



IAEA

International Atomic Energy Agency

SARIS Guidelines

2014 Edition

Vienna, April 2014

Services Series 27

IAEA SAFETY STANDARDS AND RELATED PUBLICATIONS

IAEA SAFETY STANDARDS

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IAEA SERVICES SERIES No. 27

SARIS GUIDELINES

2014 EDITION

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SARIS GUIDELINES — 2014 EDITION

IAEA, VIENNA, 2014

IAEA-SVS-27

ISSN 1816-9309

© IAEA, 2014

Printed by the IAEA in Austria

April 2014

FOREWORD

The IAEA fundamental safety principles provide the basis for IAEA safety standards and IAEA related programmes. IAEA safety standards reflect an international consensus on what constitutes a high level of safety for protecting people and the environment, and therefore represent what all regulators should achieve. These standards, in particular IAEA Safety Standards Series No. GSR Part 1, Governmental, Legal and Regulatory Framework for Safety, provide the basics for establishing, maintaining and continuously improving the governmental, legal and regulatory framework for safety.

Additional IAEA requirements and guidance, such as the IAEA Safety Standards Series No. GSR Part 3 (Interim), Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, and IAEA Safety Standards Series No. GS-R-3, The Management System for Facilities and Activities, are also used to establish and develop the national infrastructure for safety and for establishing and implementing a management system.

Assessment of the regulatory framework for safety with respect to the IAEA safety standards can be made either through an external review or through internal self-assessment. Self-assessment offers a mechanism by which an organization can assess its performance against established standards and models and thereby identify areas for improvement.

The IAEA has developed a methodology and tool for Self-assessment of the Regulatory Infrastructure for Safety (SARIS), to assist States in undertaking self-assessment of their national safety framework in accordance with the requirements and recommendations of the IAEA safety standards, and to develop an action plan for improvement.

The IAEA self-assessment methodology and the associated tools are fully compatible with the IAEA safety standards and are also used in the preparation for regulatory review missions, such as the Integrated Regulatory Review Service and advisory missions.

These guidelines have been developed to describe the IAEA methodology on SARIS. The guidelines can be used by all regulatory bodies and also by relevant service providers and end users with regard to occupational and medical radiation protection.

These guidelines were compiled by experts in the Division of Radiation, Transport and Waste Safety, and the Division of Nuclear Installation Safety.

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1. INTRODUCTION

The national regulatory infrastructure for nuclear and radiation safety should be established, structured, resourced and maintained in a manner commensurate with the potential magnitude and nature of the hazards associated with the facilities and activities in the country.

Once the regulatory framework is established with all its legal and international commitments in place, the regulatory body should strive to develop and improve its performance on a continuous basis, within an effective integrated management system. In so doing, the regulatory body should take account of IAEA Safety Standards such as GSR Part 1 [1] which stipulates the governmental, legal and regulatory framework for safety and GS-R-3 [2] that stipulates the management system for facilities and activities, as well as other management and quality standards.

Various management system models have been developed internationally (such as the International Standards Organization (ISO)), regionally (such as the European Foundation for Quality Management (EFQM)) and nationally (such as the Finnish Standards Organization (SFS)). These models provide organizations with a common management language and tools to facilitate the sharing of good practice across sectors and provide criteria against which an organization's progress as a "quality organization" may be assessed.

Definition of self-assessment

Self-assessment is an organization's internal process to review its current status, processes and performance against predefined criteria and thereby provide key elements for the organization's continuous development and improvement. Self-assessment helps the organization to think through what it is expected to do, what it is actually doing in comparison with these expectations and selected standards, why it is doing it, how it is performing and what is necessary to improve performance, achieve expectations and be in compliance with the selected standards.

The self-assessment process converts knowledge into action. This means engaging the board/senior management, staff, and appropriate stakeholders in a challenging process of organizational self-discovery.

Self-assessment is much more than answering a set of predefined questions; it is learning and investigation process and an integral part of the establishment of a regulatory body and its continuous development towards becoming an excellent organization. Self-assessment is a progressive process.

Self-assessment can be said to be analogous to practicing sport; at the beginner level practicing most sports is basic and it is the same for all participants. Then with time, experience, skills and maturity come specialization and more demanding goals. The same applies to self-assessment in relation to the development of the regulatory organization.

2. OVERVIEW

2.1. OBJECTIVES

The objective of self-assessment is to improve regulatory performance, i.e. effectiveness and efficiency of the organization and its activities and to strive for continuous improvement in performance. In particular, self-assessment aims to:

- Verify that the regulatory body performs its functions in an effective and efficient manner in regulating nuclear and radiation safety;
- Indicate priority actions to prevent degradation of safety and to promote safety improvements;
- Ensure that regulatory functions are timely, cost-effective and provided in a manner that builds confidence in the regulatory process amongst operating organizations, the general public and government.

Self-assessment is a means for:

- Preparing and sharing vision(s);
- Selecting performance standards (against which the organization is assessed);
- Identifying and eliminating deficiencies and known shortcomings;
- Implementing the principle of continuous improvement;
- Developing and maintaining an adequate level of competence;
- Analysing the changing operational environment;
- Identifying policy level issues to be addressed.

2.2. MOTIVATION FOR AND EXPECTATIONS FROM SELF-ASSESSMENT

Systematic self-assessment is a complex undertaking which requires time, effort and resources. In return, it provides many benefits to the organization, which justify the resources and time invested. Benefits include the following:

- Continuous improvement of the regulatory body, its performance and accountability, thereby improving regulatory control of facilities and activities and enhancing radiation and nuclear safety.
- Assurance that regulatory functions and activities are comprehensive, proper (from a legal and regulatory point of view) and fit for purpose in accordance with a graded approach to safety.
- A means by which the Regulatory Body can identify its own strengths, weaknesses, opportunities and threats. Self-assessment is often a better motivator for improvement than assessment done by external experts.
- A mechanism for management to inform staff of important aspects of regulatory strategy, objectives, process and performance; accordingly, it offers an effective way to educate and develop staff.
- Improved understanding of what is required to establish a regulatory body fit for purpose and to ensure continuous improvement in a changing operational environment.
- Staff commitment to the regulatory body and its processes.
- Harmonization of regulatory processes and practices.

- Comparison, when carried out periodically, of progress since the previous period.
- Early detection of factors which could have an impact on the effectiveness of the regulatory process and maintenance of the regulatory body’s capacity to perform its duties. Based on self-assessment findings, corrective measures may be established to eliminate adverse elements.

