

Safety Reports Series

No. 69

Management System Standards: Comparison between IAEA GS-R-3 and ISO 9001:2008



IAEA

International Atomic Energy Agency

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MANAGEMENT SYSTEM STANDARDS:
COMPARISON BETWEEN
IAEA GS-R-3 AND ISO 9001:2008

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SAFETY REPORTS SERIES No. 69

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STANDARDS:
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INTERNATIONAL ATOMIC ENERGY AGENCY
VIENNA, 2012

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FOREWORD

IAEA safety standards reflect an international consensus on what constitutes a high level of safety for protecting people and the environment. They often serve as safety regulatory documents. In practice, to be fully effective the IAEA safety standards need to be complemented by industry standards and must be implemented within an appropriate national regulatory infrastructure. The IAEA produces a wide range of technical publications and reports to help Member States in developing this national infrastructure and the associated standards. Regarding management systems and integrated management systems, IAEA Safety Standards Series No. GS-R-3, The Management System for Facilities and Activities (IAEA GS-R-3), defines the requirements for establishing, implementing, assessing and continually improving a management system. IAEA GS-R-3, together with its supporting Safety Guides, supersedes Safety Series No. 50-C/SG-Q, Quality Assurance for Safety in Nuclear Power Plants and other Nuclear Installations.

IAEA GS-R-3 establishes management system requirements for nuclear facilities and activities for operating organizations, but also for other interested parties, such as regulatory bodies, suppliers and customers.

Where International Organization for Standardization (ISO) and other standards are used, an appropriate and adequate safety management system can be achieved by imposing additional requirements on an organization, over and above those contained within the ISO 9001:2008 standard on Quality Management Systems.

Differences between IAEA GS-R-3 and ISO 9001:2008 exist, as the objectives, approaches and perspectives adopted in developing the requirements in each standard are different. IAEA GS-R-3 requires that health, environmental, security, quality and economic requirements be considered in conjunction with safety requirements, to help preclude possible negative impacts on safety. The approach used in the ISO standards is to develop requirements specific to a given area (e.g. quality management or environmental management) and leave it to an organization to select and use the set of ISO standards relevant to its areas of operation. Comparing the requirements of one such standard with those of an integrated management system standard will reveal inherent differences between them.

The IAEA has provided guidance to support practical measures for achieving safety when ISO 9001:2008 is used in nuclear installations. The publication Quality Standards: Comparison between IAEA 50-C/SG-Q and ISO 9001:2000, Safety Reports Series No. 22, was published in 2002 to update IAEA-TECDOC-1182, Quality Assurance Standards: Comparison between IAEA 50-C/SG-Q and ISO 9001:1994. After the publication of IAEA GS-R-3,

prescribing the new IAEA management system requirements, there was a need to update the comparison of IAEA and ISO management system standards. The result is presented in this publication, which provides information and guidance that may be considered when ISO 9001:2008 is used by the nuclear industry.

In this publication, 'should' statements are used to provide guidance based on expert judgement; they do not stem from a consensus of IAEA Member States. The guidance provided does not relieve the users of their responsibility to comply with the requirements of the standards.

The IAEA wishes to thank all of the contributors to this Safety Report, especially the members of the FORATOM Management System Task Force, M. Hille (Germany) and J. Majola (Canada), for their efforts and valuable assistance. The IAEA officers responsible for this publication were P. Vincze, C.R. Clark and J.P. Boogaard of the Division of Nuclear Power, and C. Viktorsson of the Division of the Nuclear Safety of Nuclear Installations.

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1. INTRODUCTION

1.1. BACKGROUND

The IAEA Safety Requirements publication on The Management System for Facilities and Activities, IAEA Safety Standards Series No. GS-R-3 [1] (IAEA GS-R-3), defines the requirements for establishing, implementing, assessing and continually improving a management system for facilities and activities that integrates safety, health, environmental, security, quality and economic elements. The IAEA Safety Guides on the Application of the Management System for Facilities and Activities [2] and on The Management System for Nuclear Installations [3], as well as other IAEA Safety Guides specific to technical areas, provide recommendations on how to fulfil the requirements specified in IAEA GS-R-3.

The management systems of operators or organizations that provide nuclear items or products and services must comply with safety requirements, including those prescribed in IAEA safety standards (e.g. IAEA GS-R-3) that are adopted by Member States. The utility or the owner/operator of a nuclear facility or installation has the ultimate responsibility to ensure that the management system implemented provides for an adequate level of safety. IAEA GS-R-3 helps an organization to put in place a management system that fosters a strong safety culture and improves safety performance.

In the conduct of their operations, organizations often use other standards in their interfaces with suppliers and other interested parties. Organizations conducting nuclear activities and nuclear facilities frequently use the International Organization for Standardization (ISO) 9001:2008 standard on Quality Management Systems — Requirements [4] at the interface between the nuclear facility owner/operator and suppliers. ISO 9001:2008 cancels and replaces ISO 9001:2000, which was amended to clarify points in the text and to enhance compatibility with the ISO 14001:2004 standard on Environmental Management Systems — Requirements with Guidance for Use [5].

Having a management system that complies with ISO 9001:2008 allows an organization to demonstrate its ability to meet customer and applicable regulatory requirements, in addition to its own organizational requirements. The IAEA safety standards need to be complemented by industry standards to address specific technical and regulatory requirements. The standards developed by the ISO are complementary technical documents that emphasize industrial application and contractual aspects.

ISO 9001:2008 [4] is often used as a complementary standard for defining the quality management system requirements at the interface between the nuclear

installation owner/operator and the supplier/contractor. ISO 14001:2004 [5] is often used as a complementary standard for defining the environmental management system, to comply with legal and regulatory environmental requirements. Also, some organizations use requirements from ISO 14001:2004 and other complementary standards and specifications¹ to integrate environmental aspects into their ISO 9001:2008 based management system.

Recognizing that the IAEA safety standards often need to be complemented by industry standards for practical effect, IAEA GS-R-3 was developed taking into account international standards such as those of the ISO as well as the experience of Member States in developing, implementing and improving management systems. Consequently, there are similarities between the requirements in IAEA GS-R-3 (which integrates safety, health, environmental, security, quality and economic elements) and those in ISO 9001:2008. However, there are differences between them as well. This publication compares these two standards.

This report is a follow-up of previous similar comparisons of IAEA and ISO management system standards, such as the comparison of the IAEA 50-C/SG-Q Code and Safety Guides [7] and the ISO standards, reported in IAEA-TECDOC-1182 [8] and in IAEA Safety Reports Series No. 22 [9].

1.2. OBJECTIVE

The objective of this Safety Report is to compare the requirements of IAEA GS-R-3 with those of ISO 9001:2008, in order to identify the main differences between them. This report also provides information and guidance that may be considered when ISO 9001:2008 is used by the nuclear industry to complement safety specific management system standards or quality management system standards.

¹ For example, the OHSAS 18001 Occupational Health and Safety Management Systems Requirements Standard (OHSAS 18001:2007) [6] establishes requirements for an occupational health and safety management system, to enable an organization to control its occupational health and safety risks and improve its performance. OHSAS 18001:2007 was developed to be compatible with ISO 9001:2000, which has been replaced by the ISO 9001:2008 [4] and ISO 14001:2004 [5] management system standards, to facilitate the integration of quality, environmental, and occupational health and safety management systems by organizations, should they wish to do so.

1.3. SCOPE

This report compares the requirements in the following publications:

- IAEA Safety Standards Series No. GS-R-3, The Management System for Facilities and Activities [1];
- ISO 9001:2008, Quality Management Systems – Requirements [4].

The recommendations provided in Ref. [2] and the fundamentals and vocabulary contained in ISO 9000:2005, Quality Management Systems — Fundamentals and Vocabulary [10], have been used, as necessary and appropriate, to inform and facilitate the comparison.

1.4. USERS

This Safety Report is intended primarily for the use of owners, operators and employees of nuclear facilities and installations, regulatory bodies, suppliers, research and development organizations, and other interested parties. It will be of particular interest to organizations wishing to procure items, products or services for use in the nuclear industry as a source of guidance on specifying additional management system requirements to suppliers with management systems that comply with ISO 9001:2008.

2. APPLICATION OF IAEA GS-R-3 AND ISO 9001:2008 STANDARDS

Figure 1 illustrates the use of IAEA GS-R-3 and ISO 9001:2008 requirements by an operator of a nuclear facility, or by an organization conducting a nuclear activity, at the interfaces between the operator, the nuclear regulatory body and a supplier. The figure also illustrates how a regulatory body might use IAEA GS-R-3 at the interfaces between the regulatory body, an operator of a nuclear facility or an organization conducting a nuclear activity, and the government.

