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IAEA Safety Standards

for protecting people and the environment

The Management System for Technical Services in Radiation Safety

Safety Guide

No. GS-G-3.2



IAEA

International Atomic Energy Agency

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THE MANAGEMENT SYSTEM
FOR TECHNICAL SERVICES
IN RADIATION SAFETY

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The Agency's Statute was approved on 23 October 1956 by the Conference on the Statute of the IAEA held at United Nations Headquarters, New York; it entered into force on 29 July 1957. The Headquarters of the Agency are situated in Vienna. Its principal objective is "to accelerate and enlarge the contribution of atomic energy to peace, health and prosperity throughout the world".

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THE MANAGEMENT SYSTEM FOR TECHNICAL SERVICES IN RADIATION SAFETY

INTERNATIONAL ATOMIC ENERGY AGENCY
VIENNA, 2008

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FOREWORD

by Mohamed ElBaradei
Director General

The IAEA's Statute authorizes the Agency to establish safety standards to protect health and minimize danger to life and property — standards which the IAEA must use in its own operations, and which a State can apply by means of its regulatory provisions for nuclear and radiation safety. A comprehensive body of safety standards under regular review, together with the IAEA's assistance in their application, has become a key element in a global safety regime.

In the mid-1990s, a major overhaul of the IAEA's safety standards programme was initiated, with a revised oversight committee structure and a systematic approach to updating the entire corpus of standards. The new standards that have resulted are of a high calibre and reflect best practices in Member States. With the assistance of the Commission on Safety Standards, the IAEA is working to promote the global acceptance and use of its safety standards.

Safety standards are only effective, however, if they are properly applied in practice. The IAEA's safety services — which range in scope from engineering safety, operational safety, and radiation, transport and waste safety to regulatory matters and safety culture in organizations — assist Member States in applying the standards and appraise their effectiveness. These safety services enable valuable insights to be shared and I continue to urge all Member States to make use of them.

Regulating nuclear and radiation safety is a national responsibility, and many Member States have decided to adopt the IAEA's safety standards for use in their national regulations. For the Contracting Parties to the various international safety conventions, IAEA standards provide a consistent, reliable means of ensuring the effective fulfilment of obligations under the conventions. The standards are also applied by designers, manufacturers and operators around the world to enhance nuclear and radiation safety in power generation, medicine, industry, agriculture, research and education.

The IAEA takes seriously the enduring challenge for users and regulators everywhere: that of ensuring a high level of safety in the use of nuclear materials and radiation sources around the world. Their continuing utilization for the benefit of humankind must be managed in a safe manner, and the IAEA safety standards are designed to facilitate the achievement of that goal.

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EDITORIAL NOTE

An appendix, when included, is considered to form an integral part of the standard and to have the same status as the main text. Annexes, footnotes and bibliographies, if included, are used to provide additional information or practical examples that might be helpful to the user.

The safety standards use the form 'shall' in making statements about requirements, responsibilities and obligations. Use of the form 'should' denotes recommendations of a desired option.

CONTENTS

1.	INTRODUCTION	1
	Background (1.1–1.7).....	1
	Objective (1.8)	2
	Scope (1.9–1.13)	3
	Structure (1.14–1.15)	3
2.	MANAGEMENT SYSTEM	4
	General (2.1–2.8)	4
	Safety culture (2.9).....	5
	Grading the application of management system requirements (2.10–2.11).....	6
	Documentation of the management system (2.12–2.16)	6
	Control of records (2.17).....	7
3.	MANAGEMENT RESPONSIBILITY	8
	Management commitment (3.1)	8
	Customer satisfaction (3.2–3.6)	8
	Organizational policies (3.7–3.9)	9
	Planning (3.10–3.12).....	10
	Responsibility and authority for the management system (3.13–3.14).....	11
4.	RESOURCE MANAGEMENT	12
	Provision of resources (4.1).....	12
	Human resources (4.2)	12
	Infrastructure and working environment (4.3–4.8)	12
5.	PROCESS IMPLEMENTATION	13
	Developing processes (5.1–5.3)	13
	Process management (5.4–5.7)	14
	Control of products (5.8–5.16)	15
	Purchasing (5.17)	16

Communication (5.18).....	16
Managing organizational change (5.19).....	16
6. MEASUREMENT, ASSESSMENT AND IMPROVEMENT	17
Monitoring and measurement (6.1–6.2)	17
Self-assessment (6.3)	18
Independent assessment (6.4–6.9)	18
Management system review (6.10–6.12)	19
Non-conformances and corrective and preventive actions (6.13–6.19)	20
Improvement of services (6.20)	21
7. ADDITIONAL GUIDANCE FOR ORGANIZATIONS PROVIDING CALIBRATION OR TESTING SERVICES	21
Organization (7.1–7.5).....	21
Review of requests, tenders and contracts (7.6).....	22
Subcontracting of tests and calibrations (7.7–7.10).....	22
Service to the client (7.11–7.12)	23
Customer feedback (7.13).....	23
Control of records (7.14–7.17)	24
Internal audit (7.18–7.19)	24
Infrastructure: Laboratory facilities (7.20)	25
Test and calibration methods and validation of methods (7.21–7.22).....	25
Test and calibration equipment (7.23–7.27)	26
Measurement traceability (7.28–7.30)	27
Sampling (7.31–7.32)	28
Handling of items for testing and calibration (7.33)	28
Ensuring the quality of test and calibration results (7.34–7.35)	29
Reporting of results (7.36–7.37)	29
APPENDIX: GENERAL GUIDANCE ON ESTABLISHING A MANAGEMENT SYSTEM	30
REFERENCES	38
ANNEX I: CHECKLIST FOR JOB DESCRIPTIONS.....	39
ANNEX II: MANAGEMENT POLICY.....	41

This publication has been superseded by GSG-7.

ANNEX III:	MANAGEMENT OBJECTIVES.....	42
ANNEX IV:	CHECKLIST FOR EVALUATING REQUESTS FOR CONTRACTS	43
ANNEX V:	DUTIES OF THE MANAGEMENT SYSTEM MANAGER.....	44
	CONTRIBUTORS TO DRAFTING AND REVIEW.....	47
	BODIES FOR THE ENDORSEMENT OF IAEA SAFETY STANDARDS	49

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1. INTRODUCTION

BACKGROUND

1.1. Since the publication of the International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources (the BSS) in 1996, the IAEA and its Member States have devoted considerable efforts to establishing and strengthening national infrastructures for radiation protection.

1.2. The BSS (Ref. [1], para. 2.29) establish as a management requirement that:

“Quality assurance programmes shall be established that provide, as appropriate:

- (a) adequate assurance that the specified requirements relating to protection and safety are satisfied; and
- (b) quality control mechanisms and procedures for reviewing and assessing the overall effectiveness of protection and safety measures.”

1.3. In the Fundamental Safety Principles, there are clear references to quality assurance as an essential component of radiation safety (Ref. [2], para. 3.12):

“Leadership in safety matters has to be demonstrated at the highest levels in an organization. Safety has to be achieved and maintained by means of an effective management system. This system has to integrate all elements of management so that requirements for safety are established and applied coherently with other requirements, including those for human performance, quality and security, and so that safety is not compromised by other requirements or demands. The management system also has to ensure the promotion of a safety culture, the regular assessment of safety performance and the application of lessons learned from experience.”

1.4. Quality management is a term used to describe the process of ensuring that an organization achieves its stated goals effectively and efficiently.¹ According to ISO 9000:2000 [3], quality assurance (QA) and quality control (QC) are two important components of quality management. QA is an interdisciplinary management tool that provides a means for ensuring that all work is adequately planned, correctly performed and assessed, while QC is a means of applying controls to a process² to ensure that the product³ or service consistently meets specifications. The current philosophy of integrated management is to adopt a management system that addresses safety, human health, protection of the environment, security, product and service quality, and economic requirements as a single entity inherent in and applicable to all facilities and activities of the organization.⁴

1.5. Service providers in radiation safety add to the overall protection and safety by providing accurate results of monitoring processes. In Member States the achievement of this goal is often supported by means of a management system.

1.6. The Safety Guide provides additional guidance for service providers in radiation safety on meeting the requirements established in Ref. [4], with account taken of the generic guidance and examples given in Ref. [5].

1.7. This Guide will be revised periodically in the light of knowledge and experience gained on new processes, technological developments, changes in the skills and tasks of personnel as well as other, unforeseen, changes.

OBJECTIVE

1.8. The objective of this Safety Guide is to provide guidance on meeting the requirements [4] for development and implementation of management systems for technical service providers in radiation safety.

¹ Quality refers to the degree to which a product, process or service satisfies specified requirements.

² A process in this context is a set of interrelated or interacting activities that transforms inputs into outputs.

³ A product is the result or output of a process. Examples include a radionuclide, a waste package and electricity.

