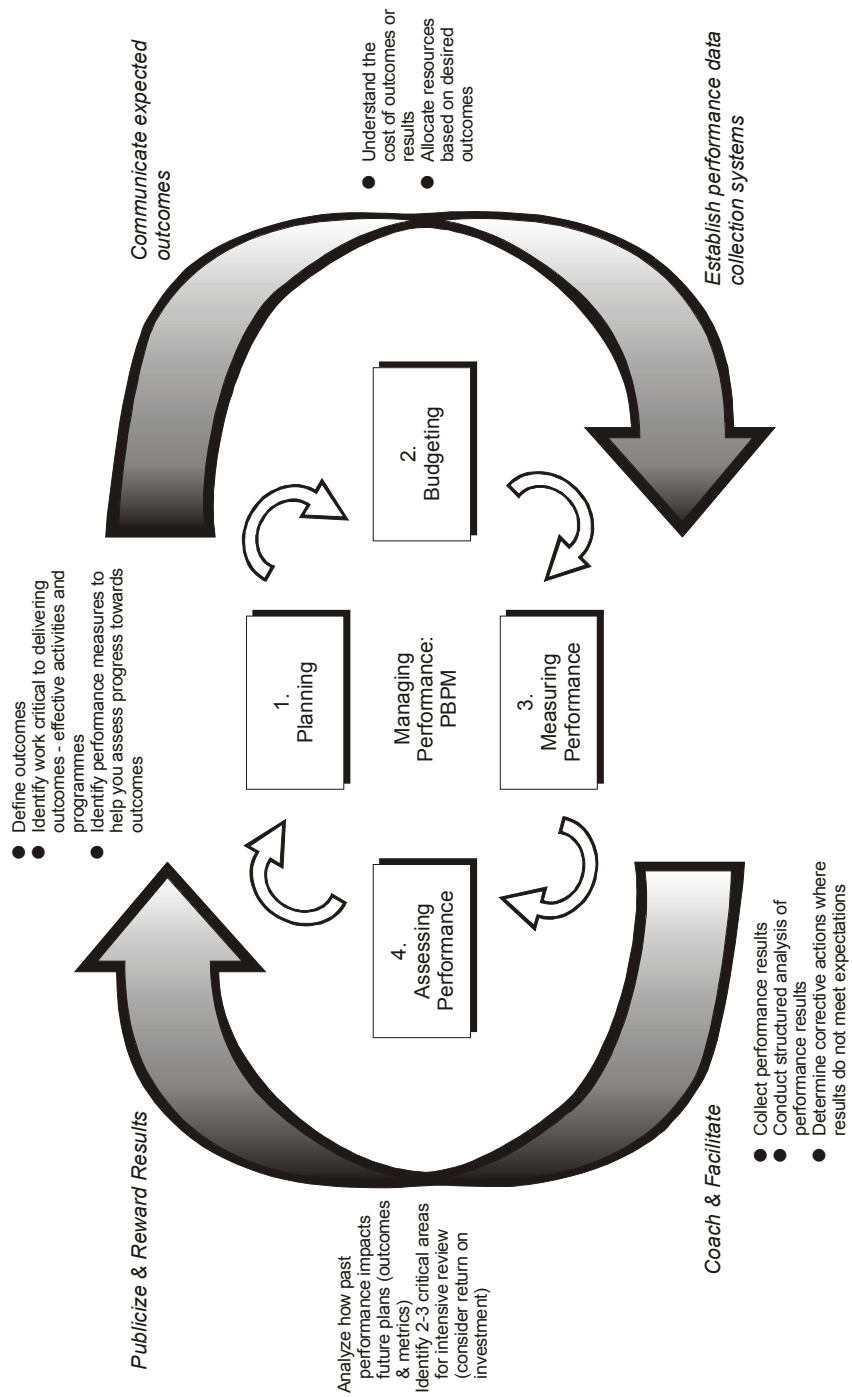
FIG. 2. Performance monitoring process for planning and budgeting

The above scenario may be applicable to a large line organization; however, a smaller matrix type organization may require a closer and more integrated approach.