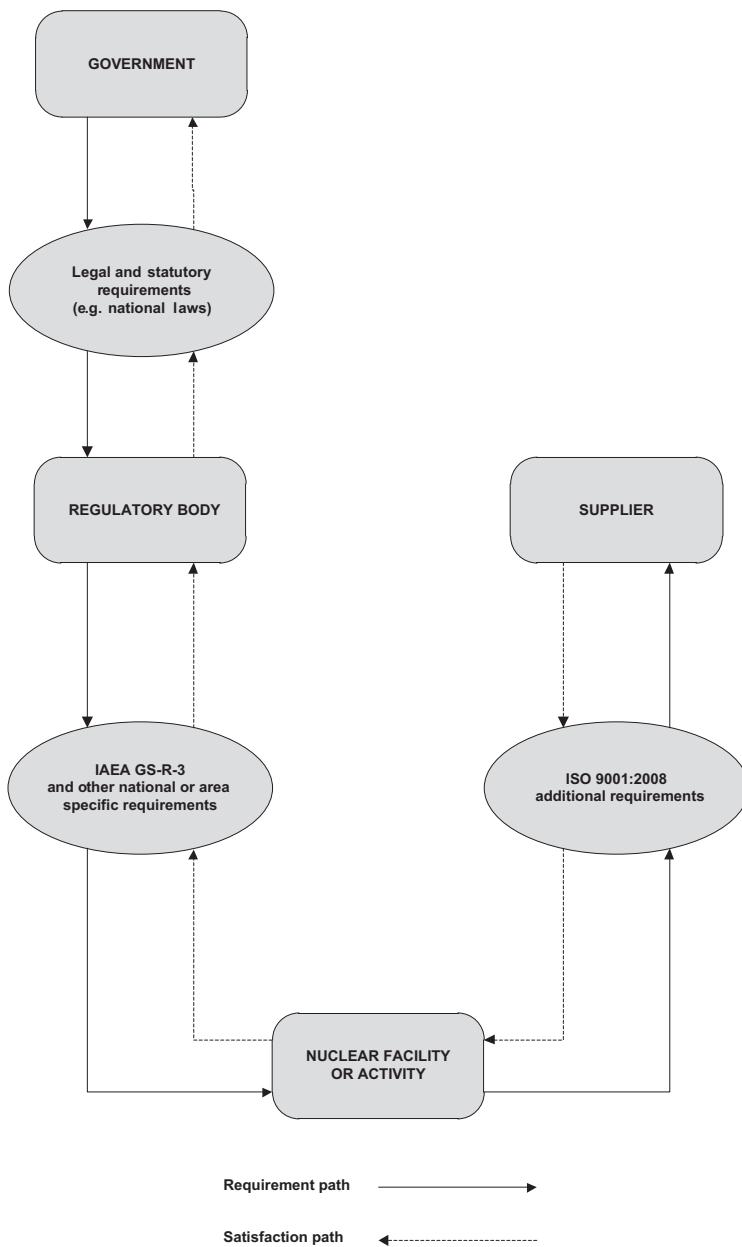


FIG. 1. Application of IAEA GS-R-3 and ISO 9001:2008. See Table 1 for examples of additional requirements.

Through governmental policy and legal or statutory instruments, a Member State might require a regulatory body to put in place regulatory and management systems for establishing policies and objectives, and for implementing them such that objectives are achieved in an efficient and effective way. Figure 1 also illustrates the use of IAEA GS-R-3 in addition to the legal, statutory and other requirements of the Member State to be imposed on a regulated organization such as an operator of a nuclear facility. It is the responsibility of the operator to put in place a management system that satisfies these requirements. At the interface between the nuclear facility operator and a supplier of items and services, the operator may require the supplier to put in place a management system for the delivery of items and services that satisfies requirements imposed by the regulatory body; these requirements may include IAEA GS-R-3 requirements. A supplier with a management system based on ISO 9001:2008 would then have to ensure that its management system satisfies these additional requirements. Figure 1 illustrates such a situation.

The development of a management system which complies with the IAEA GS-R-3 requirements involves the participation of regulatory bodies with oversight of nuclear facilities as a matter of course, while the development of a management system based on ISO 9001:2008 does not require their involvement. However, a supplier may incorporate product related regulatory requirements set by a regulatory body or the government when establishing a management system based on ISO 9001:2008.

Both standards specify requirements for use by an organization internally, or for contractual purposes, to enhance and demonstrate the effectiveness of its management system. Both standards can be used by external parties as the basis of assessing the organization's management system.

Unlike IAEA GS-R-3, however, ISO 9001:2008 also can be used by external parties, such as certification bodies, for certification purposes. The IAEA does not encourage the certification of an organization's management system against the requirements of IAEA GS-R-3. The compliance of a management system with IAEA GS-R-3 requirements is normally assessed and enforced by the regulatory bodies of Member States that have adopted IAEA GS-R-3 for use in their regulatory systems.

3. MAJOR DIFFERENCES AND CORRELATIONS

This section provides a summary comparing and contrasting the approaches of IAEA GS-R-3 and ISO 9001:2008 in the major areas of interest. A more detailed comparison is provided in the Appendix to this publication.

3.1. GENERAL APPROACH

3.1.1. Objectives

IAEA GS-R-3 presents the requirements for organizations to establish, implement, assess and continually improve a management system that integrates safety, health, environmental, security, quality and economic elements, to foster a strong safety culture and improve safety performance in all the activities of the organization. In IAEA GS-R-3, safety is of primary importance, overriding all other demands.

ISO 9001:2008 allows an organization to demonstrate its ability to meet customer and applicable statutory and regulatory requirements², in addition to its own organizational requirements, and to enhance customer satisfaction. It does not include requirements to ensure safety or requirements specific to other management system aspects, such as those particular to environmental management, occupational health and safety management, financial management or risk management.

3.1.2. Management principles

Both IAEA GS-R-3 and ISO 9001:2008 are based on the following common management principles, which reflect good management practices:

- Customer focus;
- Leadership;
- Involvement of people;
- Process approach;

² ISO 9001:2008 refers to statutory and regulatory requirements as legal requirements. IAEA GS-R-3 makes a distinction between them, making reference in one of its requirements to statutory, regulatory and legal requirements.

- Systematic approach to management;
- Continual improvement;
- Factual approach to decision making;
- Mutually beneficial supplier relationships.

IAEA GS-R-3 is also based on the principle of an integrated management system, which includes all factors affecting the activities and safety performance of an organization. Safety culture and human performance are important management principles in IAEA GS-R-3 and are part of the focus of the standard. Risk management is another important management principle included in IAEA GS-R-3.

IAEA GS-R-3 requires proactive strategic thinking and planning, integrating all goals, strategies and objectives, while the emphasis of ISO 9001:2008 is on the operational level of product and ‘quality management’ requirements. Consequently, the scope of application and integration of management principles is much greater in IAEA GS-R-3 than in ISO 9001:2008.

ISO 9001:2008 has no requirement to integrate safety, health, environmental, security, quality and economic elements of the management system to ensure that safety is properly taken into account in all activities of the organization.

3.1.3. Focus and structure

Figure 2 illustrates the differences of focus and the similarities of structure between IAEA GS-R-3 and ISO 9001:2008.

3.1.3.1. Focus

IAEA GS-R-3 is a safety standard, whereas ISO 9001:2008 is not. IAEA GS-R-3 is a standard specific to the nuclear industry, and its focus is on achieving and enhancing safety. It establishes requirements designed to achieve and enhance safety, while enhancing the satisfaction of interested parties. IAEA GS-R-3 is applicable to the establishment, implementation, assessment and continual improvement of management systems for:

- Nuclear facilities;
- Activities using sources of ionizing radiation;
- Radioactive waste management;
- Transport of radioactive material;
- Radiation protection activities;

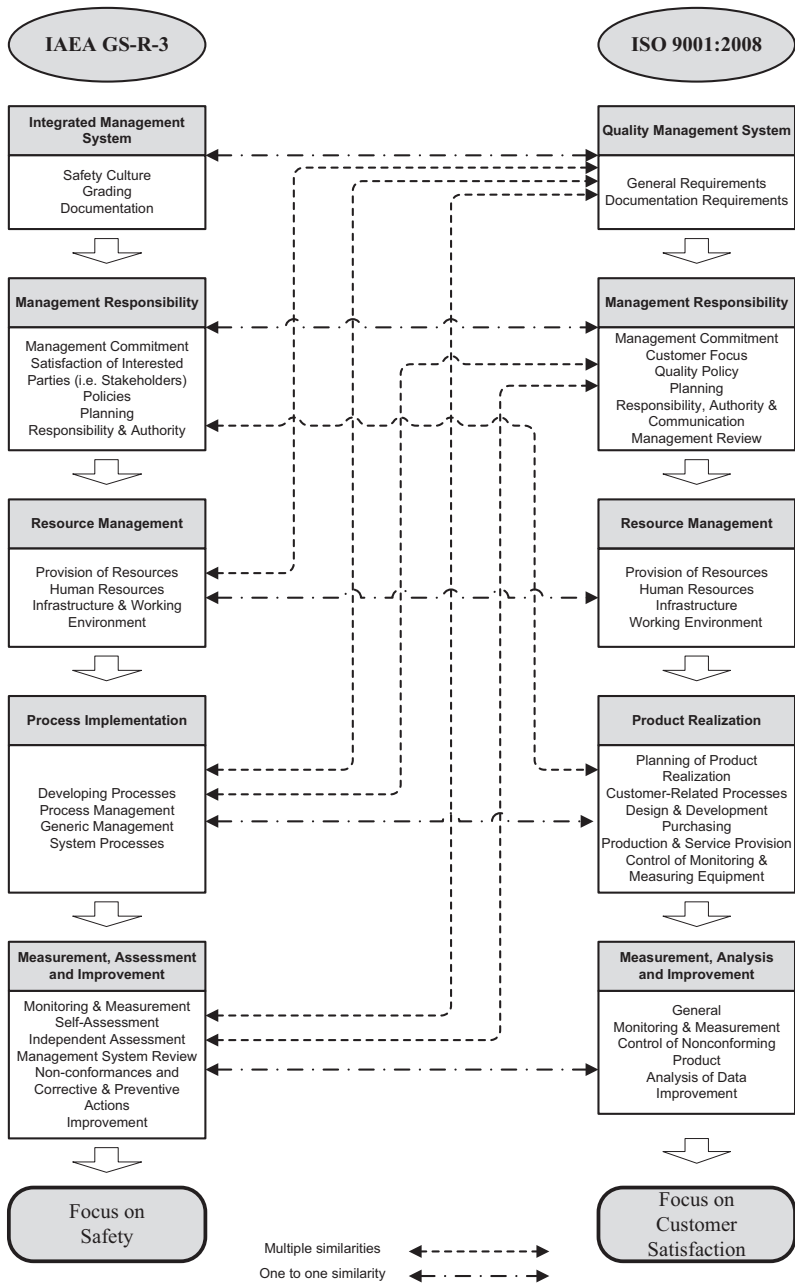


FIG. 2. Differences of focus and similarities of structure between IAEA GS-R-3 and ISO 9001:2008.