⁴ An organization is a group of people and facilities with an arrangement of responsibilities, authorities and relationships.

SCOPE

1.9. This Safety Guide focuses on technical service providers in radiation safety, providing either consultancy and maintenance services or calibration and testing services.

1.10. Consultancy and maintenance services could include:

- (a) Radiation safety consultancy;
- (b) Shielding calculations;
- (c) Modelling for dose assessment, containment and ventilation;
- (d) Maintenance services covering both in-house operations and services contracted with an outside organization.

1.11. Calibration and testing/assay services could include:

- (a) Monitoring services, including individual, workplace and environmental monitoring;
- (b) Calibration and calibration verification services for monitoring devices and radiation sources.

1.12. Issues relating to management systems for transport, waste management, education and training, apart from radiation safety services rendered by technical service providers in these thematic areas, are outside the scope of this Safety Guide.

1.13. This Safety Guide applies to organizations that are directly involved in, or that regulate, the facilities and activities described in paras 1.10–1.12, and to suppliers of nuclear safety related products who are required to fulfil some or all of the requirements established in Ref. [4].

STRUCTURE

1.14. This Safety Guide follows the structure of Ref. [4].

1.15. Reference [3] provides basic general guidance, information and examples. This Safety Guide provides supplementary guidance and explanation for technical service providers in radiation safety. Section 2 establishes the key elements of a management system for technical service providers in radiation safety, including general considerations, graded application of requirements,

documentation, safety culture and control of records.⁵ Section 3 discusses management roles and responsibilities for the development and implementation of an effective management system. Section 4 covers resource management, including the provision of resources, human resources, and infrastructure and the working environment. Section 5 provides guidance on the planning and control of the processes used for the activities of the organization, purchasing, communication and managing organizational change. Section 6 covers the measurement, assessment and improvement of the management system. Section 7 gives additional guidance for organizations providing calibration and/or testing services. The appendix gives an example of a process to implement a management system in an organization. Annex I gives an example of a job description. Annex II shows an example of a management policy statement. Annex III presents different examples for statements of management objectives. Annex IV presents an example of a checklist for contract evaluation. Annex V lists an example of the duties of a management system manager.

2. MANAGEMENT SYSTEM

GENERAL

2.1. The management system for service providers in radiation safety should be graded to the scope of their activities. The service provider should document its management system, which may include policies, processes and procedures, and instructions. The management system should be documented to the extent necessary to ensure the quality of the service provided, such as consultancy services, testing and calibration. An example of how to develop a management system for a service provider is provided in the appendix.

2.2. The management system for a service provider should cover work carried out in permanent facilities, at sites away from permanent facilities, or in associated temporary or mobile facilities.

⁵ A record in this context is a document stating results achieved, or providing evidence of activities performed.

2.3. The management system of a service provider using ionizing radiation should apply all relevant IAEA safety standards.

2.4. Safety should be of paramount importance for all service providers that use ionizing radiation in their activities.

2.5. Where a service provider is part of a larger organization, the organizational arrangements should be such that departments that may have conflicting interests, such as production, commercial marketing or financing departments, do not adversely influence the service providers' ability to comply with the requirements of their management system.

2.6. If the service provider wishes to be recognized as a third party organization, it should be able to demonstrate that it is impartial and that it and its personnel are free from any undue commercial, financial or other pressures that might compromise their technical judgement.

2.7. The third party organization should therefore not engage in any activities that may endanger trust in its independence of judgement and integrity in relation to its services.

2.8. In many Member States, this demonstration of fulfilment is achieved through third party audit or accreditation to internationally accepted management standards, as, for example, ISO 17025 [6]. It is the responsibility of the service provider to carry out its activities in such a way as to satisfy the needs of its customers. See Ref. [4], paras 2.1–2.4, and Ref. [5], paras 2.1–2.21.

SAFETY CULTURE

2.9. For a service provider, safety culture can be established by:

- (a) Promoting the knowledge of relevant safety standards within the organization;
- (b) Carrying out a risk analysis of the procedures applied;
- (c) Establishing proper rules and procedures and observing regulatory requirements to keep risk at a minimum;
- (d) Periodically evaluating the observance of these rules and procedures;
- (e) Periodically training the staff according to an established programme to follow the rules and procedures correctly;
- (f) Discussion of the established programme among trained staff;

- (g) Periodically updating the training programmes and coordinating them with the requirements of legal and regulatory bodies, which will check the effectiveness of these programmes;
- (h) Dissemination and promotion of knowledge of actual incidents and accidents to learn from their occurrence and to improve the safety culture;
- (i) Soliciting safety related proposals from the staff through an incentive system.

See Ref. [4], para. 2.5, and Ref. [5], paras 2.32–2.36.

GRADING THE APPLICATION OF MANAGEMENT SYSTEM REQUIREMENTS

2.10. The graded approach normally adopted by service providers is such that any differences in the controls to be applied to the products or services are identified within each process and are based on the influence of the process on the final product quality.

2.11. In the graded approach adopted, account should also be taken of the size and functions of the organization. This Safety Guide also provides guidance on the establishment of a management system in large organizations. In some cases, smaller organizations will not have the personnel to fulfil all the functions described in this Safety Guide with separate staffing. However, it remains critical that the functions, including promoting safety culture, ensuring independence, documentation and record keeping, be fulfilled to achieve the performance outcomes given herein. See Ref. [4], paras 2.6–2.7 and Ref. [5], paras 2.37–2.44.

DOCUMENTATION OF THE MANAGEMENT SYSTEM

2.12. The management system documentation is often contained in a quality manual that includes or makes reference to the supporting documents,⁶ including:

⁶ Documents may include: policies; procedures; instructions; specifications and drawings (or representations in other media); training materials; and any other texts that describe processes, specify requirements or establish product specifications.

- (a) A description of the management system;
- (b) Management documents;
- (c) Detailed working documents and job descriptions (for an example of a job description, see Annex I);
- (d) Additional technical documents and/or data, including:
 - (i) Databases of radionuclides or technical databases;
 - (ii) Operating manuals for equipment and software;
 - (iii) Reagent data sheets;
 - (iv) Requirements of national authorities (in laws and regulations);
 - (v) Managerial and technical standards.

2.13. The additional technical documents are often external documents that are not within the influence of the service provider. Nevertheless these documents and data also have to be controlled.

2.14. A document may be defined as 'information and its support media'. Documents may be organized in any relevant media used within the organization so long as an appropriate system of control is used.

2.15. The procedure that describes how documents are to be controlled within the organization should include a periodic review of valid documents to determine whether an update (revision) may be necessary.

2.16. The form and layout of the management system documentation should fit into the internal communication culture of the organization. See Ref. [4], paras 2.8–2.10, 5.12 and 5.13, and Ref. [5], paras 2.45–2.62, 5.24–5.28.

CONTROL OF RECORDS

2.17. No recommendations are necessary on meeting the requirements on the control of records. See Ref. [4], paras 5.21 and 5.22, and Ref. [5], paras 5.35–5.49.

3. MANAGEMENT RESPONSIBILITY

MANAGEMENT COMMITMENT

3.1. A ‘management commitment’ should be signed by senior management⁷ to acknowledge the management’s responsibility to establish a management system, to provide the necessary resources, to guarantee the review and revision of the system as necessary and to define the organizational policies (see Annex II) and objectives (see Annex III) that will govern the system. After it is issued, the management commitment document is brought to the awareness of staff. In this context, ‘necessary resources’ may include the staff, infrastructure, working environment, information, supplies and partnerships, natural resources and financial resources necessary to accomplish the objectives of the organization. See Ref. [4], paras 3.1–3.5, and Ref. [5], paras 3.1–3.7.

CUSTOMER SATISFACTION

3.2. For organizations providing technical services in radiation safety, interested parties (also known as stakeholders)⁸ are typically customers, staff, regulators, suppliers, the public and owners. Of these, customers are the most important, since the interests of the other interested parties can generally be satisfied by observing existing laws, rules and regulations.

⁷ ‘Senior management’ means the person who, or group of people which, directs, controls and assesses an organization at the highest level. Many different terms are used, including, for example: chief executive officer (CEO), director general, executive team, plant manager, top manager, chief regulator, managing director and laboratory director.

⁸ A stakeholder in this context is a person, group, company or other entity with an interest in the performance of an organization, business, system, etc. Those who can influence events may effectively become interested parties — whether their ‘interest’ is regarded as ‘genuine’ or not — in the sense that their views need to be considered. Interested parties have typically included the following: customers, owners, operators, employees, suppliers, partners, trade unions, the regulated industry or professionals; scientific bodies; governmental agencies or regulators (local, regional and national) whose responsibilities may cover nuclear energy; the media; the public (individuals, community groups and interest groups); and other States, especially neighbouring States that have entered into agreements providing for an exchange of information concerning possible transboundary impacts, or States involved in the export or import of certain technologies or materials.