4.2. IDENTIFYING PERFORMANCE INDICATORS FOR A QM SYSTEM

Performance indicators are an important component of the QM system. These help assess the progress in achieving outcomes. They support the management system by tracking key activities, indicating quality, efficiency and assessing results. Performance indicators will provide an early warning when performance is off the track.

The use of performance indicators needs to be individually considered by each Member State taking into account the nuclear energy background, national culture, etc. While some indicators could be considered as common, others have limited applicability and comparability in terms of a similar regulatory approach or even the same plant design.

Desirable attributes of a performance indicator system include:
- performance indicators that relate to the overall mission and objectives of the regulator,
- data that are simple to collect, evaluate and analyse,
- input data that are reliable, representative, accurate and repeatable,
- an evaluation process that is cost effective and uses resources commensurate with the overall programme,
- results that can be used as feedback for resource allocation decisions,
- objectives that are understandable to all stakeholders,
- a set of indicators that provides as complete a picture as possible.

Keeping the above attributes in mind, certain potential performance indicators can be identified. Some indicators may have the ability to identify declining performance trends or problem areas so that after proper review, management could take timely corrective actions to improve performance.

Because the mission of regulators is to protect the health and safety of the public and workers, it may be appropriate to evaluate certain external indicators in an attempt to fully evaluate the regulatory effectiveness of the regulator. A measure of regulatory effectiveness would include both measures of the regulator's QM process as well as selected performance measures of operator safety performance and public confidence. It is not possible to completely separate the regulator's performance from the operators' safety performance.

A safety indicator system — which includes both the operator's safety performance and the regulator's internal QM performance — that is applied in a Member State, is presented in Table I for purposes of illustration.

A few potential external indicators are listed below:
- Public confidence in the regulator: This will be a measure of public confidence and can be determined by surveys or other means of gathering the views, perceptions or attitude of the public towards regulatory performance. This has assumed greater importance over the past years and relates directly to stakeholder expectation.

TABLE I. EXAMPLE OF A SAFETY INDICATOR SYSTEM

A. Safety of Nuclear Facilities		B. Regulatory Activities	
A1 **Safety and quality culture**	A1.1 Failures and their repairs A1.2 Number of exemptions and deviations from Technical Specifications A1.3 Availability of safety systems A1.4 Radiation doses A1.5 Radioactive releases A1.6 Documentation	**B1** **Working processes**	B1.1 Fulfilment of outcome targets B1.2 Timely decision making B1.3 Maintenance of regulations B1.4 Implementation of inspection programme B1.5 Steering of contracted safety research B1.6 Actions in abnormal situations
A2 **Operational events**	A2.1 Number of events A2.2 Significance of events A2.3 Causes of events A2.4 Number of fire alarms	**B2** **Resource management**	B2.1 Resources for regulatory control of nuclear safety B2.2 Distribution of workload
A3 **Structural integrity**	A3.1 Integrity of nuclear fuel A3.2 Integrity of primary circuit A3.3 Integrity of containment	**B3** **Regeneration and ability to work**	B3.1 Maintenance of the Quality Manual B3.2 Execution of development projects B3.3 Execution of training programme B3.4 Work satisfaction B3.5 Compliance with values

- Radiological releases exceeding the specified limits.
- Safety performance indicators for nuclear power plants (e.g. selected WANO indicators).
- Number of facility events reaching a certain significance level.

The use of external and operator indicators in the establishment of regulatory performance indicators needs to be approached with caution to ensure that the correct weighting is placed on the relevant indicator inputs.

The functions of the QM system could be evaluated separately by using performance indicators for each regulatory function. The following potential indicators are suggested to evaluate the QM process:
- work completion — % work completed vs. work planned;
- productivity — resources utilization;
- staff effort utilization factor: Actual vs. planned;
- timeliness;
- procedures availability and adequacy;
- results achievement factor: actual vs. target;
- number of recommendations, corrective actions and findings. This is evaluated with respect to safety performance of the licensees;
- number of enforcement actions achieved vs. total corrective actions/recommendations;
- personnel management and staffing;
- morale of employees — surveys;

- Human resource development and training;
- Adequacy of staff;
- Absenteeism, overtime.