- Any other practices or circumstances in which people may be exposed to radiation from naturally occurring or artificial sources;
- Regulation of such facilities and activities.

ISO 9001:2008 is a general quality management system standard applicable to any organization. Its focus is on providing products and services that meet customer and applicable statutory and regulatory requirements, and on enhancing customer satisfaction. It concentrates on the effectiveness of the quality management system in meeting these objectives, not on enhancing safety. ISO 9001:2008 states that it does not include requirements specific to other management systems, such as those particular to environmental management, occupational health and safety management, financial management or risk management. It specifies requirements designed to demonstrate an organization's ability to consistently provide products that meet customer and applicable statutory and regulatory requirements, and to enhance customer satisfaction through the effective application of the system, including processes for continual improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements [4].

3.1.3.2. Structure

There are similarities in structure between IAEA GS-R-3 and ISO 9001:2008, in spite of the differences in focus and overall objective. The requirements in both standards have been structured in terms of the following main categories:

- Management system versus quality management system;
- Management responsibility;
- Resource management;
- Process implementation versus product realization;
- Measurement, assessment and improvement versus measurement, analysis and improvement.

However, there are differences in emphasis and detail within these main categories of requirements.

3.1.4. Terminology

There are some differences in terminology between IAEA GS-R-3 and ISO 9001:2008. The vocabulary used in IAEA GS-R-3 is defined in the IAEA Safety Glossary [11], and terms relating to the management system are included in a

glossary of terms in IAEA GS-R-3 [1]. The vocabulary for ISO 9001:2008 is contained in ISO 9000:2005 [10].

Note that both standards use the concept of ‘product’ to mean both items and services. Also, IAEA GS-R-3 makes reference to interested parties, while ISO 9001:2008 restricts its focus to suppliers, organizations and customers, and points to ISO 9004:2009 [12] for a wider focus on quality management that addresses the needs and expectations of all interested parties, and their satisfaction, by the systematic and continual improvement of the organization’s performance.

3.2. MANAGEMENT SYSTEM

3.2.1. General requirements

3.2.1.1. *Level of detail of requirements*

There are differences in the level of detail in topics common to both standards. IAEA GS-R-3 is supported by Refs [2] and [3] and by similar guides, which provide recommendations on the implementation of the requirements in IAEA GS-R-3. ISO 9001:2008 does not provide such separate guidance on the implementation of its requirements.

3.2.1.2. *Integration of requirements from other standards*

IAEA GS-R-3 requires an integrated management system. It makes specific provision for the integration of requirements of regulatory bodies and of other interested parties into the management system. It also provides an explicit mechanism for integrating requirements from other codes and standards into the management system.

ISO 9001:2008 focuses on quality management. It does not include a requirement to integrate the requirements of other management system standards but states that an organization can use ISO 9001:2008 to align or integrate its quality management system with related management system requirements. ISO 9001:2008 considers statutory and regulatory requirements, but only those applicable to the product, as well as additional requirements identified by the organization. The application of statutory and regulatory requirements to the totality of the quality management system is not considered.

3.2.2. Safety culture

The promotion of and support for a strong safety culture is an integral part of the integrated management system described in IAEA GS-R-3. A safety culture is not a requirement of ISO 9001:2008.

3.2.3. Grading the application of management system requirements

IAEA GS-R-3 states that the application of management system requirements shall be graded so as to deploy appropriate resources, but this is not a stated requirement in ISO 9001:2008. In the latter, however, there is the implied use of the concept of a graded approach in the application of a few specific requirements, for instance, by the use of wording such as “as appropriate”, “where appropriate”, “where applicable”, “as necessary” or “where necessary” in the text or explanatory notes of these requirements.

A graded approach to the application of requirements allows an organization to deploy resources and to determine the types and extent of controls to be applied to specific items, services and processes in a manner that is commensurate with the significance and complexity of, and risks (hazards and consequences) associated with, these items, products or services, to ensure that they are produced and/or delivered correctly and safely.

3.2.3.1. Exclusion of requirements

IAEA GS-R-3 does not make provision for the exclusion of any of its requirements; it makes provision only for varying degrees of application of the requirements through the graded approach.

ISO 9001:2008 allows the exclusion of requirements within clause 7, where such exclusions do not affect the organization’s ability, or responsibility, to provide products or services that meet customer and applicable statutory and regulatory requirements.

3.2.4. Documentation of the system

IAEA GS-R-3 does not specify the processes to be documented, but requires the management system to include the following:

- The policy statements of the organization.
- A description of the management system.
- A description of the structure of the organization.

- A description of the functional responsibilities, accountability, levels of authority and interactions of those managing, performing and assessing work.
- A description of the processes and supporting information explaining how work is to be prepared, reviewed, carried out, recorded, assessed and improved.
- Records, specified in the process documentation, that are required to demonstrate that the process results have been achieved. It should be noted that IAEA GS-R-3 treats records as outputs of processes, and not as documentation of the management system.

Also, IAEA GS-R-3 requires the documentation of the management system to reflect the characteristics of the organization and its activities, and the complexities of processes and their interactions.

ISO 9001:2008 requires the quality management system documentation to include:

- Documented statements of a quality policy and quality objectives.
- A quality manual.
- Documented procedures and records, including documented procedures for:
 - Control of documents;
 - Control of records;
 - Internal audit;
 - Control of non-conforming product;
 - Corrective action;
 - Preventive action.
- Documents, including records, needed to ensure the effective planning, operation and control of processes.

ISO 9001:2008 recognizes that the extent of the documentation will depend on the size of the organization, the types of activity being undertaken, the complexity of the processes and their interactions, and the competence of personnel.

3.3. MANAGEMENT RESPONSIBILITY

3.3.1. Management commitment

IAEA GS-R-3 places requirements on all levels of management, while ISO 9001:2008 places requirements only on top management.

In IAEA GS-R-3, senior management³ has a number of responsibilities not specified in ISO 9001:2008; they include:

- Developing individual values, institutional values and behavioural expectations for the organization to support the implementation of the management system, and acting as role models in the promulgation of these values and expectations.
- Communicating to individuals the need to adopt these values and expectations.
- Fostering the involvement of all individuals in the implementation and continual improvement of the management system.
- Developing organizational policies not limited to the quality policy; as ISO 9001:2008 is a quality management system standard, states that top management is responsible only for the quality policy.
- Establishing goals, strategies, plans and objectives that are consistent with the policies of the organization.
- Developing the goals, strategies, plans and objectives of the organization in an integrated manner so that their collective impact on safety is understood and managed.

Senior management has the responsibility of carrying out self-assessment to evaluate the performance of work and the improvement of the safety culture; this responsibility is shared with management at all other levels of the organization.

IAEA GS-R-3 has a broader view of leadership and management responsibility than does ISO 9001:2008. The latter addresses leadership in its requirements, but does not explicitly address the particular aspects listed above.

³ ‘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; ISO 9001:2008 uses the term ‘top management’.

3.3.2. Satisfaction of interested parties

IAEA GS-R-3 requires senior management to consider the expectations and the satisfaction of interested parties in the processes of its management system, while ISO 9001:2008 focuses only on customers. Thus, the focus in IAEA GS-R-3 is on safety but with due consideration of the requirements and expectations of interested parties as far as they directly or indirectly affect the activities of an organization. IAEA GS-R-3 focuses on a broader range of interested parties than does ISO 9001:2008.

IAEA GS-R-3 addresses customer satisfaction by requiring the enhancement of interested party satisfaction, as long as safety is not compromised, in the activities and interactions of the organization. ISO 9001:2008 establishes the requirement for customer satisfaction as part of the monitoring and measurement of the performance of the quality management system.

3.4. RESOURCE MANAGEMENT

3.4.1. Provision of resources

IAEA GS-R-3 places the responsibility specifically on senior management to provide the resources necessary to carry out the activities of the organization and to establish, implement, assess and continually improve the management system. ISO 9001:2008 places this responsibility on the organization, but requires top management to ensure that responsibilities and authorities are defined for this and other activities.

3.4.1.1. Management of information and knowledge

IAEA GS-R-3 highlights the requirement to manage information and knowledge as a resource. ISO 9001:2008 has several requirements to manage information, but it has no requirement for knowledge management.

3.4.2. Human resources

Both IAEA GS-R-3 and ISO 9001:2008 have requirements to determine the necessary competence of personnel performing work, and to provide training and/or take other actions to satisfy these needs and achieve the required level of competence.

Both standards also have requirements to evaluate the effectiveness of the actions taken, to ensure that suitable proficiency is achieved; IAEA GS-R-3 also requires that the proficiency be maintained.