3.3. A process should be established for identifying and documenting the requirements for fulfilling a contract for service. This should include the identification of:

- (a) Customer requirements;
- (b) Related statutory and regulatory requirements;
- (c) Organizational resources necessary;
- (d) Requirements for communication with the customer.

3.4. An example of a checklist to evaluate customers' needs in requests for contracts is provided in Annex IV.

3.5. The organization should ensure that customers' reactions are considered. Feedback, including both favourable and unfavourable reactions, should be collected and evaluated. To this end, the management should establish a monitoring process under the management system that is designed to assess and analyse all customer reactions so as to enable the organization to take actions designed to result in the continuous improvement of effectiveness.

3.6. The organization should have a procedure in place stating how it protects client confidentiality, while recognizing and acceding to any legal requests to advise regulatory bodies of any breach of a regulatory request or limit, such as exceeding personal dose limits. See Ref. [4], para. 3.6, and Ref. [5], paras 3.8 and 3.9.

ORGANIZATIONAL POLICIES

3.7. Typically, a service provider would only have one organizational policy. The policy should be simple (concise) and easily understandable for all members of the organization (staff).

3.8. The policy should include brief descriptions of actions designed to address such matters as:

- (a) Defining and maintaining the expected level of customer satisfaction;
- (b) Identifying opportunities and needs for continual improvement;
- (c) Ensuring commitment to provide the resources necessary to accomplish the task;

- (d) Ensuring contributions of suppliers and partners (confirming that suppliers and partners are capable of providing goods and services that meet the established quality standards);
- (e) Ensuring commitment to adopt professional good practices when providing services;
- (f) Making the commitment to ensure the competence (qualification) of the personnel involved in the execution of services;
- (g) Committing to meet the requirements of the relevant standards;
- (h) Ensuring safety, health, quality, environmental, security and economic aspects as appropriate.

3.9. Once established, the policy should be translated into measurable objectives. The achievement of these objectives should be checked during the management review. Equally, their adequacy for the existing management system should be evaluated during this review meeting. See Ref. [4], para. 3.7, and Ref. [5], paras 3.10–3.12.

PLANNING

3.10. A plan should be developed to provide the organization with a series of clearly defined objectives. This means that a series of goals or objectives should be established at different levels of the organization. These objectives should be established during the planning process, and they should be consistent with the organization's policy or policies. At the technical level, objectives should be quantifiable.

3.11. Information sources such as internal audit reports, process reviews and feedback from customers can all help in identifying appropriate objectives. As an example, an initial objective for a testing laboratory might be to provide a result to the customer that meets certain performance testing criteria. Over time, if the organization consistently demonstrates its ability to meet those criteria, other factors, such as improving customer satisfaction through shorter turnaround times for tests, might be made additional objectives. Thus, objectives are established after the consideration of many factors, including the current and future needs of the organization, the needs of the market served, and regulatory requirements.

3.12. To ensure that the planning process remains focused on the defined objectives, planning activities should be systematic and should be documented. Senior management has a responsibility to ensure that adequate resources are

provided to make it possible to meet the defined objectives. See Ref. [4], paras 3.8–3.11, and Ref. [5], paras 3.13–3.16.

RESPONSIBILITY AND AUTHORITY FOR THE MANAGEMENT SYSTEM

3.13. In an organization that provides services in radiation safety, it is often the case that the top manager appoints one person as management system manager to act on his or her behalf regardless of other duties. The management system manager should have appropriate experience in the tasks for which he or she is appointed and should have the authority, assigned in a written document, to do the following:

- (a) Develop and manage the management system, which includes performing activities designed to ensure compliance with relevant standards, harmonizing procedures and documents, reviewing operations, identifying and reporting any non-conformance⁹ to the management and/or conducting training in awareness of the management system for the staff;
- (b) Communicate on quality issues as may be required by the regulatory body and/or accreditation bodies;
- (c) Communicate directly with senior management at all times on issues relating to the management system;
- (d) Act as the focal point for problem reports regarding quality and suggestions for improvement;
- (e) Stop work that is not being performed according to established procedures.

3.14. An example of a duty list for a management system manager is provided in Annex V. See Ref. [4], paras 3.12–3.14, and Ref. [5], paras 3.17–3.20.

⁹ ‘Non-conformance’ means the non-fulfilment of a requirement.

4. RESOURCE MANAGEMENT

PROVISION OF RESOURCES

4.1. Resources are essential items needed for conducting processes. They include staff, equipment and supplies, information, physical facilities, infrastructure services, workplaces with appropriate conditions and monetary funds.

HUMAN RESOURCES

4.2. Human resources include all the people in the organization who are involved in achieving the objectives. Issues such as staffing levels, education, training, experience, qualifications and periodic performance reviews should all be taken into account when considering human resources.

INFRASTRUCTURE AND WORKING ENVIRONMENT

4.3. The infrastructure requirements of each process should be reviewed to identify the resources that will be required for the successful accomplishment of the stated objectives. For calibration and testing laboratories, where the workplace environment could influence the quality of the results, the regulatory body may impose additional requirements such as special authorities to be used for calibration services to ensure the correct certification and calibration of equipment.

4.4. The objective of the process to control monitoring and measuring devices is to establish an effective means of ensuring, with a high degree of confidence, that the data generated by these devices and used as the basis for reported results, conclusions and interpretations are accurate within prescribed requirements. Monitoring and measuring devices include the instruments, software and calibration standards used to perform measurements and surveys.

4.5. The process should confirm that these devices are suitable for the intended use, tested, calibrated and verified as functional within specified performance limits. Physical protection of the devices also needs to be provided, with the goal of eliminating the potential for process errors.

4.6. Software used to collect data, and to perform calculations on the data collected, should be validated before being put into use and should be protected against unauthorized modification. Its functionality should be re-verified following any change made to the computer's basic operating system or network control parameters, or any activity that could have an impact on the functionality of the application software. Consideration should be given to the need to retain (archive) the different software versions so as to be able to access older records generated by specific versions of the software.

4.7. Additional requirements established by other regulatory bodies may concern matters such as safety in the workplace and in associated facilities, protection of personal privacy and confidentiality of data, and backup of records kept in electronic media.

4.8. With regard to the working environment, consideration should be given to how best to combine the consideration of human factors and physical factors with achieving the goal of enhancing the performance of the organization. Attention to workload, stress factors, social structure within the organization, internal communication, workplace safety, ergonomics, lighting, ventilation and many other factors can all be combined to enhance the overall effectiveness of the organization in achieving its objectives. The organization should develop descriptions of minimum criteria for the workplace conditions necessary to achieve the various objectives. See Ref. [4], paras 4.1–4.5, and Ref. [5], paras 4.1–4.29.

5. PROCESS IMPLEMENTATION

DEVELOPING PROCESSES

5.1. The products of organizations providing technical services in radiation safety are those services themselves, which are delivered by using established processes. Development of new processes to supply new services should be carefully planned.

5.2. The management of the organization providing technical services should nominate a technical project leader to be in charge of the planning of new processes. It will be the task of the project leader to schedule the planning for the new process, by applying technical knowledge and experience together with

knowledge of the product requirements that is necessary to the technical service concerned.

5.3. In the planning schedule, account should also be taken of the need for planning for ensuring the traceability of measurement results to the SI system and for establishing information on uncertainties for these measurement results. See Ref. [4], paras 5.1–5.5, and Ref. [5], paras 5.1–5.9.

PROCESS MANAGEMENT

5.4. In an organization providing technical services in radiation safety, there are generally two types of processes:

- (a) Processes of the management system (administrative processes and key processes);
- (b) Processes to deliver the services and products of the organization (technical processes and core processes).

5.5. In monitoring the performance of its processes to ensure that the processes remain effective and that customer satisfaction is provided, a service organization should review the following:

- (a) Timeliness – reaction to the customer as influenced by the process structure;
- (b) Capability – amount of throughput for the process;
- (c) Efficiency – resources allocated to the process and the possibilities for their reduction.

5.6. Data can be derived from monitoring of different types during the operation of all ongoing processes. The data can be put to use as a basis for decisions within the organization, by means of adequate analysis. The application of statistical methods to raw data may be especially useful for determining trends in the performance of persons and instruments, by describing improvements or deteriorations. This may provide an opportunity for early action to prevent non-conformances.

5.7. The application of similar statistical techniques to the monitoring of customer satisfaction, resource economics and the performance of suppliers, among other things, may likewise be useful. See Ref. [4], paras 5.6–5.10, and Ref. [5], paras 5.10–5.23.

CONTROL OF PRODUCTS

5.8. In service-providing organizations for radiation safety, the product is generally controlled by controlling the production (i.e. service providing) process.