This list is not exhaustive and will vary from one regulator to another. The IAEA PDRP-4 Report [5] contains a list of other indicators which can also be considered.

4.3. IMPROVEMENT

Improvement process

For any improvement process it is necessary to take the following steps:
- establish a mechanism to identify strengths and weaknesses
- define the starting point
- determine the desired outcome or result
- draw up and implement an improvement plan
- assess the success of the improvement plan and review and revise it as necessary.

To determine the starting point some kind of model could be used: this depends on the level of the current QM system. The starting point may be from a level that simply requires compliance with the legislation, or it may be from a total quality management (TQM) or a QA system.

Improvement tools

Improvement tools are the means by which improvement is driven in a full QM system. In some Member States, a 'quality committee' has been set up. It has the responsibility to make improvement proposals. The EFQM EM is used by these Member States to focus on areas which are most in need of improvement. To assist in this process, external consultants have been called on to help in using the model. In other Member States a 'continuous improvement programme board' has been sent up with roughly the same purpose and ways of working as the aforementioned quality committee. This has resulted in improvement plans for areas like communications and planning systems. It is important that senior management be represented on the quality committee.

It is essential to have a systematic approach to QM; for Member States not operating within a TQM framework, improvement can be driven in a number of ways. For instance, reports to the International Convention on Nuclear Safety can be a strong driver for improvement. The preparation of such reports can reveal areas in an organization that have to be improved. Similarly, the IAEA reports may also suggest improvements.

There are a number of tools which can be used for improvement, such as audits as it is important that any QM system is audited. Likewise, it is important that it be used not just for seeking out non-compliance. A successful auditing system depends on openness and trust. It will seek to improve the QM system and examine the management processes to promote improvements in the way the regulator is managed.

Other improvement tools include:
Improvement teams: as identified improvements need to be prioritized, some Member States use improvement teams to take these forward. It is important to select the right people for these teams as they need to be competent for their task and able to work to time-scales. In some Member States, improvement teams have been set up using outside consultants who

have particular skills. This was done for a knowledge management project. The recommendations from improvement teams need to be put before top management for acceptance and reasons need to be given, if any, if their recommendations are not accepted. This culminates in a presentation to staff of the improvement programme and an explanation of the reasons for any changes.

Benchmarking: benchmarking can mean many things. At its most fundamental, it is a case of looking at the way a 'best in class' organizes itself. It is a source of information. Nevertheless, care should be taken not to simply copy some other organization, but to incorporate improvements in a systematic and applicable way.

Management level assessment: assessment at the intermediate management level may add benefit in improving processes. Staff experience may also be shared during some meetings. The results of assessments need to be evaluated and recognized by the top management and included in the overall strategic plan.

Annual reports: the issuing process of annual reports from the regulator needs to be conducted in such a manner as to highlight improvements.

Staff feedback: staff are encouraged to use the QM system feedback for any problems, or any suggestions for improvement. The feedback process ensures that every issue raised by staff is dealt with in a timely manner. This promotes a sense of 'ownership' of the QM system.

Excellence models: the use of excellence models such as the EFQM EM provides a thorough approach to self-assessment at all levels in the development of a QM system. Experience in some Member States has shown that this is best achieved using consultants to facilitate the process. At the early stage of QM system development these models can be used in a fairly general way to identify the main areas for improvement. Later, the model can be used more thoroughly to enable improvements to be demonstrated in a specific manner. Some Member States have found that reassessments every two years are most suitable.

External certification: ISO 9000 or 'Investors in People' are also schemes which lead to certification after external assessment and these can also foster improvements.

Personal work plans: in some Member States each individual is given improvement tasks which need to be carried out to meet the work commitment for the year. Included in this is a requirement to spend up to 5% of the work time on continuous improvement.