2.3. SELF-ASSESSMENT MODEL

The model for IAEA self-assessment of national regulatory infrastructure for safety is based on a three-tier approach (see Fig. 1). This model can be adopted by any organization engaged in regulatory activities at any stage of maturity.

Depending on the status of the national regulatory infrastructure, a modular approach is used when selecting criteria against which current performance of the infrastructure is assessed. The basic modules discussed below are “*First level generic criteria*”, “*Second level generic criteria*” and “*Third level targeted criteria*”.

2.3.1. First level generic criteria

The primary requirement for establishment and sustainability of a regulatory infrastructure is a legal and governmental framework for nuclear, radiation, radioactive waste and transport safety. IAEA safety standards reflect an international consensus on what constitutes a high level of safety and represent, therefore, a level that all regulators should aim for. These safety standards, in particular GSR Part 1 [1], should be used as a prime reference for developing the national regulatory infrastructure for safety.

2.3.2. Second level generic criteria

In this level, IAEA safety standards additional to GSR Part 1 [1], such as GS-R-3 [2] and GSR Part 3 [3], may be used together with other requirements and guides, as applicable, as an important reference basis for further developing the regulatory body and assessing its performance. Thus the second level goes beyond the legislative infrastructure and looks into the efficiency and effectiveness of the regulatory body.

2.3.3. Third level targeted criteria

An effective, competent and independent regulatory body is established, structured and resourced in a manner commensurate with the potential magnitude and nature of the hazards associated with the existing facilities and activities. Additionally not only should the regulatory body fulfil its legal requirements and international commitments and standards, but it should also, in accordance with good safety (and security) culture, strive to develop and improve its performance on a continuous basis.

To guide an organization to further improve its performance, a variety of excellence, management and quality system models have been developed internationally, regionally and nationally. In a more mature stage, self-assessments may be targeted at particular areas of known sub-optimal performance, at a key process, or at other organizational issue. Senior management of the regulatory body, for instance, may select the focus of assessment on (for example):

- Stakeholder feedback;
- Audit results;
- Relevant industrial standard(s);
- Performance indicators;
- Concepts such as ‘Balanced Score Card’ analysis, or ‘SWOT’ (Strengths, Weaknesses, Opportunities and Threats);

- Benchmarking with other national or international organizations.

Organizations may also draft unique questions to focus the self-assessment on particular issues that senior management considers may benefit from closer review and assessment.

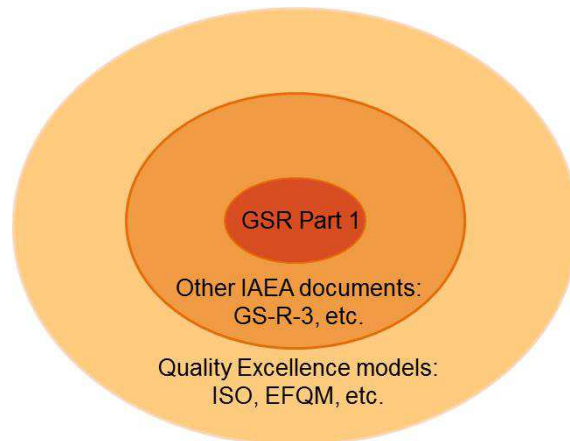


FIG. 1. A Self-assessment model for regulatory bodies.

3. METHODOLOGY

Self-assessment is routinely repeated at regular intervals (typically every 1 to 3 years). The main input for each self-assessment is the result of the previous one (in other words, the extent and impact of implementation of the action plan arising from the last assessment).

The initiation of a self-assessment is usually linked to the organization's annual and/or strategic planning cycle. Additionally, a self-assessment using this IAEA Methodology would usually precede IAEA review and appraisal services such as IAEA Advisory Missions and the Integrated Regulatory Review Service (IRRS).

3.1. PRECONDITIONS

Before a Regulatory Body begins a self-assessment, the following should be fulfilled as a minimum:

3.1.1. Senior management commitment

The Regulatory Body's management should commit itself to:

- allocating adequate resources for completion of the self-assessment project;
- encouraging staff to perform self-assessment in a frank and honest manner and a blame-free environment; and
- Considering self-assessment conclusions openly and transparently and acting to ensure continuous improvement in light of the outcomes.

3.1.2. Management system

The self-assessment process should be an integral part of the regulatory body management system and used periodically as a tool for improvement.

3.1.3. Staff involvement

Involvement of all staff members, to the extent possible, is a prerequisite to self-assessment using the IAEA Methodology. Self-assessment is an opportunity to develop or reinforce a continuous improvement culture across the organization.

According to the self-assessment project scope, the project manager should select widely from all relevant staff members to ensure the self-assessment responses and their evaluated outcomes are pertinent and coherent and 'owned' throughout the organization.

3.2. SELF-ASSESSMENT PROCESS PHASES

The self-assessment project manager, as assigned by senior management, is responsible for the conduct and monitoring of the self-assessment process. Once the pre-conditions are satisfied, the self-assessment process can begin. Self-assessment is a cyclic process comprising five phases:

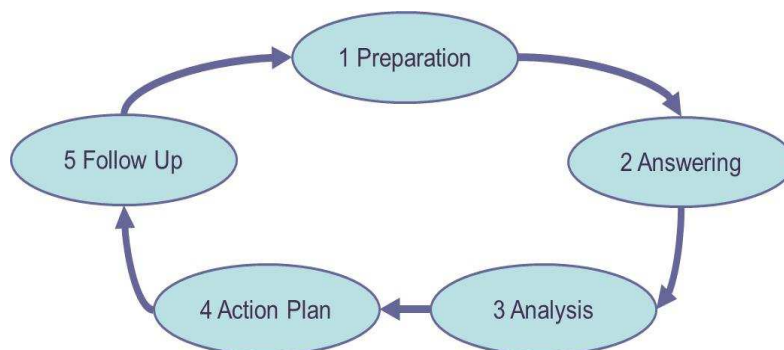


FIG. 2. The phases of the self-assessment process.

3.2.1. Phase 1: Preparation

During this phase, the self-assessment programme is prepared and organized. This includes defining the scope, preparing/selecting the corresponding questionnaire and assessment criteria and formalising a self-assessment implementation plan. The plan defines the self-assessment scope and the resources allocated to each step of the process, the milestones, time schedules and responsible individuals. For larger organizations, a Self-Assessment Project Management Team (PMT) may be established at this stage, headed by the Project Manager (PM).