5.9. The processes of the organization should include any necessary measurements to ensure that the delivered product or service fulfils the requirements and expectations of the customer.

5.10. For consultancy services, these measurements could be:

- (a) Additional calculations using other algorithms;
- (b) Checks on data entry;
- (c) Comparison of the results with previous experience.

5.11. For measurement and calibration services these checks could be:

- (a) Repeated tests (possibly done using different instruments for analysis);
- (b) Checks on introduced blank or test samples;
- (c) Plausibility tests on the results, done by applying expert knowledge, etc.

The results of these measurements should be recorded as proof of the control of the production process.

5.12. The conformance of the product, or of parts of it, should be ensured by specifying the conditions for identification, storage, handling, protection and delivery.

5.13. Moreover, when a product can be fully verified only after delivery, each process that contributes to its production should be verified to specify acceptable and suitable criteria for the equipment and methods used and the qualification of the personnel involved. A list of parameters linked to the proper completion of each step is generally useful to keep the process exact and consistent. Verification usually requires the production of records, such as checklists, to be completed and evaluated for the final value to be assigned. In practice, the checklist can have the form of a record in a database file and the verification process can be established by means of a software routine.

5.14. If the creation of a product requires several steps, tracking of the product's status may be necessary, if required by regulation, to identify each

step's output. Generating a record such as a checklist confirming the completion of all necessary steps can be helpful.

5.15. Customers' property, including intellectual property, should be safeguarded throughout all the production processes. Customers' property, and methods to protect it, should be specified in advance. For example, only a limited number of persons should be permitted to access data provided by customers.

5.16. In the case of a consultancy for radiation protection, the customer's property could be detailed information about the customer's facilities, data on exposures or sources, or any method developed by the customer in relation to the service requested. Moreover, the service provided in relation to radiation protection becomes the property of the customer and information on it (i.e. reports on doses or calibrations) should be treated as confidential. See Ref. [4], paras 5.14–5.20, and Ref. [5], paras 5.29–5.33.

PURCHASING

5.17. No recommendations are necessary on meeting the requirements on purchasing. See Ref. [4], paras 5.23–5.25, and Ref. [5], paras 5.50 and 5.51.

COMMUNICATION

5.18. Communication in an organization providing services in radiation safety can be achieved by:

- (a) Organizing regular meetings of key personnel;
- (b) Using communication tools (electronic billboards, intranet, etc.);
- (c) Having similar methods of internal communication.

See Ref. [4], paras 5.26 and 5.27, and Ref. [5], paras 5.52–5.55.

MANAGING ORGANIZATIONAL CHANGE

5.19. Organizational changes in service-providing organizations rarely have a direct impact on safety. If they do, the guidance in Ref. [5] should be followed

to ensure that there is no adverse effect on product or service quality. See Ref. [4], paras 5.28 and 5.29, and Ref. [5], paras 5.56–5.71.

6. MEASUREMENT, ASSESSMENT AND IMPROVEMENT

MONITORING AND MEASUREMENT

6.1. For all phases in the development and operation of technical services, the technical service provider should define, plan and implement measurement and monitoring activities relating to the management system necessary to ensure conformance with applicable standards, laws and regulations and to achieve improvements. These activities should include determining the need for, and specifying the use of, applicable methods, including statistical techniques.

6.2. The general process of measurement, analysis and improvement includes the following:

- (a) Actions taken on an ongoing basis to monitor the overall effectiveness of the system, identifying areas, through appropriate metrics, where improvement may be appropriate.
- (b) Application of basic statistical methods (histograms, distributional analysis, mean values, etc.) to monitoring data on customer satisfaction, the performance of equipment, measurement throughput and similar indicators of the effectiveness of services provided to the customer.
- (c) Actions taken on a proactive basis to prevent non-conformances, to improve the system and to optimize the service to the client. The internal audit process, together with improvement activities, is part of these actions.
- (d) Actions taken on a reactive basis to correct non-conformance identified by, among other things, self-assessment, complaints by clients or recommendations of an internal or external audit.

See Ref. [4], para. 6.1, and Ref. [5], paras 6.1–6.5.

SELF-ASSESSMENT

6.3. Self-assessment is a tool used by those actually carrying out work to identify possibilities for improvement. If a service-providing organization wishes to adopt the practice of self-assessment, it should follow the guidance provided in Ref. [5]. See Ref. [4], para. 6.2, and Ref. [5], paras 6.6–6.21.

INDEPENDENT ASSESSMENT

6.4. Audits may be spread over the year or undertaken concurrently. Conducting internal audits on a progressive schedule has several advantages:

- (a) It helps to emphasize that the internal audit process is a continuous activity designed to improve the management system.
- (b) It helps to reduce the additional workload for individuals selected to conduct the audit.
- (c) It is useful in promptly identifying items of potential non-conformance and areas in which improvements may be appropriate.
- (d) It helps to monitor progress in accomplishing any corrective actions¹⁰ that may have been recommended in previous audits.

6.5. Ad hoc internal audits could be carried out following customers' complaints, repeated non-conformances or major changes in the organization.

6.6. The rotation of internal auditors through different aspects of technical applications within an organization can serve to increase job satisfaction by allowing employees to play an important role in maintaining the organization's management system.

6.7. It is common practice that an audit schedule encompasses all elements of the management system in all parts of the organization on an annual basis. The extent of the audit and the parts of the organization to be audited should be planned with consideration given to changes in staff or methods, workload,

¹⁰ A corrective action is an action to eliminate the cause of a detected non-conformance.

customer complaints, findings of previous audits and ongoing corrective or preventive actions.¹¹

6.8. Customers whose work may have been affected by problems identified during an audit should be notified in writing. For some findings, a formal system for corrective actions should be used; for others there may be simpler remedies.

6.9. If it is necessary to check the effectiveness of corrective actions quickly, a follow-up audit should be considered. Corrective measures undertaken should be analysed to evaluate their effectiveness. See Ref. [4], paras 6.3–6.6, and Ref. [5], paras 6.22–6.44.

MANAGEMENT SYSTEM REVIEW

6.10. In addition to the review inputs identified in Ref. [4], an organization providing services in radiation safety should consider the results of inter-laboratory comparisons or proficiency tests.

6.11. Decisions made during the management review and any actions arising from them should be recorded. The management review report should include details of:

- (a) The persons who were involved in the review;
- (b) Factors that were considered;
- (c) Decisions that were reached;
- (d) Actions that were planned, the persons responsible for the actions and the time schedules that were decided upon;
- (e) The provision for review and approval of the report.

6.12. Results should be incorporated into the laboratory planning system and should include the goals, objectives and action plans for the coming year. Management should ensure that planned actions are carried out within the agreed timescale and that their completion is documented. See Ref. [4], paras 6.7–6.10, and Ref. [5], paras 6.45–6.49.

¹¹ A preventive action is an action to eliminate the cause of a potential non-conformance.

NON-CONFORMANCES AND CORRECTIVE AND PREVENTIVE ACTIONS

6.13. For services in radiation safety, non-conformances could include:

- (a) Incorrectly entered raw data;
- (b) Data results obtained by applying incorrect algorithms;
- (c) Incorrect calibration data or factors;
- (d) Measurement results produced by using instruments outside of their application range;
- (e) Calibration data obtained by using the wrong irradiation conditions.

6.14. An analysis of the impacts of revealed non-conformances on safety should be performed, followed by the notification of management at the appropriate level.

6.15. A corrective action procedure is started after a complaint is made by, or feedback is received from, a customer, or upon the discovery of a non-conformance by staff or during an audit. Corrective actions should be appropriate to the magnitude of the problem and the associated risks.

6.16. A preventive action may have to follow a corrective action, or may be taken alone, during the development of new testing or management procedures or because of a decision taken during a management review. Preventive actions and corrective actions follow similar courses, the one prospective and the other retrospective. While preventive actions are intended to eliminate the risk that non-conformances occur at all, corrective actions apply to existing non-conformances.

6.17. A corrective action begins with an investigation to determine the cause(s) of a problem. Depending on the nature of the problem, this investigation may be informal or may be formal and extensive.

6.18. Some questions that should be considered when determining the root cause of a problem include:

- (a) Has the issue been validated as a problem?
- (b) Have the client's requirements changed?
- (c) Have the characteristics of the sample changed?
- (d) Are the methods and procedures for performing the task adequate?
- (e) Is there a need for additional staff training or development of skills?

- (f) Does the relevant equipment function properly?
- (g) Has the calibration of equipment been verified?
- (h) Have the specifications of consumable supplies used in support of the operation in question been changed?

6.19. Preventive action is a proactive process to identify opportunities for improvement rather than a response to the identification of problems or to complaints. Apart from the review of the operational procedures, the preventive action might involve the analysis of data, including trend analyses and risk analyses and the results of proficiency testing. The planning, development, implementation and monitoring of preventive actions will probably involve a pattern of activities similar to that for corrective actions, except that the activities are proactive in nature. See Ref. [4], paras 6.11–6.16, and Ref. [5], paras 6.50–6.77.