IAEA GS-R-3 requires senior management to ensure not only that individuals are competent to perform their assigned work, but also that they understand the consequences for safety of their activities. It requires individuals to receive appropriate education and training and to acquire suitable skills, knowledge and experience, to ensure their competence and to promote compliance with the requirements of the management system and adoption of the values and expectations promulgated by management. Consequently, the training provided is required to ensure that individuals are aware of the relevance and importance of their activities, and of how their activities contribute to safety in the achievement of the organization's objectives.

Except for a specific requirement for the process owner⁴ to ensure that the process documentation specifies the records required to demonstrate that the process results have been achieved, IAEA GS-R-3 does not explicitly set a requirement for training records to be maintained. Retention of records is addressed in annex II of the companion Safety Guide [2].

ISO 9001:2008 requires the organization to ensure that its personnel are aware of the relevance and importance of their activities, and of how these activities contribute to the achievement of the quality objectives. IAEA GS-R-3 requires the organization to ensure that its personnel are competent to perform their assigned work and that they understand the consequences for safety of their activities. Also in this area, ISO 9001:2008 focuses on the quality aspects, in contrast to the strong focus on safety in IAEA GS-R-3. The organization is also required to maintain appropriate records of education, training, skills and experience.

3.4.3. Infrastructure and the working environment

IAEA GS-R-3 does not set detailed requirements regarding infrastructure; however, guidance is provided in Ref. [2]. IAEA GS-R-3 requires senior management to determine, provide, maintain and re-evaluate the infrastructure and the working environment necessary for requirements to be met and for work to be carried out in a safe manner.

ISO 9001:2008 contains more requirements for infrastructure than does IAEA GS-R-3, but with a focus on the infrastructure needed to achieve conformity to product requirements.

⁴ The individual designated as having the authority and responsibility for a process is often referred to as the 'process owner'.

3.5. PROCESS IMPLEMENTATION

3.5.1. Process development and management

3.5.1.1. *Process and product focus*

Both standards adopt the process approach, based on the concept that work may be structured and interpreted as a set of interacting processes. IAEA GS-R-3 puts a strong focus on processes, requiring a graded application of management system requirements to the products and activities of each process. ISO 9001:2008 considers processes needed for product realization and focuses mainly on product quality.

3.5.1.2. *Process owner*

IAEA GS-R-3 has a specific requirement for a designated individual with the authority and responsibility for developing, documenting, monitoring and promoting improvement of each process, while ISO 9001:2008 does not.

3.5.1.3. *Process models*

IAEA GS-R-3 does not specify or rely on a particular process model to present process implementation requirements. It provides generic requirements for developing and managing processes, focusing on a number of generic management system processes for the control of documents, products, records and purchasing, and for communication and managing organizational change, without reference to any particular model.

However, IAEA GS-R-3 process development requirements explicitly include the specification and addressing of applicable regulatory, statutory, legal, safety, health, environmental, security, quality and economic requirements. There is also a requirement to identify hazards and risks, along with actions to mitigate them. ISO 9001:2008 only requires that statutory and regulatory requirements applicable to the product be addressed.

ISO 9001:2008 includes a process model that identifies the importance of understanding and meeting requirements, the need to consider processes in terms of added value, the need to monitor performance and effectiveness, and the need for continual improvement based on objective measurement. The model emphasizes the responsibility of management to manage resources, establish product realization processes and monitor process effectiveness in delivering products and services conforming to applicable requirements. Although IAEA GS-R-3 does not discuss a particular process model, it also specifies requirements discussed in the process model of ISO 9001:2008.

3.5.2. Generic management system processes

3.5.2.1. Control of products

There are differences between IAEA GS-R-3 and ISO 9001:2008 in the way in which the requirements for control of products are presented.

3.5.2.2. Planning of product realization

IAEA GS-R-3 does not establish detailed and specific requirements on product realization planning, while ISO 9001:2008 does.

3.5.2.3. Determination of interested party requirements

IAEA GS-R-3 requires the management system to identify and integrate any requirements formally agreed with interested parties. It also requires senior management to consider the expectations of interested parties in process activities and interactions, with the aim of enhancing the satisfaction of interested parties while ensuring that safety is not compromised.

IAEA GS-R-3 makes reference to applicable requirements of interested parties without specifying the source of those requirements at the product level; however, the scope of the interested party requirements considered is larger, since the scope of interested parties considered in IAEA GS-R-3 extends beyond those specified in ISO 9001:2008.⁵

ISO 9001:2008 explicitly addresses the input of customers, the organization and regulatory or statutory bodies in the determination of requirements that only relate to the product. It sets out detailed requirements for determining customer requirements relating to the product, but without mentioning safety, as this standard was not developed for safety applications.

3.5.2.4. Specification of requirements

IAEA GS-R-3 requirements for process development, product control and purchasing are not as detailed, or as specific, as the explicit requirements for product realization in ISO 9001:2008.

⁵ Customers, as addressed by the requirements of ISO 9001:2008, are included among the interested parties addressed by IAEA GS-R-3.

3.5.2.5. Review of requirements

IAEA GS-R-3 requirements for product control and purchasing as part of the generic management processes are not as detailed as the requirements in ISO 9001:2008 for review of the requirements related to the product.

3.5.2.6. Design

The focus of IAEA GS-R-3 on processes means that the requirements are sufficiently generic to be applicable to design.

ISO 9001:2008 includes specific requirements relating to design and development planning, the determination of design inputs and outputs, design review, verification and validation, and the control of design changes.

3.5.2.7. Other stages of product realization

The focus on processes in IAEA GS-R-3 means that the requirements are sufficiently generic to be applicable to all processes without regard to what a given process is designed to achieve. IAEA GS-R-3 requirements apply equally at the design stage as at subsequent developmental, implementation, or product obsolescence and decommissioning or disposition stages; the requirements are addressed only in a generic way in IAEA GS-R-3, without reference to the developmental phases of products.

ISO 9001:2008 includes generic requirements for processes that control production and service provision, and for the validation of such processes. In general, ISO 9001:2008 requirements in relation to product realization are more specific than those in IAEA GS-R-3.

3.5.2.8. Control of monitoring and measuring devices

IAEA GS-R-3 requires the tools and equipment used in activities for inspection, testing, verification and validation of products to be of the proper range, type, accuracy and precision. ISO 9001:2008 establishes similar requirements but provides more detail.

3.5.2.9. Customer property

Customer property is not addressed in IAEA GS-R-3, but is explicitly addressed in ISO 9001:2008.

3.5.2.10. Communication

IAEA GS-R-3 focuses on internal communication and communication with other interested parties, as necessary.

ISO 9001:2008 focuses on communication with the customer and on internal communication regarding the effectiveness of the quality management system. The requirements for customer focused communication in ISO 9001:2008 are equivalent to the IAEA GS-R-3 requirements for communication with internal and external interested parties as well as those for reporting and resolving product non-conformances.

3.5.2.11. Managing organizational change

IAEA GS-R-3 has specific requirements for: evaluating and classifying organizational changes according to their importance to safety; justifying each change; and planning, controlling, communicating, monitoring, tracking and recording the implementation of such changes to ensure that safety is not compromised.

ISO 9001:2008 has several explicit requirements for managing changes to product realization and other elements of a quality management system, but not for managing organizational change.

3.6. MEASUREMENT, ASSESSMENT AND IMPROVEMENT

3.6.1. Monitoring and measurement

IAEA GS-R-3 provides high level requirements for monitoring and measuring the effectiveness of the management system in achieving intended results, and for identifying opportunities for improvement.

ISO 9001:2008 requires the organization to monitor information relating to customer perception as to whether the organization has met customer requirements as one of the measurements of the performance of the management system. It also requires the organization to determine the methods for obtaining and using such information. IAEA GS-R-3 does not specify such requirements.

ISO 9001:2008 establishes more detailed requirements, including the requirements to determine applicable monitoring and measuring methods that include statistical techniques, and to determine the extent of their use.

3.6.2. Self-assessment

IAEA GS-R-3 requires senior management and management at all other levels of the organization to carry out self-assessments to evaluate not just the performance of work but also the improvement of the safety culture. ISO 9001:2008 has no equivalent requirements for self-assessment.

3.6.3. Independent assessment

IAEA GS-R-3 requires independent assessments to be conducted to: determine, among other things, effectiveness in achieving goals, strategies, plans and objectives; determine the adequacy of work performance and leadership; and evaluate the organization's safety culture.

It also requires the establishment of an organizational unit with the responsibility for conducting independent assessments. Senior management is required to evaluate the results of the independent assessments and to take any necessary steps to address those results, with the decisions and reasons for them recorded and communicated.

There are no similar requirements for independent assessment in ISO 9001:2008; however, audits can be conducted by an independent organization, as it is left to the organization to assign responsibility for audits in a documented procedure.

ISO 9001:2008 requires internal audits of the quality management system to be conducted in order to determine the effectiveness of its implementation and whether it conforms to the planned arrangements, the requirements of ISO 9001:2008 and any other requirements established by the organization. It also requires assessment of the effectiveness of processes and of the product to verify that product requirements have been met.

ISO 9001:2008 does not specifically place the responsibility for audits on management, but it requires the responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records, to be defined in a documented procedure.

3.6.4. Management system review

In IAEA GS-R-3, management system review is considered to be part of the measurement, assessment and improvement of the management system. IAEA GS-R-3 requires the management system review to cover: outputs from all forms of assessment; results delivered and objectives achieved; non-conformances, and corrective and preventive actions; lessons learned from other organizations; and opportunities for improvement.