3.2.2. Phase 2: Answering

The objective of the answering phase is to provide descriptive, factual responses to questions and to append all necessary documentary evidence to support the responses. At this stage responses should avoid any expression of opinion that cannot be objectively supported by evidence. Questions are answered by a Respondent Team (RT) comprising as many regulatory staff as practically possible, including junior staff and senior managers together with specialist and technical staff from cross-functional areas within the organization(s).

3.2.3. Phase 3: Analysis of responses

The analysis phase is expected to identify the strengths and weaknesses of the regulatory body, together with opportunities for improvement and risks if action is not taken. It provides the expert opinion and recommendations necessary for senior management to prepare an action plan for improvement.

The Analysis Team (AT) is independent of the respondent team(s) and to the extent possible, is made up of individuals who had no part in the answering phase. Analysts are usually the more senior staff of the relevant parts of the organization. Analysis is based on a comparison of the answers to the questions relative to the expectations and assessment criteria for the questions.

The analysis team can consult/interview the respondent team for clarification of answers or require more documentary evidence in support for a given response, until consensus is reached between respondents and analysts that the topic has been comprehensively and accurately addressed. However, in case of dispute between the AT and RT, the PMT resolves the issue and will have the final say.

3.2.4. Phase 4: Action planning

Upon completion of the self-assessment analysis phase, an action plan is developed by the senior management. The main inputs for the action plan are the results (conclusions and recommendations) of the analysis phase, together with the documentary evidence gathered during the answering phase.

3.2.5. Phase 5: Implementing the action plan and follow-up

Senior management is responsible for the implementation of the action plan. This phase should include detailed and transparent communication of results, conclusions and the proposed action plan to the organization's staff, in order to gain their commitment and motivation to implement the plan.

This phase also follows up progress with the implementation, including indicators of how implementing the plan is affecting regulatory performance. A formal and structured follow-up of the implementation should not be overlooked, since this is the mechanism by which the regulator ensures the action plan is delivering the desired results and objectives.

3.3. PROCESS MAPS

3.3.1. A process map for phase 1: Preparation

No.	Process step	Details	Responsibility	Output
1.	Input: Identified need to perform a self-assessment (SA) and/or results from implementation of the action plan of a previous SA.	The initiative or need to perform a SA can come from multiple sources, which may include one or more of the following: the board/senior management (SM), IAEA review/appraisal, the management system, staff concerns, etc.		
2.	Senior management (SM) or the board as appropriate makes the decision to perform a self-assessment and commits all resources necessary for the SA to be effective.	<p>SM commitment is important in particular considering that self-assessment can be time-consuming and requires allocation of adequate resources which can be significant. However, SM should not influence the RT when answering questions, or the AT when analysing the answers.</p> <p>The SM should formalise the following decisions:</p> <ul style="list-style-type: none"> • Their commitment to complete the self-assessment, develop an action plan and follow-up including implementation. • The assignment of a PM or PMT if appropriate who will have specific authority for managing the project. PM (or PMT members) should neither answer self-assessment questions, nor analyse them. • The objectives and, as necessary, the overall boundary of the self-assessments. • The milestones, including when SM approval is requested, and the 	SM (or board)	Official statement including published decisions and assignments for PMT

No.	Process step	Details	Responsibility	Output
3.	Determining the scope of the self-assessment (SA).	<p>corresponding schedule. These decisions should be published.</p> <p>The scope should match objectives and limits set by SM. It is established by considering, among others the following:</p> <ul style="list-style-type: none"> • Organizational goals and objectives. • The size and scope of organization. • The relative stage of development of the organization (e.g. mature or developing). • Competencies available within the organization, especially competency to conduct self- assessment. • Weaknesses already identified during previous self-assessment(s). • Suggestions and recommendations from past IAEA reviews and appraisal services and other external events. • The agreed scope, including the thematic modules, of a forthcoming IAEA review (such as the IRRS) or similar events. • Organizational infrastructure factors to be considered when deciding the scope (e.g. legal and governmental infrastructure, size of the Regulatory Body (RB), hazards, competences, etc.). <p>The SA scope should be thoroughly and formally defined within the overall limits set by SM and should be approved by SM.</p>	PM suggests, SM decides	Decided scope

No.	Process step	Details	Responsibility	Output
4.	Development of a detailed SA questionnaire and the selection of criteria for assessing responses to the questionnaire.	<p>A detailed questionnaire with established criteria for its assessment is essential to performing the SA of a RB. The questionnaire and criteria will therefore be based on the agreed scope of the planned self-assessment.</p> <p>Questions and assessment criteria may vary for different organizations based on their level of maturity (see “self-assessment model”) and the scope of the SA.</p> <p>GSR Part 1 [1] requirements should be used as the first level of SA questions and criteria for any newly established or early developing RB. A mature RB may choose to introduce more depth and include additional IAEA safety standards and guides as second level questions with their corresponding criteria.</p> <p>These two levels of questions and their criteria can be further augmented with other standards and tailor-made questions and their corresponding criteria (criteria: = what constitutes a good answer and what is acceptable)?</p> <p>This questionnaire and criteria for self-assessment should be approved by SM.</p> <p>The IAEA has developed SARIS questionnaire (and associated tool), based on the IAEA safety standards, to support Member States in their self-assessment undertaking.</p>	PM	Question set and criteria for assessment
5.	Prepare background materials and selection of tools (papers, IT)	<p>The standards and guides used to set up criteria are considered part of background materials.</p> <p>The tools selected should encourage a thinking</p>	PM	List of background materials and tool selected.

No.	Process step	Details	Responsibility	Output
6.	Select Respondent Team	<p>attitude. The SA is not only a “yes-or-no” approach. It is an opportunity to think about organization and practices.</p> <p>The selection has to be done on the basis of competence in all the areas within the scope of the proposed SA.</p> <p>The tasks of the RT and AT should be defined (see section for definitions).</p> <p>As necessary, the questionnaire is divided in several modules. Individuals (one or several) are designated to answer the parts of the questionnaire relevant to their respective areas of competence.</p>	PM	Selected individuals
7.	Select Analysis Team	<p>The AT members should not be the same as the members of the RT. AT members should be of sufficient seniority and experience to be able to make detailed judgements about all responses to the questionnaire in accordance with the agreed criteria.</p>	PM	Selected individuals
8.	Support/consultant and/or partnership requests to be considered	<p>According to the national regulatory organization(s) and the SA scope, partnerships may be necessary to adequately perform the SA.</p> <p>A consultant may be engaged as necessary to provide support if the RB has lack of experience in conducting self-assessment.</p> <p>Furthermore, support can be sought as necessary either from the IAEA, experienced Member State RBs, etc.</p>	PM	Access to external support and advice on self-assessment.