IMPROVEMENT OF SERVICES

6.20. The organization should always try to improve the services to the customer, and the internal processes necessary to arrive at the product. Correction of errors and prevention of losses are two ways to make improvements within an organization. See Ref. [4], paras 6.17 and 6.18, and Ref. [5], paras 6.78–6.84.

7. ADDITIONAL GUIDANCE FOR ORGANIZATIONS PROVIDING CALIBRATION OR TESTING SERVICES

ORGANIZATION

7.1. In some States, organizations providing calibration or testing¹² services seek accreditation by third parties to internationally recognized standards such as ISO 17025 [6]. The guidance provided here will help such organizations to develop a management system that could be accredited if there is a strong business case for pursuing accreditation.

¹² In some States the term ‘assay’ is used instead of ‘test’.

7.2. Special organizational requirements of ISO 17025 [6] for calibration and testing laboratories emphasize that it should be possible to hold the laboratory legally responsible for the services provided.

7.3. The organization should have a formal declaration as part of its management system to affirm that management and personnel are free from any undue internal or external commercial, financial or other pressures or influences that may adversely affect the quality of their work. In addition to being stated in the quality manual, this formal declaration might also be included in documents such as a separate policy statement, a clause in a labour contract or an employee handbook.

7.4. To be sure that tests and calibrations are performed according to established quality standards, laboratories have to provide for the adequate supervision of testing and calibration staff, including trainees, by persons familiar with methods and procedures, with the purpose of each test or calibration, and with the assessment of the results of tests or calibrations.

7.5. Laboratories should appoint deputies for key personnel, including the technical director and the quality manager, to provide continuity of qualified management even when primary individuals may be absent.

REVIEW OF REQUESTS, TENDERS AND CONTRACTS

7.6. When reviewing requests, tenders and contracts, laboratory personnel should ensure that the appropriate test or calibration method is selected and that it is capable of meeting the clients' requirements. The review of contracts should also extend to any work that is to be subcontracted by the laboratory.

SUBCONTRACTING OF TESTS AND CALIBRATIONS

7.7. For calibration and testing laboratories, subcontracting means placing work within the scope of its accreditation with a third party outside the immediate control of the primary contracting laboratory. It does not include, for example, contracting with a reference laboratory to provide intercomparison samples, contracting with an employment agency to provide supplementary support workers, or similar activities. Subcontractors should be required to demonstrate the same level of competence as is the accredited laboratory that is serving as prime contractor. This can be accomplished either

by the subcontractor holding an equivalent accreditation in its own right or by the prime contractor completing a quality system audit of the subcontractor's operation.

7.8. Laboratories proposing to subcontract tests and calibrations should inform the affected clients of the arrangements in writing and, as appropriate, gain the approval of the client, preferably in writing.

7.9. The laboratory is responsible to the client for the subcontractor's work, except in the case where the client or a regulatory body specifies which subcontractor is to be used. In the case of a deficiency or non-conformance attributable to a subcontractor, the laboratory has the same responsibility to notify its clients and to issue corrected reports as if the deficiency or non-conformance had occurred at its own facility.

7.10. The laboratory should maintain a register of all the subcontractors that it uses for tests or calibrations. The evidence should be recorded of how each subcontractor establishes its compliance with international standards (technical and managerial) applicable to the work in question.

SERVICE TO THE CLIENT

7.11. In addition to maintaining good communication with clients, laboratories may be required to allow clients to monitor their performance. This can be accomplished by allowing the client reasonable access to the laboratory for the purpose of witnessing tests or calibrations, by providing the client an opportunity to submit items for verification purposes, by using client feedback surveys or by other means.

7.12. All activities involving monitoring by clients should be conducted in a manner that preserves the confidentiality of the laboratory's relationship with other clients. Feedback from client monitoring should be documented and used to improve the management system.

CUSTOMER FEEDBACK

7.13. The laboratory should have a policy and procedure for the resolution of complaints received from clients or other parties. Records should be

maintained of all complaints and of the investigations and corrective actions undertaken by the laboratory.

CONTROL OF RECORDS

7.14. With regard to technical records, the laboratory should retain the records of original observations, derived data and sufficient information to establish an audit trail, calibration records, and a copy of each test report or calibration certificate issued for a defined period. The records for each test or calibration should include sufficient information to facilitate, if necessary, the identification of factors affecting uncertainty and to enable the test or calibration to be repeated under conditions as close as possible to the original conditions. The records should include the identity of personnel responsible for sampling, performing each test or calibration, and checking results.

7.15. In certain fields, it may be impossible or impractical to retain records of all original observations.

7.16. Technical records are accumulations of data and information that result from carrying out tests or calibrations and which indicate whether specified values for quality or process parameters were achieved. They may include forms, contracts, worksheets, workbooks, checklists, work notes, control graphs, external and internal test reports and calibration certificates, clients' notes, papers and information from feedback. Observations, data and calculations should be recorded at the time that they are made and it should be possible to link them to the specific task concerned.

7.17. Each mistake that occurs in records should be crossed out (not erased, made illegible or deleted), and the correct value should be entered alongside it. All such alterations to records should be signed or initialled by the person making the correction. In the case of records stored electronically, equivalent measures should be taken to avoid the loss of, or changes to, original data.

INTERNAL AUDIT

7.18. The internal audit programme should address all the elements of the management system, including testing or calibration activities.

7.19. When audit findings cast doubt on the effectiveness of the operations or on the correctness or validity of the laboratory's test or calibration results, the laboratory should take timely corrective action, and it should notify clients in writing if investigations show that the laboratory results may have been affected.

INFRASTRUCTURE: LABORATORY FACILITIES

7.20. Management has to provide adequate laboratory facilities to perform all processes under consistent and familiar conditions. Management has to ensure the following:

- (a) That technical standards and requirements are fulfilled (facilities, computers, programs);
- (b) That adequate technical documentation is available (handbooks, tables, manuals);
- (c) That necessary environmental conditions (which may influence results) are well known, correctly upheld, documented, monitored and recorded (thresholds and the assignment of responsibility for stopping a task should be specified);
- (d) That access to the facilities is restricted and monitored;
- (e) That procedures for good housekeeping have been specified and documented;
- (f) That work in one room should not disturb the process in an adjoining room.

TEST AND CALIBRATION METHODS AND VALIDATION OF METHODS

7.21. Each measurement method should be well documented in a procedure that describes the task step by step, if this is deemed necessary. The management should ensure that staff are using an up to date method and that they carry out their daily work guided by these documented methods. The selected method should be well known (in terms of its accuracy, correctness, repeatability, reproducibility, robustness, etc.), and the range of uncertainties in measurements should be known and should be shown on the measurement report. Each measurement method should be validated in accordance with the laboratory's procedure for validation.

7.22. Consideration should be given as appropriate to these points in following the above recommendations:

- (a) Methods should be planned methodically and documented in a form suitable to the working style of the laboratory.
- (b) The documentation should describe the method of measurement on a step by step basis, as appropriate, and should include guidance on how to keep the necessary records.
- (c) As a first method of validation, the newly developed method of measurement should be tested using different parameters, and the results should be documented and assessed.
- (d) An additional step of validation providing a 'go/no go' decision could be incorporated into the method.
- (e) The actions to be taken when a deviation (error) occurs (i.e. who has to do what and when) should be determined.
- (f) The data flow of measurement results (who needs what information, when and in which form, and how the backup of data can be ensured) should be organized.

TEST AND CALIBRATION EQUIPMENT

7.23. The laboratory should possess adequate equipment to perform the necessary services to the customer, including sampling, sample preparation, measurement or calibration, calculations and reporting. The equipment necessary to produce the measurement results should be functional and should be able to be used for day to day measurements.

7.24. The following activities may help to ascertain that the relevant requirements of Ref. [4] are fulfilled:

- (a) Periodic and documented calibrations should be performed to guarantee correct measurement results.
- (b) Periodic and documented functional tests should be performed between the calibration times to test the correct functioning of the equipment.
- (c) All maintenance work provided for by the equipment manufacturer should be done and should be documented in an equipment file.
- (d) Training and periodic retraining of every equipment operator should be completed to ensure that the staff are familiar with the equipment.

7.25. All equipment and self-designed software should be clearly identified. This may be accomplished through documentation that is sufficient to enable the validation of software and the proper setting up of equipment.

7.26. Checks on outgoing and incoming equipment should be performed if a piece of equipment is used outside the laboratory.

7.27. All calculations, including those performed using commercial off-the-shelf software (e.g. for spreadsheets) in respect of the equipment, should be documented and validated.