Key outputs from such reviews are the identification of obstacles and of the need to make changes or improvements to policies, goals, strategies, plans, objectives and processes.

IAEA GS-R-3 does not explicitly state who is responsible for conducting the review of the management system.

In ISO 9001:2008, management system review is addressed in the context of management responsibility. ISO 9001:2008 establishes detailed requirements for reviews of the quality management system with inputs that are similar to those in IAEA GS-R-3, except for the IAEA GS-R-3 requirement to address lessons learned from other organizations.

Key outputs from ISO 9001:2008 reviews relate to: improvement of the effectiveness of the quality management system and its processes; improvement of product relating to customer requirements; and resource needs. ISO 9001:2008 explicitly requires top management to conduct such reviews.

4. NOTES TO AID USERS IN MEETING ADDITIONAL REQUIREMENTS

Table 1 identifies requirements on the management system established in IAEA GS-R-3 that are not addressed in ISO 9001:2008. The table provides notes to aid users of ISO 9001:2008 in meeting these additional IAEA GS-R-3 requirements. Table 2 identifies requirements on the quality management system established in ISO 9001:2008 that are not addressed in IAEA GS-R-3. The table provides notes to aid users of IAEA GS-R-3 in meeting these additional ISO 9001:2008 requirements.

The tables identify the additional requirements to be met in circumstances where only one standard is currently implemented. It should be noted that there may be alternate approaches to satisfy the requirements of one standard or the other, and the notes present only one viable approach to meeting the requirements.

In Tables 1 and 2, the notes to aid users in meeting the requirements relate to the text in italics. For those sections in each of the standards that are not addressed in these tables, the requirements are considered to be equivalent.

In the tables, ‘should’ statements are used to provide guidance based on expert judgement; they do not stem from a consensus of IAEA Member States. The guidance provided does not relieve the users of their responsibility to comply with the requirements of the standards.

TABLE 1. IAEA GS-R-3 REQUIREMENTS NOT CONTAINED IN ISO 9001:2008

(Notes to aid users in meeting the requirements relate to the text in italics.)

Paragraph	IAEA GS-R-3 requirements	Notes to aid users of ISO 9001:2008 in meeting the IAEA GS-R-3 requirements
2.1–2.10 Management system		
General requirements		
2.1	<p>A <i>management system</i> shall be established, implemented, assessed and continually improved. It shall be aligned with the goals of the organization and shall contribute to their achievement. The main aim of the management system shall be to achieve and <i>enhance safety</i> by:</p> <ul style="list-style-type: none"> – <i>Bringing together in a coherent manner all the requirements for managing the organization;</i> – Describing the planned and systematic actions necessary to provide adequate confidence that all these requirements are satisfied; – <i>Ensuring that health, environmental, security, quality and economic requirements are not considered separately from safety requirements, to help preclude their possible negative impact on safety.</i> 	<p>A management system should be established that integrates safety, health, environmental, security and economic requirements with the ISO 9001:2008 quality management system requirements.</p>
2.2	<p><i>Safety shall be paramount within the management system, overriding all other demands.</i></p>	<p>Safety needs to be ensured when using ISO 9001:2008 in a nuclear environment. For example, safety should be made a priority in policies, processes, procedures, training and communication; a strong safety culture should be promoted and supported; and the values and expectations supporting safety should be developed, established, stated and clearly communicated.</p>

TABLE 1. IAEA GS-R-3 REQUIREMENTS NOT CONTAINED IN ISO 9001:2008 (cont.)

(Notes to aid users in meeting the requirements relate to the text in italics.)

Paragraph	IAEA GS-R-3 requirements	Notes to aid users of ISO 9001:2008 in meeting the IAEA GS-R-3 requirements
2.3	<p>The management system shall identify and integrate with the requirements contained within [IAEA GS-R-3]:</p> <ul style="list-style-type: none"> – The statutory and regulatory requirements of the Member State; – <i>Any requirements formally agreed with interested parties (also known as ‘stakeholders’);</i> – <i>All other relevant IAEA Safety Requirements publications, such as those on emergency preparedness and response and safety assessment;</i> – <i>Requirements from other relevant codes and standards adopted for use by the organization.</i> 	<p>The organization should identify all formally agreed requirements of interested parties and integrate them into the management system.</p> <p>The organization should identify the relevant IAEA requirements and integrate them into the management system.</p> <p>The organization should identify requirements from other relevant codes and standards and integrate them into the management system.</p>

Safety culture

2.5	<p>The management system shall be used to promote and support a strong safety culture by:</p> <ul style="list-style-type: none"> – <i>Ensuring a common understanding of the key aspects of safety culture within the organization;</i> – <i>Providing the means by which the organization supports individuals and teams in carrying out their tasks safely and successfully, taking into account the interaction between individuals, technology and the organization;</i> – <i>Reinforcing a learning and questioning attitude at all levels of the organization;</i> – <i>Providing the means by which the organization continually seeks to develop and improve its safety culture.</i> 	<p>Safety culture is not addressed in ISO 9001:2008 but should be promoted and supported by the management system.</p>
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TABLE 1. IAEA GS-R-3 REQUIREMENTS NOT CONTAINED IN ISO 9001:2008 (cont.)

(Notes to aid users in meeting the requirements relate to the text in italics.)

Paragraph	IAEA GS-R-3 requirements	Notes to aid users of ISO 9001:2008 in meeting the IAEA GS-R-3 requirements
Grading the application of management system requirements		
2.6	<p><i>The application of management system requirements shall be graded so as to deploy appropriate resources, on the basis of the consideration of:</i></p> <ul style="list-style-type: none"> – <i>The significance and complexity of each product or activity;</i> – <i>The hazards and the magnitude of the potential impact (risks) associated with the safety, health, environmental, security, quality and economic elements of each product or activity;</i> – <i>The possible consequences if a product fails or an activity is carried out incorrectly.</i> 	<p>The resources and effort expended, and the extent to which management system requirements are applied to a particular product, activity or process, should be commensurate with:</p> <ul style="list-style-type: none"> – The importance and complexity of the product, activity or process; – The potential impact of that product, activity or process on safety, health, environmental, security, quality and economic priorities of the organization; – The consequences of mistakes or product, activity or process failure.
2.7	<p><i>Grading of the application of management system requirements shall be applied to the products and activities of each process.</i></p>	<p>See the note to aid users relating to Requirement 2.6 above.</p>
Documentation of the management system		
2.8	<p><i>The documentation of the management system shall include the following:</i></p> <ul style="list-style-type: none"> – <i>The policy statements of the organization;</i> – <i>A description of the management system;</i> – <i>A description of the structure of the organization;</i> – <i>A description of the functional responsibilities, accountability, levels of authority and interactions of those managing, performing and assessing work;</i> – <i>A description of the processes and supporting information that explain how work is to be prepared, reviewed, carried out, recorded, assessed and improved.</i> 	<p>In the documentation of the management system, all requirements should be addressed, that is, safety, health, environmental, security, quality and economic requirements.</p>

TABLE 1. IAEA GS-R-3 REQUIREMENTS NOT CONTAINED IN ISO 9001:2008 (cont.)

(Notes to aid users in meeting the requirements relate to the text in italics.)

Paragraph	IAEA GS-R-3 requirements	Notes to aid users of ISO 9001:2008 in meeting the IAEA GS-R-3 requirements
2.9	<i>The documentation of the management system shall be developed to be understandable to those who use it.</i> Documents shall be readable, readily identifiable and available at the point of use.	When preparing documentation of the management system, consideration should be given to the accessibility and ease of use of documents, with particular attention to, for instance, appropriate language and format, avoidance of jargon, and provision of clear definitions.
3.1–3.14 Management responsibility		
Management commitment		
3.1	<i>Management at all levels shall demonstrate its commitment to the establishment, implementation, assessment and continual improvement of the management system</i> and shall allocate adequate resources to carry out these activities.	The principle of management commitment should be extended to all levels of management.
3.2	<i>Senior management shall develop individual values, institutional values and behavioural expectations for the organization to support the implementation of the management system and shall act as role models in the promulgation of these values and expectations.</i>	Management at all levels should develop, establish, state, clearly communicate and foster a culture of shared values and expectations by developing individual and institutional or corporate values, as well as behavioural expectations for the individuals in the organization. Management should then lead by example to promulgate these values and expectations throughout the organization.
3.3	<i>Management at all levels shall communicate to individuals the need to adopt these individual values, institutional values and behavioural expectations as well as to comply with the requirements of the management system.</i>	See the notes to aid users relating to Requirement 3.2 above.

TABLE 1. IAEA GS-R-3 REQUIREMENTS NOT CONTAINED IN ISO 9001:2008 (cont.)

(Notes to aid users in meeting the requirements relate to the text in italics.)