No.	Process step	Details	Responsibility	Output
9.	To increase the organization's awareness about SA	<p>The success of a self-assessment is based on the motivation level of the staff and all the self-assessment teams themselves.</p> <p>During the preparation phase, the PMT should communicate widely on self-assessment in such a way that the objectives of SA are fully understood and accepted by the organization.</p>	PM	Staff of the organization fully support the proposed SA.
10.	Output: Develop Self-Assessment Plan (SAP)	<p>A typical SAP includes at least the following:</p> <ul style="list-style-type: none"> • Scope. • Self-assessment organization (teams etc.). • Time schedules. • Resources allocated at each step. • Responsibilities. • Pre-SA training requirements. <p>The SAP should be approved by SM.</p>	PM suggest, SM approves	Self-assessment plan and background materials, Approved questionnaire and associated criteria.

3.3.2. A process map for phase 2: Answering

No.	Process step	Details	Responsibility	Output
1.	Input: Self-assessment plan and background materials, Questionnaire and associated criteria from the preparation phase.	All relevant materials and questionnaires given to the Respondent Team (RT) (which comprises individuals having the expertise and experience to cover the spectrum of activities within the scope of the SA).	PM	Comprehensive documentation and other necessary resources facilitate the answering phase
2.	Training of RT and any other co-opted members	Training should include the details of self-assessment questionnaire, understanding of scope, objectives and the answering process.	PM and consultants	Respondent Team competent to answer all questions in the agreed scope of the SA.

No.	Process step	Details	Responsibility	Output
3.	Responding to the questionnaire	<p>Training should also include on using self-assessment software (SARIS).</p> <p>RT should provide thorough, in-depth descriptive responses to the self- assessment questionnaire together with all documentary evidence necessary to support the answers. The responses should describe the current situation within the organization and care should be taken to avoid making aspirational responses, such as desired or planned improvements not yet achieved.</p> <p>Descriptive responses can be tricky and training should have addressed this aspect. Care should be taken in writing the responses so that they are neither too concise, thus failing to fully explain the current status, nor too detailed so that the essence is lost.</p> <p>Similarly, collecting documentary evidence can also be tricky. For mature regulatory bodies with well-established electronic data management systems, the collection of documentary evidence is relatively easy as those documents such as process description, rules and procedure are well documented and in electronic form which can be hyperlinked/attached. But for newly established and developing regulatory body this can become a long, time-consuming task of collecting documents from many sources. Careful consideration should be given to what evidence is sufficient to support the answer given. No additional material would then be required.</p>	RT and co-opted members	Fully developed responses to questions from all areas within the scope of the SA

No.	Process step	Details	Responsibility	Output
		<p>Many national Regulatory Bodies have not yet developed their own management manuals but the absence of a well-documented management manual and procedures do not necessarily mean the lack of a management system.</p> <p>Many regulatory bodies use rules, regulations and procedures of management issued by central government of the country and well established practices that should be taken into account when responding to the questionnaire.</p> <p>Responding to the questionnaire is a time consuming and resource intensive task so it is advisable to complete it within a manageable time frame usually as group exercises in which the whole or subsets of the RT are present. Care should be taken to avoid giving responses individually. Where feasible, carrying out the answering phase outside the office premises could be considered.</p>		
4.	Quality check of responses	<p>Descriptive responses and their documentary evidence should be checked by the PM for quality, consistency and completeness. The responses could be broadly discussed with senior management (SM) before handing to AT for analysis, to ensure the answering phase has followed the purpose and intent of the SA appropriately.</p> <p>However, care should be taken while discussing responses with SM to ensure it does not influence the Analysis Team or introduce undue biases and pressure to change the responses.</p>	PM	Confidence that the answers have been completed adequately and are ready to be forwarded to the Analysis Team

No.	Process step	Details	Responsibility	Output
5.	Output: finalized response file	A clear and consistent document containing all responses to the SA questionnaire should be prepared by the RT, using a template agreed at the outset of the SA project.	RT	Reponses file with the essential documentary evidence in hard copy and /or electronic form, as appropriate.

3.3.3. A process map for phase 3: Analysis

No.	Process step	Details	Responsibility	Output
1.	Input: Responses file with documentary evidence in hard copy or electronic form, as available.	<p>The Analysis Team (AT) must be assuredly independent (as far as is practical) from the Project Management Team;</p> <p>AT Members should be fully trained for the task they are about to undertake.</p> <p>AT Members should be informed about the relevant procedures, which cover the Analysis Phase activities.</p> <p>There should be an ‘Entrance Meeting’ (with the PM, RT leader and AT in attendance) to transfer all information from previous phases to the AT.</p> <p>The participation of Respondent Team Members should be welcomed – if necessary they can further explain their answers in peer discussion, or be requested to provide further information or evidence.</p> <p>Typical agenda would be presentation of the Respondent Team Report and Questions and Answers Session.</p>	PM, AT	Analysis Team competent and adequately resourced to analyse the responses to the questionnaire
2.	Launch Analysis Phase	Provide the information on the scope and extent	PM, AT	Analysis begins

No.	Process step	Details	Responsibility	Output
		<p>of the Analysis Phase; Distribute the answers to the AT Members, as appropriate; Obtain preliminary comments from the AT Members.</p>		
3.	Analysis of responses	<p>To review the answers against the agreed assessment criteria (in SARIS, the IAEA safety standards); To assess the completeness of responses and their relevance; To review the provided further evidence and references for the objectivity of the answers; To clarify answers, when needed; To conduct SWOT analysis and provide recommendations for developing an action plan for improvement To provide a structured, concise report on the analysis performed, including a proposal (recommendations) for the content of the Action Plan and arguments/justifications for these proposals.</p>	AT	Formal, structured review of the responses and drafting of a report of the analysis phase.
4.	Validation of the Analysis	<p>To present the results to PMT & RT; To resolve conflicts, if any. There may be a difference of opinions in interpreting questions/responses between the RT and AT; in such cases the PM has the final word. To ensure compliance with the self-assessment procedure.</p>	PM, AT	Assurance that the respondent and analysis phases have been conducted appropriately, in accordance with the requirements and scope of the SA.