MEASUREMENT TRACEABILITY

7.28. To be sure that the measurement results will comply with international standards, each measurement device that has an influence on the results should be calibrated before being put into service and at defined intervals afterwards. The standards used for these calibrations should be traceable to the International System of Units (SI). In some cases — e.g. in connection with ^{222}Rn — the only means of providing confidence in measurements is through participation in suitable international intercomparison exercises.

7.29. Calibration services have to trace their standards and measuring instruments to the SI System by means of an unbroken chain of calibrations or comparisons linking them to relevant primary standards for the SI units of measurement. For measurement services, this traceability can be achieved by using a calibration service.

7.30. To keep a calibration service or measurement service operational, it may be helpful to do the following:

- (a) Organize information on all calibration standards used into a database file, giving:
 - (i) Calibration data;
 - (ii) Serial numbers of units calibrated;
 - (iii) Date of last and next calibrations;
 - (iv) Location and name of the tester.
- (b) Store all calibration procedures and their outcome, the calibration certificates, in the laboratory.
- (c) Support periodic calibration with a time schedule programme.

- (d) Keep calibrated spare parts available for important devices to shorten the down time in case of a malfunction.

SAMPLING

7.31. If a testing laboratory also performs sampling, it should do so according to accepted standards or documented procedures. If a subcontractor or a customer performs sampling, it should be ensured that the same restrictions and conditions apply as for the laboratory.

7.32. Consideration should be given, as appropriate, to the following points in implementing a procedure for sampling:

- (a) The requirements of relevant standards and those of customers (in relation to the sampling location, sampling time, name of the person responsible for sampling, technical conditions, etc.) should be addressed.
- (b) Any possible negative influence on the samples during sampling, transport of samples, handling, storage and analysis should be avoided.
- (c) Procedures should be well documented and they should, as appropriate, use statistical methods as a basis for providing well identified samples and sample data for the measurement process.
- (d) Information should be given to the customer if the sampling process reveals problems or errors, or in the event that the sampling was performed incorrectly.

HANDLING OF ITEMS FOR TESTING AND CALIBRATION

7.33. Test and calibration items should be handled with extreme care to maintain their identity. The item and its description should never be separated. The laboratory should have a procedure in place that provides:

- (a) Identification and labelling of incoming test and calibration items;
- (b) Reporting of any abnormalities found for the items handled;
- (c) Instructions for handling, storage and transport, and on the necessary environmental conditions to be maintained for the testing or calibration items;
- (d) Instructions on the return of the items to the customer or any kind of approved disposal routine.

ENSURING THE QUALITY OF TEST AND CALIBRATION RESULTS

7.34. The laboratory needs to have a process and procedure in place to ensure continuous control of the quality of the services rendered to the customer.

7.35. When designing such a process and procedure, consideration should be given, as appropriate, to:

- (a) Using only certified (reference) materials for calibration purposes and internal quality control;
- (b) Carrying out all measurements and calibrations in accordance with the applicable documentation;
- (c) Participating in interlaboratory comparison exercises or proficiency testing programmes;
- (d) Replicating tests or calibrations using the same or different methods;
- (e) Retesting or recalibration of retained items;
- (f) Correlation of results for different characteristics of an item;
- (g) Using statistical methods, such as control charts, to determine the quality of calibration results over a longer time period so as to identify possible trends in the degradation of instruments.

REPORTING OF RESULTS

7.36. Results should be reported to the customer accurately and in a comprehensible way so as to fulfil the requirements of the regulatory bodies and to meet the customers' needs.

7.37. The laboratory should devise a layout for its reports in which recognition is given to:

- (a) The requirements of regulatory bodies;
- (b) The requirements of the relevant standards;
- (c) The internal rules for reporting within the organization.

Care should be taken to clearly designate data coming from a subcontractor. The laboratory should have a procedure in place for changing reports in the event that errors are detected in the original version. All reports issued should be considered to be records and should be treated accordingly.

Appendix

GENERAL GUIDANCE ON ESTABLISHING A MANAGEMENT SYSTEM

A.1. This appendix provides a method for establishing a management system in an organization in which there is no established management system.

INTRODUCTION

A.2. A management system consists of a set of interrelated or interacting elements. It is designed to establish the overall intentions and direction of an organization in relation to the ability of a product, system or service to fulfil the requirements of customers and other interested parties (see Fig. A.1).

A.3. A process approach is encouraged for developing the management system. In this context, any activity that receives inputs and converts them to outputs can be considered a process. For organizations to function effectively, they have to identify and manage numerous linked processes. Often the output from one process will be the direct input into the next process. The systematic identification and management of the processes applied within an organization and the interactions between such processes may be referred to as the process approach.

A.4. Reference [5], paras I.1–I.2, provides a conceptual illustration of one model of the process approach. In a service provider organization it should be reflected in the model that customers play a significant role in defining requirements for inputs. The satisfaction of customers should be monitored to evaluate and validate whether customers' requirements have been met.

REQUIREMENTS OF RELEVANT STANDARDS

A.5. A management system should enable an organization:

- (a) To demonstrate its ability to deliver a product that consistently meets the customers' requirements and applicable regulatory requirements;
- (b) To achieve customer satisfaction through effective application of the system, including processes for continual improvement and for the prevention of non-conformances.

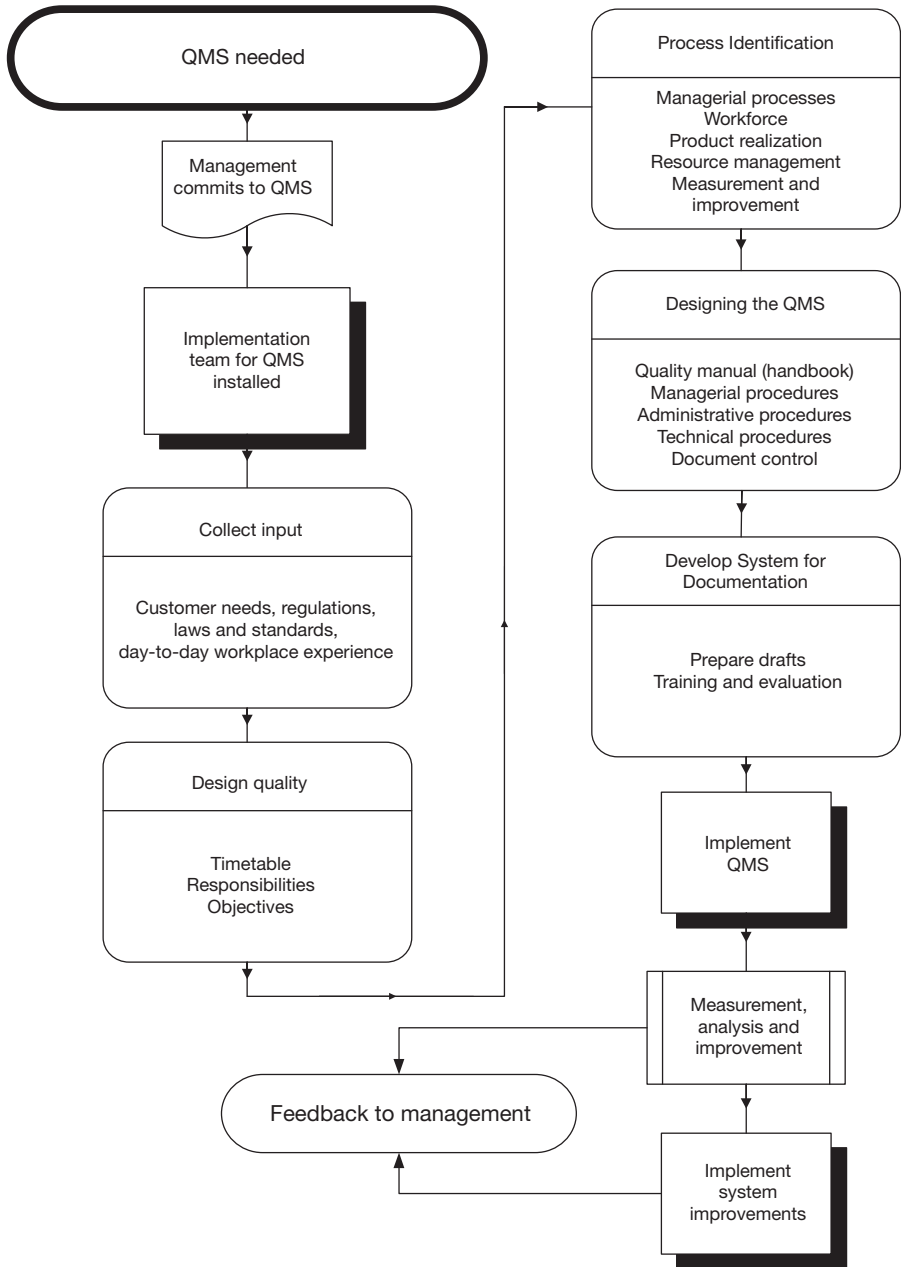


FIG. A.1. Flowchart for establishing a management system, in this case a quality management system (QMS).