Paragraph	IAEA GS-R-3 requirements	Notes to aid users of ISO 9001:2008 in meeting the IAEA GS-R-3 requirements
3.4	<i>Management at all levels shall foster the involvement of all individuals in the implementation and continual improvement of the management system.</i>	The basic quality management principle of ISO 9000:2005 item 0.2(c), “involvement of people” [10], should be implemented by involving all individuals in the implementation and continual improvement of the management system.
3.5	<i>Senior management shall ensure that it is clear when, how and by whom decisions are to be made within the management system.</i>	Responsibilities and authorities for making decisions should be clear.
Satisfaction of interested parties		
3.6	The expectations of interested parties shall be considered by senior management in the activities and interactions in the processes of the management system, with the aim of enhancing the satisfaction of interested parties <i>while at the same time ensuring that safety is not compromised.</i>	Senior management should expand the customer focus to all interested parties while ensuring that safety is not compromised.
Organizational policies		
3.7	<i>Senior management shall develop the policies of the organization. The policies shall be appropriate to the activities and facilities of the organization.</i>	Top management should develop policies in addition to, or should extend, the existing quality policy to cover all elements of the management system, including safety, health, the environment, security and economics, as appropriate.
Planning		
3.8	<i>Senior management shall establish goals, strategies, plans and objectives that are consistent with the policies of the organization.</i>	Top management should extend the existing quality objectives to cover all elements of the management system, including safety, health, the environment, security and economics, as appropriate.

TABLE 1. IAEA GS-R-3 REQUIREMENTS NOT CONTAINED IN ISO 9001:2008 (cont.)

(Notes to aid users in meeting the requirements relate to the text in italics.)

Paragraph	IAEA GS-R-3 requirements	Notes to aid users of ISO 9001:2008 in meeting the IAEA GS-R-3 requirements
3.9	Senior management shall develop the goals, strategies, plans and objectives of the organization in an integrated manner so <i>that their collective impact on safety is understood and managed.</i>	A leading principle of the management system should be strategic planning that focuses on safety. Senior management should develop the goals, strategies, plans and objectives of the organization in an integrated manner so that their collective impact on safety is understood and managed. In addition, see the notes to aid users relating to Requirements 2.1 and 2.2 above.
Responsibility and authority for the management system		
3.12	Senior management <i>shall be ultimately responsible for the management system</i> and shall ensure that it is established, implemented, assessed and continually improved.	Top management should retain the responsibility and authority for the management system.
3.13	An individual reporting directly to senior management shall have specific responsibility and authority for: <ul style="list-style-type: none"> – Coordinating the development and implementation of the management system, and its assessment and continual improvement; – <i>Reporting on the performance of the management system, including its influence on safety and safety culture,</i> and any need for improvement; – Resolving any potential conflicts between requirements and within the processes of the management system. 	Top management should assign an individual to report directly to top management on the performance of the whole management system, including its influence on safety and safety culture.
4.1–4.5 Resource management		
Provision of resources		
4.2	<i>The information and knowledge of the organization shall be managed as a resource.</i>	The organization should manage information and knowledge as a resource.

TABLE 1. IAEA GS-R-3 REQUIREMENTS NOT CONTAINED IN ISO 9001:2008 (cont.)

(Notes to aid users in meeting the requirements relate to the text in italics.)

Paragraph	IAEA GS-R-3 requirements	Notes to aid users of ISO 9001:2008 in meeting the IAEA GS-R-3 requirements
Human resources		
4.4	Senior management shall ensure that individuals are competent to perform their assigned work and that they understand the <i>consequences for safety of their activities</i> . Individuals shall have received appropriate education and training, and shall have acquired suitable skills, knowledge and experience to ensure their competence. Training shall ensure that individuals are aware of the relevance and importance of their activities and of <i>how their activities contribute to safety</i> in the achievement of the organization's objectives.	See the notes to aid users relating to Requirement 2.2 above.
Infrastructure and the working environment		
4.5	Senior management shall determine, provide, maintain and re-evaluate the infrastructure and the working environment necessary for work to be <i>carried out in a safe manner</i> and for requirements to be met.	See the notes to aid users relating to Requirement 2.2 above.
5.1–5.29	Process implementation	
Developing processes		
5.4	The development of each process shall ensure that the following are achieved: <ul style="list-style-type: none"> – Process requirements, such as applicable regulatory, statutory, legal, <i>safety, health, environmental, security, quality and economic</i> requirements, are specified and addressed. – <i>Hazards and risks are identified, together with any necessary mitigatory actions.</i> – Interactions with interfacing processes are identified. – Process inputs are identified. – The process flow is described. – Process outputs (products) are identified. – Process measurement criteria are established. 	All requirements (for product and processes) should be identified and addressed in the management system. Risk management should be included in the management system of the organization.

TABLE 1. IAEA GS-R-3 REQUIREMENTS NOT CONTAINED IN ISO 9001:2008 (cont.)

(Notes to aid users in meeting the requirements relate to the text in italics.)

Paragraph	IAEA GS-R-3 requirements	Notes to aid users of ISO 9001:2008 in meeting the IAEA GS-R-3 requirements
5.5	<i>The activities of and interfaces between different individuals or groups involved in a single process shall be planned, controlled and managed in a manner that ensures effective communication and the clear assignment of responsibilities.</i>	The organization should apply the requirement from clause 7.3.1 (“The organization shall manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility”) to all processes.
Process management		
5.6	<i>For each process a designated individual shall be given the authority and responsibility for:</i> <ul style="list-style-type: none"> – Developing and documenting the process and maintaining the necessary supporting documentation; – Ensuring that there is effective interaction between interfacing processes; – Ensuring that process documentation is consistent with any existing documents; – Ensuring that the records required to demonstrate that the process results have been achieved are specified in the process documentation; – Monitoring and reporting on the performance of the process; – Promoting improvement in the process; – Ensuring that the process, including any subsequent changes to it, is aligned with the goals, strategies, plans and objectives of the organization. 	The organization should explicitly identify a designated individual (the process owner) to be responsible and accountable for each process.
5.10	<i>The control of processes contracted to external organizations shall be identified within the management system. The organization shall retain overall responsibility when contracting any processes.</i>	The requirements of ISO 9001:2008 on outsourcing should be extended to all types of contract.

TABLE 1. IAEA GS-R-3 REQUIREMENTS NOT CONTAINED IN ISO 9001:2008 (cont.)

(Notes to aid users in meeting the requirements relate to the text in italics.)

Paragraph	IAEA GS-R-3 requirements	Notes to aid users of ISO 9001:2008 in meeting the IAEA GS-R-3 requirements
Generic management system processes		
5.12	<p>Control of documents Documents shall be controlled. All individuals involved in preparing, revising, reviewing or approving documents shall be specifically assigned this work, shall be competent to carry it out and shall be given access to appropriate information on which to base their input or decisions. <i>It shall be ensured that document users are aware of and use appropriate and correct documents.</i></p>	<p>When preparing documentation of the management system, consideration should be given to the use of appropriate language and format, avoidance of jargon, and the provision of clear definitions.</p>
5.14	<p>Control of products Specifications and requirements for products, including any subsequent changes, shall be in accordance with established standards and shall incorporate applicable requirements. <i>Products that interface or interact with each other shall be identified and controlled.</i></p>	<p>The requirements of clause 7.4.1 of ISO 9001:2008 (purchasing process requirements) should be extended in order to cover internal products so that products that interface or interact with each other are identified and controlled.</p>
5.28	<p>Managing organizational change <i>Organizational changes shall be evaluated and classified according to their importance to safety and each change shall be justified.</i></p>	<p>The organization should classify and prioritize organizational changes according to their importance, especially their impact on or significance to safety, and should justify each organizational change.</p>
5.29	<p><i>The implementation of such changes shall be planned, controlled, communicated, monitored, tracked and recorded to ensure that safety is not compromised.</i></p>	<p>Organizational changes, including changes to the management system, should include provision for control, communication, monitoring, tracking and recording to ensure that safety is not compromised.</p>

TABLE 1. IAEA GS-R-3 REQUIREMENTS NOT CONTAINED IN ISO 9001:2008 (cont.)

(Notes to aid users in meeting the requirements relate to the text in italics.)

Paragraph	IAEA GS-R-3 requirements	Notes to aid users of ISO 9001:2008 in meeting the IAEA GS-R-3 requirements
6.1–6.18 Measurement, assessment and improvement		
Self-assessment		
6.2	<i>Senior management and management at all other levels of the organization shall carry out self-assessment to evaluate the performance of work and the improvement of the safety culture.</i>	Self-assessment to evaluate the performance of work and the improvement of the safety culture should be included in the management system.
Independent assessment		
6.3	Independent assessments shall be conducted regularly on behalf of <i>senior management</i> : <ul style="list-style-type: none"> – To evaluate the effectiveness of processes in meeting and fulfilling goals, strategies, plans and objectives; – To determine the adequacy of work performance and <i>leadership</i>; – <i>To evaluate the organization’s safety culture</i>; – To monitor product quality; – To identify opportunities for improvement. 	The organization should include the safety culture and leadership in the internal audit programme.
6.4	<i>An organizational unit shall be established with the responsibility for conducting independent assessments.</i> This unit shall have sufficient authority to discharge its responsibilities.	An independent assessment unit should be established.
Management system review		
6.8	The review shall cover but shall not be limited to: <ul style="list-style-type: none"> – Outputs from all forms of assessment; – Results delivered and objectives achieved by the organization and its processes; – Non-conformances and corrective and preventive actions; – <i>Lessons learned from other organizations</i>; – Opportunities for improvement. 	Management system reviews should include lessons learned from other organizations.

TABLE 1. IAEA GS-R-3 REQUIREMENTS NOT CONTAINED IN ISO 9001:2008 (cont.)

(Notes to aid users in meeting the requirements relate to the text in italics.)