No.	Process step	Details	Responsibility	Output
5.	Output	Report to SM on methodology used, results, differences justification, conclusions and suggestions for the Action Plan.	PM, AT	Analysis report

3.3.4. A process map for phase 4: Action planning

No.	Process step	Details	Responsibility	Output
1.	Input: analysis report from analysis phase	The Analysis Report provides the raw material for developing an action plan for the continuous improvement of the regulatory body	PM, AT	
2.	Senior management to evaluate the analysis report. Every finding and conclusion of the report to be addressed, and evaluated.	<p>The PMT is responsible for the self-assessment process until the analysis report is finalized. From this point forward senior management might take the principal role in reviewing, discussing and evaluating the Analysis Report. Based on the analysis report, the SM prepares an Action Plan to improve the performance, effectiveness and efficiency of the regulatory body and undertakes to be responsible for its implementation.</p> <p>Setting of improvement priorities may be necessary since available resources (such as manpower, time and funds) may not allow all necessary actions to be taken at the same time. It is advisable that the SM designates a responsible manager to manage the action plan preparation (i.e. the process owner).</p>	SM	SM-evaluated analysis report and appointment of a manager responsible for Action Plan preparation.
3.	Senior management documents the evaluation.	Evaluation should be documented in a transparent and traceable way.	SM	Minutes of the SM meeting or other relevant document showing SM's evaluation findings of the

No.	Process step	Details	Responsibility	Output
4.	Establish criteria and categories of compliance.	<p>To support priority setting and preparation of the Action Plan, grouping of the findings of each topic addressed in the analysis phase is essential. SM conclusions and recommendations regarding how well the assessment criteria were fulfilled could be grouped in four categories:</p> <ul style="list-style-type: none"> (0) non-compliance, (1) poor compliance, (2) close compliance and (3) good compliance. <p>These grouping termed as priority assignment (PA) is also used in SARIS.</p> <p>Grouping offers a good distinction between topics that are fully achieved relative to those that inadequately comply with the criteria. It allows also trending (plotting the scores may indicate trends of low compliance and weaknesses in one area, and/or high compliance and strengths in another).</p>	SM	<p>analysis report and its commitment to improvements based on the analysis.</p> <p>Analysis results divided into four groups in order to identify priorities for improvement</p>
5.	Each senior manager to develop a work plan to address (eliminate or strengthen) every identified improvement area under his line of responsibility.	<p>The manager has best understanding of what it takes to address the issue (in terms of practical activities, manpower, funds and time).</p> <p>This work plan is created for each topic and translates the issue into necessary actions and resource needs.</p>	Responsible manager	Work-plan for each improvement topic

No.	Process step	Details	Responsibility	Output
6.	Review work plans.	<p>Senior managers review all work plans collectively and set priorities with time-lines for their execution. This prioritized and time lined file of work plans forms the core of the Action Plan.</p> <p>SM finalises the Action Plan and signs it. Senior managers jointly establish an implementation sequence for all work plans. Usually it is not possible to carry out all the development work simultaneously (for example due to manpower and funding limitation), and therefore an overall prioritization is needed. It is expected that weaknesses in categories 0-1 are to be eliminated as a priority and strengths in categories 2-3 are noted or further improvement as necessary.</p> <p>Elimination of weaknesses might demand some tough decisions, including the giving up of an activity altogether, or outsourcing, recruitment of new expertise, etc.</p>	SM, and for each work plan, a responsible individual, i.e. "topic owner" is designated	The Action Plan contains prioritized actions, each having a work-plan.
7.	Action plan reviewed by peers	<p>The SM could consider requesting for a peer review to ensure that the action plan is properly established, realistic and appropriate.</p> <p>(A thorough peer review of regulatory infrastructure for nuclear and radiation safety is provided by IAEA's IRRS, for which the Secretariat can provide implementation Guidelines).</p> <p>To complete the organization's understanding of its current status against the IAEA safety standards, such an international peer review</p>	SM	Decision on external peer review of the SA Action Plan.
			SM	Updated action plan, based on the suggestions and recommendations of peers external to the

No.	Process step	Details	Responsibility	Output
		may be organized. In due course, the results of the peer review should be reflected in the Action Plan.		organization.
8.	Output	When all steps have been taken to identify and prioritise an Action Plan for the continuous improvement of the regulatory body, the Action Plan should be published and circulated widely, including to all those who have a part to play in its implementation.		Publication of a prioritized Action Plan

3.3.5. A process map for phase 5: Implementation and follow-up

No.	Process step	Details	Responsibility	Output
1.	Input: Prioritized Action Plan	A published Action Plan has been made available to all interested parties, particularly those who will have some part in its implementation (including all staff of the organization).	SM	Distribution of the published Action Plan
2.	A line manager is designated responsible for each action (single work plan) of the implementation phase	SM ensures that for every action in the plan, there is a person with a clearly assigned responsibility for its implementation.	SM to designate responsible manager	Clearly assigned line-management responsibility for the implementation of every action identified in the Action Plan.
3.	Action Plan made available to all staff members, and self-assessment results actively communicated to all interested parties	It is essential that findings and conclusions of self-assessment are widely publicized and explained fully within the organization so that everyone remains on board and contributes to implementation of the action plan	SM	Raised awareness among staff members and understanding of the vision and objectives arising from the Action Plan.

No.	Process step	Details	Responsibility	Output
4.	Designated managers review and update, if needed, the work plan for activities under their responsibility	Action plans and launch actions (work plans assigned to responsible individuals with allocated resources) are implemented in accordance with the agreed timescale and priorities.	Designated managers responsible for each activity	Updated work-plans for implementation
5.	Ensure staff's commitment and motivation in implementing the plan.	<p>Motivational aspects should not be underestimated. Organizational and individual benefits should be stressed, and management should demonstrate its commitment to the improvements.</p> <p>Staff should be kept fully involved in the on-going implementation of the plan, ensuring that enthusiasm and support is maintained, even for the longer-term actions and those with significant implications for staff.</p>	Senior management, each manager, who is responsible for the activity	Committed staff that understand and contribute to the on-going implementation of the Action Plan.
6.	Incorporate the Action Plan (and its work plans) into the annual planning process of the regulatory body.	Ensure that all actions are incorporated into the annual plans of the departments and other units of the organization.	SM, line management	Regulatory body's annual plans include all activities from the SA Action Plan.
7.	Implement the Action Plan	The actions required to implement the Action Plan commence in the appropriate sequence and in accordance with agreed timelines.	Responsible individuals as designated in the Action Plan. Supervision by SM and line management.	Orderly, logical implementation of the SA Action Plan in accordance with priorities and resources available.
8.	Regular follow-up of progress with the implementation of the Action Plan,	Regular follow-up (at least quarterly) can be achieved for example by introducing it as a permanent item in the Management Meeting agenda.	Senior management, each manager, who is in line management responsible for the	Regular updates on the progress of implementing the Action Plan and understanding of any changes to the plan as circumstances dictate.