A.6. The organization should establish, document, implement, maintain and continually improve a management system in accordance with the requirements of relevant international standards [4] and the recommendations of this Safety Guide.

A.7. The steps that should be taken by an organization to implement a management system include:

- (a) Identifying the processes necessary for the management system;
- (b) Determining the sequence and interactions of these processes;
- (c) Determining criteria and methods necessary to ensure the effective operation and control of these processes;
- (d) Ensuring the availability of the information necessary to support the operation and monitoring of these processes;
- (e) Measuring, monitoring and analysing these processes and implementing the actions necessary to achieve the planned results and to bring about continual improvement.

IMPLEMENTATION PROCESS

A.8. The implementation of a management system in an operating organization starts with a decision by the senior management. There may be different external and internal factors that could convince the senior management of the need for such a system. Examples are:

- (a) External factors such as demands by customers or State authorities or regulatory bodies, or new information obtained at a peer meeting or conference;
- (b) Internal factors such as demand by internal customers, cost-effectiveness analysis, or the need to restructure the organization owing to major changes in the focus of work or the workforce.

MANAGEMENT COMMITMENT

A.9. After arriving at the decision to implement a management system, the senior management should demonstrate its commitment to the project by:

- (a) Appointing one of its members as the person responsible for the project;
- (b) Providing adequate funds;

- (c) Establishing an information policy to ensure that the decisions on implementation of the project and the necessary actions are transparent to both the senior management and the staff.

A.10. This commitment should be communicated to the entire organization (by issuing a policy statement on quality and preliminary quality objectives and goals) and demonstrated throughout the entire process of implementing the management system (by active participation in review meetings).

APPOINTING AN IMPLEMENTATION TEAM

A.11. The next step is to appoint a task force (implementation team) under the supervision of the appointed member of the senior management. Here, the assistance of external experts might be requested, either as leaders of the task force or as advisory members.

A.12. Each member of the task force should have good knowledge and experience or should receive training, as appropriate, in at least one of the following fields:

- (a) Structure and workload of the organization;
- (b) Relevant standards, laws and regulations;
- (c) Internal processes and procedures of the organization;
- (d) Methods of communicating effectively within the company;
- (e) Team organization and teamwork.

The team should have an appointed leader who, in the course of the implementation of the management system, may become the quality manager of the organization.

PLANNING THE IMPLEMENTATION

A.13. The first task of the implementation team should be to evaluate the workload that will be necessary to reach the goal of an implemented management system. This information may already be available within the organization or it may be gathered by means of a newly organized initiative of the implementation team.

Means of gathering this information may include:

- (a) Conducting a survey of laws, regulations and standards (in addition to the management system standards [4, 5]) applicable to the product portfolio of the organization;
- (b) Collecting details of customer needs as expressed to representatives of the organization;
- (c) Reviewing the day to day work schedule of the organization by means of direct contact with the staff;
- (d) Conducting a survey and count of all processes already in operation in the organization.

A.14. Such a survey may be the first opportunity to motivate all the personnel of an organization to participate actively in the implementation of the management system.

A.15. A preliminary timetable should be established for tracking progress in developing the management system. Depending on the size of the organization and the complexity of the task, this timetable could extend over a period ranging from several months to a year or more.

A.16. The implementation team should devise a quality plan for the implementation of the system, using the information gathered by means of the aforementioned or other methods. This plan should include:

- (a) A representation of the workload, divided into work packages;
- (b) A timetable for the completion of the different work packages;
- (c) A person responsible for each of the different work packages;
- (d) A reporting schedule for providing information to the responsible manager;
- (e) A system of quality reviews to ensure the smooth performance of the plan.

IDENTIFYING EXISTING PROCESSES

A.17. To provide an overview, the existing processes should be grouped into four categories according to the action they are describe:

- (a) Management processes;
- (b) Resource management processes;

- (c) Product realization processes;
- (d) Measurement, analysis and improvement processes.

A.18. In the identification of the processes, their interconnections should be identified in order to arrive at a process correlation diagram. This is a diagram that shows, in graphical form, how a change in one process may influence other processes and where there may be some gaps in the flow. These gaps will have to be filled by designing new processes.

A.19. The proper design of a management system requires knowledge of all existing processes and the development of a number of new ones. The best way to organize the management system depends on the organization of the laboratory providing the services.

DEFINING DOCUMENT STRUCTURE

A.20. The implementation team should define the structure of the ensuing documents to help the authors to develop their documentation. The quality manual, which contains the entire documentation of the management system, may be organized in different ways.

A.21. The quality manual may be one large manual containing all necessary statements, procedures and working instructions.

A.22. Another possibility is to create a centralized quality management document that contains the basic information about the organization and the principal commitment statements by senior management, and to supplement this with annexes containing the technical information necessary to perform the described tasks, which may be tailored to different branches of the organization.

WRITING PROCEDURES

A.23. A protocol or procedure should be written to define the process to be followed for writing, reviewing, approving and revising procedures and establishing their general format.

A.24. With this protocol or procedure in place, the search for authors should be initiated. To ensure the acceptance of the management system by all

members of the staff, as many of the staff as possible should be included in the authoring process. The implementation team should devise the procedures in relation to such central themes as the management system itself, document control and the assessment process. The assistance of, and authorship by, those people currently doing specific jobs should be solicited throughout the process of developing the management system, in particular for the technical procedures. Wherever necessary, the members of the implementation team should provide assistance in editing the process descriptions and procedures owing to their better training in the contents of standards and regulations.

A.25. All drafted procedures should be reviewed and compared by the implementation team; that is, checked against each other, against the management directives and against relevant international standards to ensure the conformance and integrity of the quality documentation. This process should include all necessary new procedures, changes to existing procedures, their authorization and their inclusion in the quality manual.

INITIAL TRAINING

A.26. In this way, the organization will arrive at a first version of the quality manual. This does not need to contain all the planned procedures, but may be used to train the personnel in the application of newly developed or revised procedures.

A.27. Members of the implementation team, together with managers of the organization, should supervise this training in the application of the management system to show the permanent commitment of management to the ideas of quality management.

IMPLEMENTATION, FIRST INTERNAL AUDIT AND MANAGEMENT REVIEW

A.28. After the training period, which in itself may reveal an additional need to revise the documentation, the management system may be implemented for an initial testing period, typically a pilot project lasting three to six months. The first assessment of the management system and the first internal audit followed by the first management review should be scheduled at the end of this period.

A.29. The outcome of these two evaluation processes will show whether additional adaptation of the documentation is still necessary. When these changes have been made, the management system will be ready for final implementation and continual improvement.

A.30. Senior management, with the assistance of the implementation team, should revise the quality policy and the quality objectives, which should be based on this policy and should be quantitative, at least at operational levels. These quality objectives may change over time, reflecting changes in the needs and priorities of the organization.

A.31. Finally, senior management should establish ways of assessing the performance of the organization by defining performance indicators (and the way these indicators should be derived on the basis of existing data) for quality related processes and the way of conducting the overall assessment of the management system through a management review.

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Annex I

CHECKLIST FOR JOB DESCRIPTIONS

I-1. The following is a checklist for job descriptions for professional posts in a testing laboratory:

CHECKLIST FOR JOB DESCRIPTIONS FOR PROFESSIONAL POSTS

- State the functional title and current grade of the post.
- Name the incumbent’s supervisor.
- State the main purposes (objectives) of the post (overall role and functions of the post with emphasis on the more important aspects).
- Summarize the major duties and responsibilities of the job in order of importance and indicate the percentage of time spent on each (most jobs have no more than five or six major responsibilities). First state what is done, then how it is done.
- Describe the minimum knowledge requirements for the job.
- State the level and field of study of the university degree (or the equivalent acquired through training or self-study).
- State the minimum length and type of practical experience required:
 - (a) At the national level;
 - (b) At the international level.
- State any language(s) required, or preferred, and the level of proficiency necessary.
- Detail the working role with information on what the job requires the incumbent to do (i.e. describe the analysis, interpretation, adaptation, innovation, planning, coordination and directing that the job requires).
- Describe the control exercised or guidance given by the supervisor in terms of planning, controlling and reviewing the incumbent’s work, e.g. how often they meet, how priorities are handled, how instructions are given.
- Indicate which regulations, manuals, precedents, policies or other administrative and technical guidelines apply to the incumbent’s work, and to what extent the incumbent is permitted to interpret or deviate from them or to establish new guidelines.
- State with whom (indicate functional title only), for what purpose and how often the incumbent is required to have contacts in the job. Describe the most typical, not the most unusual, contacts.

