

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.

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.

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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.