No.	Process step	Details	Responsibility	Output
9.	Take corrective actions as needed to keep the implementation on course.	<p>A peer review (national or international such as the IAEA's IRRS) may be requested to ensure effective and efficient implementation in accordance with international requirements and undertakings.</p> <p>Corrective actions should be taken at two different levels; Firstly, to ensure that actions taken are in line with the work plan, and secondly, that the actions taken contribute to improvements in regulatory performance.</p> <p>If actions taken and investments made show little or no real improvements, the issue must be taken to SM for review and decisions on whether to modify or discontinue the implementation of that particular work plan (i.e. Return to step 3).</p>	SM and each manager, with in line management responsibility for the activities	Updated work-plans
10.	Audit action plan, if needed	<p>If in doubt, the implementation of the Action Plan may be externally audited, and actions taken as recommended by the auditors to maintain progress (or discontinue implementation of a problematic work plan).</p> <p>Management reviews are an integral part of a QMS. If needed, return to step 3 or have a particular Action Plan activity discontinued.</p>	SM	External audit reports, updated work-plans, progress reports and final results for each topic.
11.	Progress Report of Action Plan implementation and results achieved.	<p>Reporting should be done inside and outside the RB. For example, reporting should be done in the annual report of the regulatory body.</p> <p>Repeat steps 3 - 10 until the actions needed are done and the action is approved as "completed" by the SM.</p>	SM	Progress Reports indicating the extent of implementation of the SA Action Plan.

No.	Process step	Details	Responsibility	Output
12.	Evaluation of how implementation of the Action Plan is affecting regulatory performance	<p>The regulator must be certain that the implementation of the Action Plan is taking him closer to its desired results and objectives.</p> <p>The regulator should take prompt adjustments whenever needed.</p> <p>If the investment is not producing the expected results, the work plan should be reviewed, if necessary comprehensively for all topic areas.</p>	SM	Assessment of the increased regulatory performance and adjustments to the SA Action Plan if necessary.
13.	Outcome	A fully implemented SA Action Plan prepares the RB for its next self-assessment and therefore maintains the cycle of continuous improvement.	SM	Improved regulatory performance and a decision on the scope and timescale of the next self-assessment.

3.4. DEFINITIONS USED IN THE PROCESS MAPS

3.4.1. Self-Assessment project manager (PM) and/or project management team (PMT)

The PM reports to senior management. The PM manages the self-assessment project in compliance with objectives and the scope defined by senior management. The PM has responsibility for project coordination, conflict resolution if any, reporting to senior management regarding the self-assessment implementation and consultation with senior management as needed.

3.4.2. Respondent team (RT)

The RT completes (responds to) the questionnaire(s) in a plain, factual and justified manner. Answers should strive to be transparent, frank and honest, without bias or undue emphasis. The answers should clearly identify the existence and nature of non-compliances or lack of conformity between current responsibilities, functions and activities and the criteria (benchmarks) against which the self-assessment is performed.

An RT leader may be designated where necessary to coordinate and ensure consistency between responses of sub-teams or individuals.

3.4.3. Analysis team (AT)

The AT team conducts the SWOT analysis and draws conclusions and recommendations that would be the basis for developing the Action Plan, based on the responses of the AT team. The AT should focus on the content of answers rather than the form, and develop expert conclusions based on evidence provided. AT members should not be drawn from staff that made up the Respondent Team(s).

An AT leader may be designated where necessary to coordinate and ensure consistency between the analyses of sub-teams or individuals.

4. PERFORMANCE INDICATORS

The main purpose of a performance indicator (PI) is to objectively measure progress against selected targets and keep the focus on actions in pursuit of the organization's mission and mandate. Maximum benefit can be derived from the use of performance indicators where they are part of an established management system.

For any aspect of the organization's activities the following three essential questions should be understood and addressed:

- Why are performance indicators needed?
- What benefits may be derived from the use of performance indicators?
- Are there likely to be problems if performance indicators are used?

Performance indicators represent only one of a range of management tools and should be applied on a recurring basis (typically annually, although large organizations may apply them more frequently) to measure performance against predetermined and objectively measurable targets.

PIs help in determining priorities, allocating resources and in communicating with various stakeholders, including organizations in other States. However, there are pitfalls if PIs are not used properly. A common symptom of inappropriately applied PIs is a tendency to lose focus on the actual mission or operational requirements in order to meet the PI targets.

In general, organizations should first develop a sustainable self-assessment process before developing/adopting a system of performance indicators. For more details, please see Annex 3.

5. TOOLS FOR SELF-ASSESSMENT AND PERFORMANCE INDICATORS

Self-assessment is a learning process that reveals the current situation as it truly is, relative to how it may have been perceived to be. For this learning process to be effective, it requires understanding derived from discussions and the sharing of views and opinions among all staff participating in the process.

The IAEA has developed tools for self-assessment (the *Self-Assessment of Regulatory Infrastructure for Safety (SARIS)*), incorporating basic performance indicators (priority assignments), to support regulatory bodies when performing self-assessment. These tools are intended to support the regulatory body's self-assessment process and should never be used mechanically.

SARIS currently includes, in addition to other variants, two main components each for specific purposes, the first being for a comprehensive self-assessment of the national regulatory infrastructure for nuclear and radiation safety, and the other for countries embarking on a nuclear power programme in accordance with the IAEA safety guide SSG-16 [6].

The SARIS tool, including its installation and users' guide, can be freely downloaded from the IAEA website. It can also be provided on a CD upon request.

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ANNEX 1. CONTEXT AND ROLE OF SELF-ASSESSMENT

The process to establish and develop an effective and efficient regulatory body involves continuous improvement, self-assessment, good management practices and the discipline of planning. The context of this development and improvement process reflecting the importance of self-assessment can be divided into the following main steps:

- **Assess where you are now.** The regulatory body needs to determine its current situation. One widely used way to do this is to perform self-assessment of the organization.
- **Define your vision and objectives and organizational priorities.** In order to align the organization and its activities, the regulatory body needs to understand its present strengths and areas for improvement. Self-assessment is a prime tool for identifying strengths and weaknesses, opportunities and threats.
- **Identify what needs improving.** An organization's self-assessment using a systematic method can provide a detailed map for the people in the organization to answer more specifically, the question; "*Where do we need to improve?*"
- **Identify how to improve.** There are many improvement processes, such as learning from others through benchmarking (i.e. benchmark processes, organization and/or metrics etc.) and research, and identifying the good practice of others.
- **Prioritize improvements.** The regulatory body cannot do everything and certainly not all at the same time. It is crucial to review areas of improvement and determine what actions need to take place first. For example, what improvements will have the most impact on your organization and the safety work it is doing? The organization should prioritise improvements based on importance, urgency and the availability of all required resources (i.e. realistically achievable improvement).
- **Incorporate improvements in action plans.** Some major improvements identified will require more planning and resources. It may help to manage these actions through a formal project management approach.
- **Do the improvements.** Change is an important part of the improvement process, because most often in order to improve you must change. Today's most successful organizations recognise this and they recognise that improvement is continuous.
- **Check the results.** Once improvement objectives have been achieved, it is important to be able to measure the impact the improvement has had upon the organization. The favoured approach for doing this is routinely repeated self-assessment. The organization should define and justify the appropriate intervals between self-assessments in order to track the progress. In addition, it should be recognised that successive self-assessments may become more detailed and increasingly sophisticated as the organization becomes expert in the process. Future self-assessments may also become more focused on known areas for improvement identified in past self-assessment cycles.