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- Describe the most important type(s) of decisions that the incumbent is authorized to take and state why these are important.
- Describe the most important types of proposals expected of the incumbent in the job and state why these are important.
- Describe the most damaging involuntary error(s) that could be made in the work and the effect(s) that could result.
- State the total number of staff in organizational units supervised by the incumbent. (Note: ‘supervised’ means ‘held accountable for the work’.)

Annex II

MANAGEMENT POLICY

II-1. This annex presents an example of management policy for a testing and calibration laboratory.

MANAGEMENT POLICY OF OUR ORGANIZATION

We are fully committed to meeting or exceeding our customers' expectations, and to achieving our objective of being a preferred supplier. We believe that quality in services provided consists of being on time and in conformance with customers' requirements. We believe in the effective provision of services to our customers ('doing it right the first time').

To meet the requirements of our customers, our organization applies well established good professional practices to all services and has developed a management system based on ISO 9001 and ISO/IEC 17025, which applies to all operational services. The aim of this management system is to ensure the highest quality of services to our customers.

Management commits itself, in the course of its own work, to complying with the management system that it has endorsed and to continually improving the quality of operations.

All staff members of our organization are familiar with the management system and it is their responsibility to ensure full compliance with this system. To support staff in this endeavour, the management commits itself to identifying and meeting present and anticipated training needs to increase the competence of all personnel involved in providing our services.

As a company, we are committed to continual improvement in the quality of all our services. We are also committed to continual improvement and enhancement of the relationships with our customers and others (shareholders, employees, suppliers, partners and the public).

Meeting these commitments requires management and employees to work together as a team, to establish objectives to support this commitment by management, and to continually review performance towards these objectives.

Annex III

MANAGEMENT OBJECTIVES

III-1. This annex presents examples of management objectives for a testing and calibration laboratory.

This example is valid for an organization during the implementation of a management system.

MANAGEMENT OBJECTIVES OF OUR ORGANIZATION

- (a) Supplying our customers with reliable and consistent services, and to this end implementing a management system that complies with the international standards ISO 9001 and ISO/IEC 17025;
- (b) Operating our advisory groups and laboratories under full implementation of this management system;
- (c) Acquiring accreditation for all services rendered by our laboratories.

III-2. For an organization running a well established management system, the management objectives may look different as a result of management reviews already performed, in which management objectives have been adapted:

MANAGEMENT OBJECTIVES OF OUR ORGANIZATION

- (a) Endeavouring, at all times, to maximize customers' satisfaction with the services provided;
- (b) Promoting good relationships with customers and suppliers by fulfilling customers' needs by providing the necessary service, delivered on time;
- (c) Continually improving quality and productivity and by this means obtaining and maintaining market leadership;
- (d) Promoting, developing and improving the skills of our staff at all levels to enhance quality awareness and to maintain a highly motivated and competitive team;
- (e) Maintaining the high standard of our management system by means of regular audits and reviews.

Annex IV

CHECKLIST FOR EVALUATING REQUESTS FOR CONTRACTS

This checklist can be used to evaluate the capability of a laboratory to fulfil new requests for a service or product from potential customers.

- | | | | |
|---|------------------------------|-----------------------------|------------------------------|
| Are the requirements of the request well defined? | yes <input type="checkbox"/> | no <input type="checkbox"/> | n/a <input type="checkbox"/> |
| Do we have a validated, documented and authorized method of delivering the service (test, intercomparison, training)? | yes <input type="checkbox"/> | no <input type="checkbox"/> | n/a <input type="checkbox"/> |
| Does the method achieve the necessary level of accuracy and precision (limits of uncertainty)? | yes <input type="checkbox"/> | no <input type="checkbox"/> | n/a <input type="checkbox"/> |
| Does the method reach the necessary limits of detection according to the customer's requirements? | yes <input type="checkbox"/> | no <input type="checkbox"/> | n/a <input type="checkbox"/> |
| Is the necessary equipment available within the timeframe of the request? | yes <input type="checkbox"/> | no <input type="checkbox"/> | n/a <input type="checkbox"/> |
| Do we have a valid calibration for the equipment? | yes <input type="checkbox"/> | no <input type="checkbox"/> | n/a <input type="checkbox"/> |
| Do we have time to perform a calibration? | yes <input type="checkbox"/> | no <input type="checkbox"/> | n/a <input type="checkbox"/> |
| Do we have the standards to perform a calibration? | yes <input type="checkbox"/> | no <input type="checkbox"/> | n/a <input type="checkbox"/> |
| Is a technician available to perform the calibration in time? | yes <input type="checkbox"/> | no <input type="checkbox"/> | n/a <input type="checkbox"/> |
| Are all the necessary supplies available? | yes <input type="checkbox"/> | no <input type="checkbox"/> | n/a <input type="checkbox"/> |
| Do we have time to purchase them? | yes <input type="checkbox"/> | no <input type="checkbox"/> | n/a <input type="checkbox"/> |
| Do we have funding to purchase them? | yes <input type="checkbox"/> | no <input type="checkbox"/> | n/a <input type="checkbox"/> |
| Is a technician available to perform the work within the customers' timeframe? | yes <input type="checkbox"/> | no <input type="checkbox"/> | n/a <input type="checkbox"/> |
| Is this technician experienced in the work to be done? | yes <input type="checkbox"/> | no <input type="checkbox"/> | n/a <input type="checkbox"/> |
| Can the available technician be trained in time? | yes <input type="checkbox"/> | no <input type="checkbox"/> | n/a <input type="checkbox"/> |

For a request to be approved, 'NO' is an acceptable answer for a main question provided that it is compensated for by a 'YES' in answer to all the subsidiary questions.

Date: _____ Name: _____ Signature: _____

Annex V

DUTIES OF THE MANAGEMENT SYSTEM MANAGER

V-1. This annex provides an example of the typical duties of a management system manager. These duties may differ from organization to organization depending on the organization's size and the nature of its activities and structure.

MANAGEMENT SYSTEM MANUAL

- (a) To coordinate the establishment of the management system, including its maintenance and improvement;
- (b) To ensure compliance of the documents in the management system with the relevant standards;
- (c) To keep all records (e.g. internal and external audit reports, management policy, goals of the management system, protocols of management reviews, reports of non-compliance, equipment lists) originating in the management system, if not otherwise stated in a procedure;
- (d) To organize and supervise the management system audits, to write an annual report on the management system and to organize the management review;
- (e) To provide training and assistance in management system matters to all staff;
- (f) To report on any non-compliance with the established procedures in the work of the organization.

DOCUMENT CONTROL

- (a) To keep the documentation of the management system in compliance with the relevant standards;
- (b) To update the list of internal and external management system documents in force;
- (c) To archive one copy of all distributed versions of management system documents;
- (d) To distribute management system documentation to all staff members;
- (e) To perform a review of the status of the management system documentation every two years.

REQUESTS AND CONTRACTS

To keep the records of denied requests for further evaluation.

SUBCONTRACTING

- (a) To keep the records of subcontractor evaluations;
- (b) To keep a list of competent subcontractors used by the testing laboratory.

PURCHASING SERVICES AND SUPPLIES

- (a) To validate the acceptability of documents of compliance received from suppliers;
- (b) To keep a list of acceptable suppliers.

SERVICE TO CUSTOMERS

- (a) To keep a list of customers' visits to the laboratory;
- (b) To keep records of customers' feedback;
- (c) To help gather feedback from customers at regular (annual) intervals.

COMPLAINTS

To keep the records ensuing from complaints.

CONTROL OF NON-CONFORMANCES

- (a) To keep records of non-conformances;
- (b) To assist in processing the procedure for corrective actions.

CORRECTIVE AND PREVENTIVE ACTIONS

To keep the records ensuing from corrective and preventive actions.

CONTROL OF RECORDS

As author of a procedure:

- (a) To identify necessary records to be controlled;
- (b) To propose a record keeper;
- (c) To define how records are to be stored (optional).

As nominated record keeper (nominated in a procedure):

- (a) To collect, file and store records;
- (b) To maintain the legibility of records;
- (c) To facilitate access to the records for authorized persons;
- (d) To decide how to dispose of managerial records when the period of storage has expired.

INTERNAL AUDITS

- (a) To plan audits at the prescribed intervals;
- (b) To select, train and appoint the auditor(s);
- (c) To prepare an audit questionnaire;
- (d) To confirm that the audit has been successfully completed;
- (e) To collect the individual audit reports.

Acting as auditor:

- (a) To be informed about the scope of the audit;
- (b) To read and check the relevant management system documentation;
- (c) To adapt, if deemed necessary, the audit questionnaire;
- (d) To adhere strictly to the scope and timeframe of the audit;
- (e) To record audit questions and answers and controlled documentation;
- (f) To prepare an audit report.

MANAGEMENT REVIEW

- (a) To prepare all necessary input documents;
- (b) To document the results of the review.

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