Paragraph	IAEA GS-R-3 requirements	Notes to aid users of ISO 9001:2008 in meeting the IAEA GS-R-3 requirements
Non-conformances and corrective and preventive actions		
6.12	Products and processes that do not conform to the specified requirements shall be identified, segregated, controlled, recorded and <i>reported to an appropriate level of management within the organization</i> . The impact of non-conformances shall be evaluated, and non-conforming products or processes shall be either: – Accepted; – Reworked or corrected within a specified time period; or – Rejected and discarded or destroyed to prevent their inadvertent use.	Non-conformances should be reported to an appropriate level of management within the organization.
6.15	The <i>status and effectiveness</i> of all corrective and preventive actions shall be <i>monitored</i> and reported to management at an appropriate level of the organization.	In addition to reviewing the effectiveness of corrective and preventive actions taken, monitoring of the status as well as the effectiveness of corrective and preventive actions should also be included in the documented procedures for corrective and preventive actions.
6.16	<i>Potential non-conformances that could detract from the organization's performance shall be identified. This shall be done: by using feedback from other organizations, both internal and external; through the use of technical advances and research; through the sharing of knowledge and experience; and through the use of techniques that identify best practices.</i>	The documented procedure for preventive action should include the identification of potential non-conformances through feedback from other organizations, both internal and external; through the use of technical advances and research; through the sharing of knowledge and experience; and through the use of techniques that identify best practices.
Improvement		
6.18	Improvement plans shall include plans for the provision of adequate resources. <i>Actions for improvement shall be monitored through to their completion and the effectiveness of the improvement shall be checked.</i>	A requirement to check the effectiveness of any improvement should be included in the management system.

TABLE 2. ISO 9001:2008 REQUIREMENTS NOT CONTAINED IN IAEA GS-R-3

(ISO 9001:2008 requirements are reproduced in unedited form; notes to aid users in meeting the requirements relate to the text in italics.)

Clause	ISO 9001:2008 requirements	Notes to aid users of GS-R-3 in meeting the ISO 9001:2008 requirements
4.1–4.2	Quality management system	
4.2 Documentation requirements		
4.2.1	<p>General The quality management system documentation shall include:</p> <ul style="list-style-type: none"> (a) documented statements of a quality policy and quality objectives, (b) <i>a quality manual,</i> (c) documented procedures and records required by this International Standard, and (d) documents, including records, determined by the organization to be necessary to ensure the effective planning, operation and control of its processes. 	<p>IAEA GS-R-3 requires a documented management system that addresses ‘quality’ or quality principles, but it does not explicitly mention or use the expression ‘quality manual’. Producing all the documentation required under IAEA GS-R-3 will normally address the ISO 9001:2008 requirement for a quality manual adequately. A quality manual can be readily prepared from existing documentation, if explicitly required.</p>
4.2.2	<p>Quality manual <i>The organization shall establish and maintain a quality manual that includes</i></p> <ul style="list-style-type: none"> (a) <i>the scope of the quality management system, including details of and justification for any exclusions (see 1.2),</i> (b) <i>the documented procedures established for the quality management system, or reference to them, and</i> (c) <i>a description of the interaction between the processes of the quality management system.</i> 	<p>See the notes to aid users in meeting requirement 4.2.1. There is no explicit and specific requirement for a quality manual in IAEA GS-R-3. Since quality management is one part of an integrated management system, fulfilling the management system documentation requirements of IAEA GS-R-3 (e.g. producing a description of the management system along with the other documentation of the management system stipulated in IAEA GS-R-3) will normally satisfy the requirements for a quality manual. A quality manual can be readily prepared from existing documentation, if explicitly required.</p>

TABLE 2. ISO 9001:2008 REQUIREMENTS NOT CONTAINED IN IAEA GS-R-3 (cont.)

(ISO 9001:2008 requirements are reproduced in unedited form; notes to aid users in meeting the requirements relate to the text in italics.)

Clause	ISO 9001:2008 requirements	Notes to aid users of GS-R-3 in meeting the ISO 9001:2008 requirements
4.2.4	<p>Control of records Records established to provide evidence of conformity to requirements and of the effective operation of the quality management system shall be controlled. The organization shall establish <i>a documented procedure</i> to define the controls needed for the identification, storage, protection, retrieval, retention and disposition of records. Records shall remain legible, readily identifiable and retrievable.</p>	<p>IAEA GS-R-3 does not specify the processes that are required to be documented. It gives the authority and responsibility for documentation of processes to management. A procedure describes a specific way to carry out an activity or a process. IAEA GS-R-3 has a generic requirement for documented processes, including maintaining their related supporting documentation, which may include approved current procedures, instructions, drawings, records, etc. Furthermore, IAEA GS-R-3 requires the development, implementation and management of processes for control of documents and records. Developing such processes for control of documents and records will normally ensure that this requirement of ISO 9001:2008 is met.</p>
5.1–5.4 Management responsibility		
5.1 Management commitment		
5.1	<p>Top management shall provide evidence of its commitment in the development and implementation of the quality management system and continually improving its effectiveness by:</p> <ul style="list-style-type: none"> (a) communicating to the organization the importance of meeting <i>customer</i> as well as statutory and regulatory requirements, (b) establishing the quality policy, (c) ensuring that quality objectives are established, (d) conducting management reviews, and (e) ensuring the availability of resources. 	<p>Customers are included among interested parties. Therefore these requirements are addressed in IAEA GS-R-3.</p>

TABLE 2. ISO 9001:2008 REQUIREMENTS NOT CONTAINED IN IAEA GS-R-3 (cont.)

(ISO 9001:2008 requirements are reproduced in unedited form; notes to aid users in meeting the requirements relate to the text in italics.)

Clause	ISO 9001:2008 requirements	Notes to aid users of GS-R-3 in meeting the ISO 9001:2008 requirements
5.2 Customer focus		
5.2	Top management shall ensure that <i>customer</i> requirements are determined and are met with the aims of enhancing <i>customer satisfaction</i> (see 7.2.1 and 8.2.1).	Customers are included among interested parties. Therefore these requirements are addressed in IAEA GS-R-3.
5.3 Quality policy		
5.3	Top management shall ensure that the <i>quality policy</i> : (a) is appropriate to the purpose of the organization, (b) includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system, (c) provides a framework for establishing and reviewing quality objectives, (d) is communicated, and understood within the organization, and (e) is reviewed for continuing suitability.	IAEA GS-R-3 does not specify the content of policies, but it does require policy statements of the organization that address ‘quality’, although IAEA GS-R-3 does not mention or use the term ‘quality policy’. IAEA GS-R-3 makes provision for integrating requirements from other relevant codes and standards adopted for use by an organization. The ISO 9001:2008 requirements on policy content can be incorporated into an IAEA GS-R-3 based management system through this mechanism or provision.
5.4 Planning		
5.4.1	<i>Quality objectives</i> Top management shall ensure that <i>quality objectives</i> , including those needed to meet requirements for product [see 7.1 a)], are established at relevant functions and levels within the organization. The <i>quality objectives</i> shall be measurable and consistent with the quality policy.	IAEA GS-R-3 requires senior management to establish goals, strategies, plans and objectives that are consistent with the policies of the organization. This includes ‘quality’ as well, even though the expression ‘quality objectives’ is not explicitly mentioned.

TABLE 2. ISO 9001:2008 REQUIREMENTS NOT CONTAINED IN IAEA GS-R-3 (cont.)

(ISO 9001:2008 requirements are reproduced in unedited form; notes to aid users in meeting the requirements relate to the text in italics.)

Clause	ISO 9001:2008 requirements	Notes to aid users of GS-R-3 in meeting the ISO 9001:2008 requirements
5.4.2	<p><i>Quality management system planning</i> Top management shall ensure that:</p> <p>(a) the planning of the quality management system is carried out in order to meet the requirement given in 4.1, as well as the quality objectives, and</p> <p>(b) the integrity of quality management system is maintained when changes to the quality management system are planned and implemented.</p>	<p>See the notes to aid users in meeting requirement 5.4.1.</p> <p>IAEA GS-R-3 does not contain direct reference to management system planning including maintaining the integrity of the management system when changes are made to the system.</p> <p>The requirements in IAEA GS-R-3 relating to planning should be taken to include planning of the quality management system. There is a requirement on senior management to review the implementation of plans and to take corrective or preventive action as needed.</p> <p>Processes to manage organizational change should be taken to include processes to maintain the integrity of the management system when changes to the organization or the management system are planned and implemented.</p>
5.5 Responsibility, authority and communication		
5.5.2	<p>Management representative Top management shall appoint a <i>member of the organization's management</i> who, irrespective of other responsibilities, shall have responsibility and authority that includes:</p> <p>(a) ensuring that processes needed for the quality management system are established, implemented and maintained,</p> <p>(b) reporting to top management on the performance of the quality management system, and any need for improvement, and</p> <p>(c) ensuring the promotion of awareness of <i>customer</i> requirements through the organization.</p> <p>Note: The responsibility of a management representative can include liaison with external parties on matters relating to the quality management system</p>	<p>The appointed individual (see para. 3.13 of GS-R-3) should be a member of the organization's management.</p> <p>Customers are included among interested parties. Therefore these requirements are addressed in IAEA GS-R-3.</p>

TABLE 2. ISO 9001:2008 REQUIREMENTS NOT CONTAINED IN IAEA GS-R-3 (cont.)

(ISO 9001:2008 requirements are reproduced in unedited form; notes to aid users in meeting the requirements relate to the text in italics.)