ANNEX 2. DETERMINING THE SCOPE FOR SELF-ASSESSMENT

The identification of the scope of the self-assessment is one of the most important pre-conditions as the resource needed for self-assessment varies directly with the scope agreed.

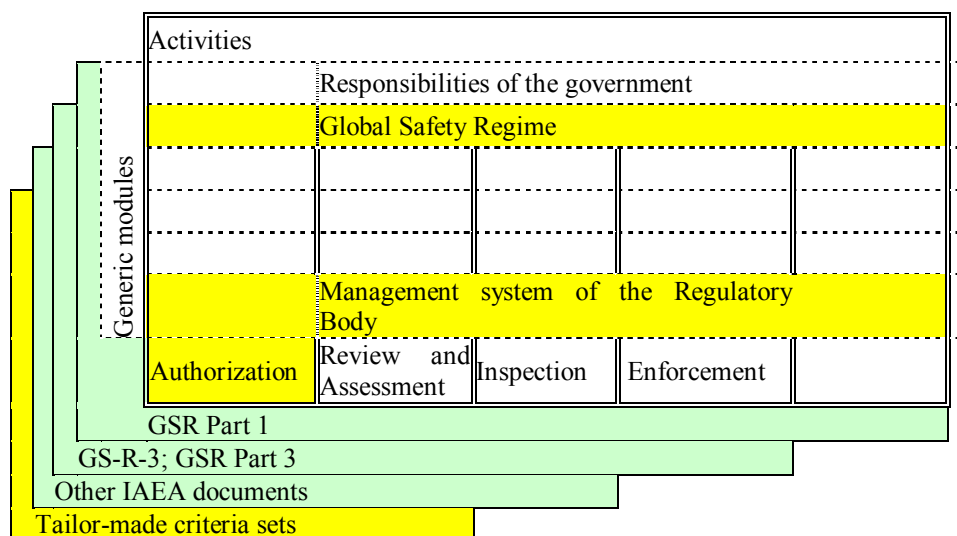


FIG. 3. Three-dimensional structure of the modular approach.

The diagram above describes the three-dimensional structure of the modular approach. The scope of a self-assessment can be drawn from generic modules (such as responsibilities of the government) and selected criteria sets (such as activities of the regulatory body).

The scope of self-assessment should be selected according to the needs and expectations of the Regulatory Body. A modular approach allows the Regulatory Body to focus on selected topics (i.e. governmental responsibilities for safety, the global safety regime, responsibilities and functions of the regulatory body, management system of the regulatory body, etc.). A module can be a series of questions based on generic theme (generic module) such as government responsibilities and management system, or based on functions and responsibilities of the Regulatory Body (activity module). Moreover, a module can be implemented either for all or part of the facilities and activities regulated by the Regulatory Body. In the case the Regulatory Body decides to use all modules for all activities and facilities, the assessment will be termed a ‘full scope self-assessment’.

The IAEA self-assessment methodology is in line with other IAEA tools and review/appraisal services. The self-assessment modular approach described in this document is consistent with the IAEA’s general approach for review and appraisal of regulatory infrastructure.

The self-assessment methodology may be universally applied, irrespective of the size, nature or maturity of any regulatory body, but it should be tailored to local circumstances; a full-scope initial self-assessment may, for example, be followed by subsequent targeted or limited scope self-assessments. The scope of self-assessment should be planned and clearly documented and considerable thought should be given to the standards and criteria against which the self-assessment will assess the regulatory body’s current performance.

The scope of self-assessment should consider inter alia:

- Previous self-assessment action plan;
- Outcomes resulting from previous review/appraisal missions;
- Areas of improvement identified as a result management system models implementation;
- Changes in the regulatory body’s organization, activities or management and modification of its environment (legislation or regulation, governmental framework, etc.);

- Stakeholder feedback;
- The availability of all resources required to carry out the proposed self-assessment.

Having taken into account all this information, the self-assessment project manager would propose a scope which should be agreed by the senior management based on the requirement that it appropriately targets areas for improvement of the organization and is considered to be realistically achievable within resources available to be assigned to it.

Definition of a Performance Indicator (PI)

- Performance indicators are one of many tools used to help answer the question: ‘How do you know what you are achieving and what is your progress?’
- One definition of a performance indicator is: *A numerical measure of the degree to which the objective is being achieved.*
- Whatever Performance Indicators are selected, they must reflect the organization's goals, they must be pertinent to its success, and they must be quantifiable (measurable). Key Performance Indicators (KPIs) are usually long-term considerations. The definition of what they are and how they are measured would be expected to remain unchanged over long periods. This allows comparisons of progress over time.
- The organization must define a target value for each PI that clearly shows what the organization is aiming to achieve.

Why PIs?

- Organizations need information that can help to determine whether their aims and objectives are being achieved and whether their strategies are being effectively implemented. PIs help in giving the holistic picture.
- Performance information can be quantitative or qualitative. Performance indicators are one kind of quantitative performance information (E.g. Proportion of staff having completed training programme, inspection programme implementation rate, and ratio of number of licensing requirements that have been met by the licensees). Information on performance is information you can use to help answer the question: Are we achieving our aims and objectives and what is our progress?
- The use of PIs allows an increased focus on long-term matters and provides a basis for adjusting priorities within the organization’s annual work plan if used properly.
- It allows the identification of poor performance and confirms the requirement for corrective action.
- It facilitates communication about the successes and failures of the organization with internal and external stakeholders;
- With target values, PIs help in improved understanding of expectations by internal and external stakeholders.
- It helps in making a more informed allocation of resources and prioritizing needs.
- Key Performance Indicators offer a performance management tool which, if used well, acts as an incentive (“carrot”). KPIs give everyone in the organization a clear picture of what is important, of what they need to make improvement happen. KPIs are fundamental to the organization and should be few in number. Properly identified and measured, KPIs can be used effectively to manage performance in a positive atmosphere of continuous improvement.
- It demonstrates the level of a long-term commitment to continuous improvement.