Stakeholder feedback: the information received from stakeholders can lead to improvements. Some Member States have applied this procedure successfully and in at least one Member State an independent consultant has performed a series of interviews and sent out questionnaires to about 120 identified groups of stakeholders. Such information is used by the regulator for continuous improvement and with a view to ensure credibility.

At a basic level improvement can be driven by reaction to events. This may not be a planned improvement, but the improvement needs to be made in a systematic way.

5. GOOD PRACTICES

In spite of the short history attached to the application of QM systems to regulatory work, some good practices were identified:

(1)   Many regulators of the Member States have published a quality policy statement where the top management have committed themselves to high quality in the regulatory work and expect (require) the same commitment from the rest of the staff. Continuous and visible management commitment is the fundamental driving factor.

(2)   A continuous improvement and learning approach has been adopted by many of the regulators.

(3)   The regulators in many Member States have discussed the roles of the stakeholders and their expectations. Preferably, interfaces with other institutions (e.g. other national regulators) are taken into account.

(4)   Many regulators have defined and applied values and ethical rules.

(5)   Top management surveys are carried out to summarize annual findings of the staff performance (initiatives, excellently performed activities, claims, good practices and recommendations based on self-assessment and audits).

(6)   Quality procedures are written in the form of a process approach to describe phases of the process as well as their inputs, outputs and feedback loops within the process and between processes. Experience with the use of process descriptions for describing activity by the regulator was found to be positive (flow charts have the advantage of being brief and easily understandable).

(7)   More attention is paid to the efficiency and effectiveness of regulatory work. Realistic goals are in balance with available human resources. The time demand for carrying out regular regulatory work should remain acceptable. In case of limited resources, consideration can be given to starting up part of the development process by using pilot projects (development in a part of the organization e.g. one department, consideration of part of the processes), allowing for different development speeds in different departments or areas, without losing sight of the goal established. It is useful to distinguish between regulatory output, over which the regulator has direct control, and the outcome or real goal (the level of public health and safety), over which the regulator has an indirect control (the regulatory control of the licensees). The evaluation of the efficiency and effectiveness of a QM system, for example through the use of indicators, can be of benefit to those regulatory activities that seek to achieve safety targets and can provide accurate feedback to a government on the safety level actually reached.

(8)   Long term strategic planning is generally used as a tool of management. The 'balanced scorecard' model is used to identify critical success factors and define appropriate measures accordingly.

(9)   Regulators have initiated development projects to utilize the current possibilities offered by information technology in order to facilitate factual decision making by the regulator.

(10)   Surveys of personnel well-being are carried out to identify organizational strengths and weaknesses. Advantages for motivating staff have been identified.

(11)   Surveys focused on public perceptions are carried out to determine the public's confidence in the regulatory work.

(12)   Significance of issues such as mission, values, vision and strategy to the overall maturity of the QM system are well understood.

(13)   Modern self-assessment methods have been used to identify strengths and weaknesses of the regulatory work and to initiate corrective actions.

(14) Efforts to develop safety indicator systems have progressed and some Member States already have an operating system. It is considered necessary to include some criteria, thresholds and weighting for each safety indicator selected. It is also useful to consider a limited number of indicators to start with and further develop the practice on the basis of experience. Communication to the public of general indicators (e.g. of safety goals) can be considered if the Member State's cultural environment is ready for such a step.

(15) Professional knowledge is understood as a key element of regulatory work. Training programmes for new and senior staff are implemented.

(16) Experience loss is duly recognized in strategic planning and change is managed accordingly by developing the younger generation of regulatory staff.

(17) Staff members who become specialists are appreciated and rewarded, including with a salary package on the same footing as those who follow a managerial career.

(18) Consultants are used to develop the QM system and to train the regulator's staff. A consultant can provide invaluable help, but management has to retain full control. Acquaintance of the consultant with the regulator's work and mission is an important factor. If a consultant is used, it is advantageous that he/she be involved as of the outset of the process.