Benefits of using PIs:

- Fosters understanding between success and failure while trying to achieve the organization's goals and objectives (including compliance with selected standards and guides).
- Helps everybody to focus on important things and issues.
- Helps in verifying that regulatory work is performed in accordance with the mission, objectives, goals, strategy and plans of the RB.
- Helps in verifying that work is done according to the internal procedures and policy of the organization.
- Helps in measuring the perception of various stakeholders and staff towards regulatory and other processes of RB.
- Enables for early identification of undesirable trends to trigger actions by the regulator.
- Suitable for further developments and/or modifications to cover gradually the entire regulatory body improvement performances process.
- Helps to focus and prioritize the regulatory body activities.
- Helps to identify the regulatory body financial, resource, QMS, competence, training etc. needs.

Problems with using PIs

- In practice, organizations looking to introduce a range of Performance Indicators discover that it is expensive or difficult to implement in all fundamental performance areas (e.g. staff morale is difficult to quantify with a number).
- A significant issue in the identification and selection of Key Performance Indicators is that in practice, once a KPI is created, it becomes difficult to change, or the yearly comparisons with previous years may be lost.
- Use of PIs may result in shifting the focus from main objectives to a culture of merely meeting the numerical targets. Once again, this reinforces the need for careful consideration in the development and selection of KPIs.
- Can lead to staff frustration if the performance indicators are too numerous, vague or unfocused on the main mission of the RB. This may be more the case where the regulatory body is under staffed or at the early stages of its development.
- Are open to misinterpretation if not defined clearly.
- Do not give the complete picture of the performance of a regulatory body. Therefore, to get a complete picture, considerations should be given to complementary (including trend analysis) and qualitative information.
- Caution must be exercised in use of PIs to avoid sacrificing quality to meet numerical targets.
- In the case of smaller organizations, the PIs approach may create difficulties due to the cost of establishing and maintaining a performance management system.
- Where PIs are not used on a regular basis, the organization may lose the value gained from previous results of the PI process.

How PIs should and should not be used?

- PIs are most typically used to indicate how the organization's objectives are achieved. Therefore, in order to develop performance indicators it is essential to have aims and objectives which specifically state what is to be achieved.
- PIs are one of the management tools that is used cyclically (typically an annual cycle, but larger organizations may use them quarterly or semi-annually). Self-assessment, as discussed in this document, would typically follow a cycle of every 2-3 years.
- Performance indicators and actual performance are in most cases not the same. For performance indicators to be used wisely they need to be seen as numerical indicators that require interpretation. They should be recognized as merely clues to help in asking the appropriate questions about performance and its continuous improvement.

How to establish PIs?

- SMART approach; PIs have to be **S**pecific, **M**easurable, **A**chievable, **R**esults oriented (i.e. written as something to be achieved), and **T**ime bound.
- PIs should be developed in accordance with a balance between effectiveness and efficiency. PIs of efficiency are perhaps more easily identified and applied than those that would measure effectiveness. PIs of effectiveness require appropriately trained or specialist staff with particular skills regarding the measurement of the effectiveness of organizational activities.
- Many things are measurable. That does not make them key to the organization's success. In selecting Key Performance Indicators, it is critical to limit them to those factors that are essential to the organization reaching its goals. It is also important to keep the number of Key Performance Indicators small just to keep everyone's attention focused on achieving the same KPIs (i.e. what really matters to the organization's success).
- Reliability of PIs:
 - This may be summed up by asking the question; 'If I measured the same thing again would I get the same result'?
 - If your organization develops performance indicators you need to make an estimate of how reliable they are and decide whether they are reliable enough for your purposes.
- Validity of the PIs:
 - Validity is about answering the question: 'Are we measuring what we say we are measuring'?
 - Do you know how valid your performance indicators are? Do you know how valid they need to be for the use you are going to put them to?

The following two-step process can be taken when establishing PIs:

- A. Establish a clear link between goals and objectives and possible PIs:
 - Identify the criteria against which performance will be measured. Organization objectives and goals, which may include safety objectives, implementation of standards and guides, communication objectives.
 - Clarify the performance that should be measured in relation to the organization's goals and objectives.

- For each performance area, list indicators which could be used for measuring it, including the corresponding target values: absolute (achievement) or relative (progress). At this stage, the only criterion to be considered is to propose measurable indicators. Performance can be monitored through several indicators and, in the opposite way, a single indicator can address several areas of performance.

B. Selection of relevant indicators

For each performance the organization wants to assess, the relevance of an indicator will be evaluated by considering:

- The ease by which it may be monitored. Whether the measurement process is realistic may be evaluated by taking account of time and resources needed, the complexity of the process to gather data and measure the indicator, together with complexity in the practical use the indicator.
- Its effectiveness to evaluate corresponding performance. At this stage, the organization should evaluate how the indicator will provide an effective measure of the corresponding performance.

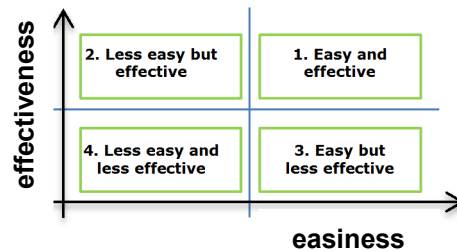


FIG. 4. Selection of relevant indicators diagram.

This matrix above is a useful tool to select the most relevant indicators. Proposed indicators may be positioned on the matrix in whichever of the four boxes best describes it. The organization will tend to select mainly those indicators positioned in box 1 (Easy and effective), possibly 2 (Less easy but effective) and will reject indicators in the boxes 3 and 4. However, due consideration should be given to the fact that some indicators may remain essential even where they fall into boxes 3 and 4.

After selecting the indicators, the organization should consider other criteria to fine tune its choice. In particular, in selecting Key Performance Indicators, it is critical to limit them to those factors that are essential to the organization reaching its goals. It is also important to keep the number of Key Performance Indicators small just to keep everyone's attention focused on achieving the same KPIs.

Conclusion

Performance indicators can be very useful tools in helping you answer the questions: How do you know what you are achieving and how can your service improve its performance?

However, if they are used simplistically the results may be less than desired and could be counter-productive or damaging to the organization.



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ISSN 1816-9309