(19) It is beneficial to manage resistance to change — staff members who are supportive of QM can play an important role in the acceptance process (not only can management or project managers promote QM, peers can play a considerable promotional role as well). Moreover, staff are more open to change when they see the benefits they stand to gain in conducting the QM process.

(20) Communications of regulatory staff on QM issues are to be attractive, clear, simple and issued on a regular basis. When all staff are involved, the motivation and support of the majority of the staff is likely to increase.

(21) The advantage of a well structured system for development and implementation of a QM system, with clear allocation of responsibilities and resources and with set milestones, is recognized: e.g. project management approach and description of tasks, responsibilities and deadlines for all the organizational units involved. Definition of a clear scope for the QM system is important and, if necessary, can be adapted during the development process on the basis of feedback from experience. Feedback during the development and improvement process is needed and is done with a QM approach (setting the example). Taking due account of the specific culture and practices of the regulator (as well as the individual Member State and its regulatory framework) improves the staff's understanding of QM and its role. A precise identification of the end of the implementation phase sends a clear message to the whole organization that the goal has been reached. After implementation, maintaining a QM system is to be considered as a non-negligible, ongoing task. Certification sets a clear goal, increases visibility to outside world and is a motivating factor in keeping up the QM system at an acceptable level.

REFERENCES

[1] INTERNATIONAL ATOMIC ENERGY AGENCY, Legal and Governmental Infrastructure for Nuclear, Radiation, Radioactive Waste and Transport Safety, Safety Standards Series No. GS-R-1, IAEA, Vienna (2000).

[2] INTERNATIONAL ORGANIZATION FOR STANDARDIZATION, Quality Management Systems — Fundamentals and Vocabulary, ISO 9000: 2000, Geneva (2000).

[3] EUROPEAN FOUNDATION FOR QUALITY MANAGEMENT, The EFQM Excellence Model, Brussels (1999).

[4] INTERNATIONAL ATOMIC ENERGY AGENCY, Quality Assurance within Regulatory Bodies, IAEA-TECDOC-1090, Vienna (1999).

[5] INTERNATIONAL ATOMIC ENERGY AGENCY, Assessment of Regulatory Effectiveness, PDRP-4, IAEA, Vienna (1999).

CONTRIBUTORS TO DRAFTING AND REVIEW
Peer Group Discussion Meetings

Vienna, 12-16 March 2001

Li, Ganjie	China
Koutaniemi, P.	Finland
Weil, L.	Germany
Niehaus, G.	Germany
Tóth, A.	Hungary
Yang, Sung-ho	Korea, Republic of
Mir, M.A.	Pakistan
Goicea, L.	Romania
Novak, S.	Slovak Republic
Cepas, J.A.	Spain
Woodhouse, P. *(Chairman)*	United Kingdom
Gibson, S.	United Kingdom
Zhong, W. *(Scientific Secretary)*	International Atomic Energy Agency

Vienna, 7–11 May 2001

Maris, M.	Belgium
Almeida, C.	Brazil
Thomas, R.	Canada
Agarwal, S.K.	India
Saeid, S.M.H.	Iran, Islamic Republic of
Yoshimura, K.	Japan
Akimoto, S.	Japan
Zilys, K.	Lithuania
González Mercado, V.	Mexico
de Vrey, G.A.	Netherlands
Gutsalov, A.	Russian Federation
Kuznetsova, E.	Russian Federation
Hall, A.C.	South Africa
Mykolaichuk, O.	Ukraine
Woodhouse, P. *(Chairman)*	United Kingdom
Borchardt, R.W.	United States of America
Zhong, W. *(Scientific Secretary)*	International Atomic Energy Agency

Vienna, 14–16 May 2001

Hall, A.	South Africa
Koutaniemi, P.	Finland
Zhong, W. *(Scientific Secretary)*	International Atomic Energy Agency

IAEA staff

Versteeg, J.; Boal, T.; Giersch, G.; Hughes, P.; Munhoz Camargo, C.; Philip, G.