Clause	ISO 9001:2008 requirements	Notes to aid users of GS-R-3 in meeting the ISO 9001:2008 requirements
5.5.3	<p>Internal communication Top management shall ensure that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the <i>quality management system</i>.</p>	<p>IAEA GS-R-3 requires internal communication between the various levels and functions of the organization regarding the implementation and effectiveness of the management system. The expression ‘effectiveness of the quality management system’ is not explicitly mentioned. Thus, there is no need for a special recommendation, as this requirement is implicitly covered in IAEA GS-R-3.</p>
5.6 Management review		
5.6.1	<p>General Top management shall review the organization’s quality management system, at planned intervals, to ensure its continued suitability, adequacy and effectiveness. This review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives. <i>Records from management review shall be maintained (see 4.2.4).</i></p>	<p>Although IAEA GS-R-3 does not contain any explicit reference to such records, they are implicitly included, as they would normally be specified in process documentation for the management system review activity or process. Records from management review should be maintained.</p>
5.6.2	<p>Review input The input to management review shall include information on (a) results of audits, (b) <i>customer feedback</i>, (c) process performance and product conformity, (d) status of preventive and corrective actions, (e) follow-up actions from previous management reviews, (f) changes that could affect the quality management system, (g) recommendations for improvement.</p>	<p>Customer feedback should be included as an input to management review in IAEA GS-R-3.</p>

TABLE 2. ISO 9001:2008 REQUIREMENTS NOT CONTAINED IN IAEA GS-R-3 (cont.)

(ISO 9001:2008 requirements are reproduced in unedited form; notes to aid users in meeting the requirements relate to the text in italics.)

Clause	ISO 9001:2008 requirements	Notes to aid users of GS-R-3 in meeting the ISO 9001:2008 requirements
5.6.3	<p><i>Review output</i> The output from the management review shall include any decisions and actions related to</p> <ul style="list-style-type: none"> (a) improvement of the effectiveness of the quality management system and its processes, (b) improvement of product related to <i>customer requirements</i>, (c) resource needs. 	<p>Any decisions and actions relating to improvement of products relating to customer requirements should be included as an output from management review in IAEA GS-R-3.</p>
6.1–6.4 Resource management		
6.1 Provision of resources		
6.1	<p>The organization shall determine and provide the resources needed</p> <ul style="list-style-type: none"> (a) to implement and maintain the quality management system and continually improve its effectiveness, and (b) to enhance <i>customer satisfaction</i> by meeting <i>customer requirements</i>. 	<p>Customers are included among interested parties. Therefore these requirements are addressed in IAEA GS-R-3.</p>
6.2 Human resources		
6.2.2	<p><i>Competence, training and awareness</i> <i>The organization shall</i></p> <ul style="list-style-type: none"> (a) determine the necessary competence for personnel performing work affecting conformity to product requirements, (b) where applicable, provide training or take other actions to achieve the necessary competence, (c) evaluate the effectiveness of the actions taken, (d) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives, and (e) <i>maintain appropriate records of education, training, skills and experience (see 4.2.4).</i> 	<p>IAEA GS-R-3 does not explicitly mention records of education, training, skills and experience. It requires records to be specified in the process documentation and control of the specified records. Records of education, training, skills and experience in their respective processes should be maintained.</p>

TABLE 2. ISO 9001:2008 REQUIREMENTS NOT CONTAINED IN IAEA GS-R-3 (cont.)

(ISO 9001:2008 requirements are reproduced in unedited form; notes to aid users in meeting the requirements relate to the text in italics.)

Clause	ISO 9001:2008 requirements	Notes to aid users of GS-R-3 in meeting the ISO 9001:2008 requirements
6.3 Infrastructure		
6.3	<p>The organization shall determine, provide and maintain the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable</p> <p>(a) <i>buildings, workspace and associated utilities,</i></p> <p>(b) <i>process equipment (both hardware and software), and</i></p> <p>(c) <i>supporting services (such as transport, communication, or information systems).</i></p>	<p>IAEA GS-R-3 does not explicitly mention the information given in ISO 9001:2008 clauses 6.3 (a), (b) and (c). The detail provided in ISO 9001:2008 should be integrated into an IAEA GS-R-3 based management system, together with the recommendations provided in Ref. [2].</p>
7.1–7.6 Product realization		
7.1 Planning of product realization		
7.1	<p>The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the <i>quality management system</i> (see 4.1).</p> <p>In planning product realization, the organization shall determine the following, as appropriate:</p> <p>(a) <i>quality objectives</i> and requirements for the product;</p> <p>(b) the need to establish processes and documents, and to provide resources specific to the product;</p> <p>(c) required verification, validation, monitoring, measurement, inspection and test activities specific to the product and the criteria for product acceptance;</p> <p>(d) records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.4).</p> <p>The output of this planning shall be in a form suitable for the organization’s method of operations.</p>	<p>GS-R-3 requires senior management to establish goals, strategies, plans and objectives that are consistent with the policies of the organization. This includes ‘quality’ as well, even if there is no explicit mention of the expression ‘quality objectives’ in GS-R-3.</p>

TABLE 2. ISO 9001:2008 REQUIREMENTS NOT CONTAINED IN IAEA GS-R-3 (cont.)

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Clause	ISO 9001:2008 requirements	Notes to aid users of GS-R-3 in meeting the ISO 9001:2008 requirements
7.2 Customer related processes		
7.2.1	<p>Determination of requirements related to the product The organization shall determine</p> <ul style="list-style-type: none"> (a) requirements specified by the <i>customer</i>, including the requirements for delivery and post-delivery activities, (b) requirements not stated by the <i>customer</i> but necessary for specified or intended use, where known, (c) statutory and regulatory requirements applicable to the product, and any additional requirements considered necessary by the organization. 	<p>Customers are included among interested parties. Therefore these requirements are addressed in IAEA GS-R-3.</p>
7.2.2	<p>Review of requirements related to the product The organization shall review the requirements related to the product. This review shall be conducted prior to the organization's commitment to supply a product to the <i>customer</i> (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and shall ensure that</p> <ul style="list-style-type: none"> (a) product requirements are defined, (b) contract or order requirements differing from those previously expressed are resolved, and (c) the organization has the ability to meet the defined requirements. <p>Records of the results of the review and actions arising from the review shall be maintained (see 4.2.4).</p> <p>Where the <i>customer</i> provides no documented statement of requirement, the customer requirements shall be confirmed by the organization before acceptance.</p> <p>Where product requirements are changed, the organization shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements</p>	<p>Customers are included among interested parties. Where the customer provides no documented statement of requirement, the customer requirements should be confirmed by the organization before acceptance.</p>

TABLE 2. ISO 9001:2008 REQUIREMENTS NOT CONTAINED IN IAEA GS-R-3 (cont.)

(ISO 9001:2008 requirements are reproduced in unedited form; notes to aid users in meeting the requirements relate to the text in italics.)

Clause	ISO 9001:2008 requirements	Notes to aid users of GS-R-3 in meeting the ISO 9001:2008 requirements
7.2.3	<p>Customer communication</p> <p>The organization shall determine and implement effective arrangements for communicating with <i>customers</i> in relation to</p> <ul style="list-style-type: none"> (a) product information, (b) enquiries, contracts or order handling, including amendments, and (c) <i>customer feedback</i>, including <i>customer complaints</i>. 	<p>Customers are included among interested parties. Therefore these requirements are addressed in IAEA GS-R-3.</p>
7.3 Design and development		
7.3.1	<p>Design and development planning</p> <p>The organization shall plan and control the design and development of product.</p> <p>During the design and development planning, the organization shall determine</p> <ul style="list-style-type: none"> (a) <i>the design and development stages</i>, (b) the review, verification and validation that are appropriate to each design and development stage, and (c) the responsibilities and authorities for design and development. <p>The organization shall manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility.</p> <p>Planning output shall be updated, as appropriate, as the design and development progresses.</p>	<p>IAEA GS-R-3 contains generic requirements for all processes, including design processes. The organization should determine the design and development stages.</p>
7.3.2	<p>Design and development inputs</p> <p>Inputs relating to product requirements shall be determined and records maintained (see 4.2.4). These inputs shall include</p> <ul style="list-style-type: none"> (a) <i>functional and performance requirements</i>, (b) applicable statutory and regulatory requirements, (c) <i>where applicable, information derived from previous similar designs, and</i> (d) <i>other requirements essential for design and development</i>. <p>The inputs shall be reviewed for adequacy. Requirements shall be complete, unambiguous and not in conflict with each other.</p>	<p>Inputs to design and development should include functional and performance requirements where applicable, information derived from previous similar designs, and other requirements essential for design and development.</p>

TABLE 2. ISO 9001:2008 REQUIREMENTS NOT CONTAINED IN IAEA GS-R-3 (cont.)

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Clause	ISO 9001:2008 requirements	Notes to aid users of GS-R-3 in meeting the ISO 9001:2008 requirements
7.3.3	<p><i>Design and development outputs</i> The outputs of design and development shall be in a form suitable for verification against the design and development input and shall be approved prior to release. Design and development outputs shall</p> <ul style="list-style-type: none"> (a) meet the input requirements for design and development, (b) <i>provide appropriate information for purchasing, production and service provision,</i> (c) contain or reference product acceptance criteria, and (d) specify the characteristics of the product that are essential for its safe and proper use. 	<p>Outputs of design and development should provide appropriate information for purchasing, production and service provision.</p>
7.3.4	<p><i>Design and development review</i> At suitable stages, systematic reviews of design and development shall be performed in accordance with planned arrangements (see 7.3.1)</p> <ul style="list-style-type: none"> (a) to evaluate the ability of the results of design and development to meet requirements, and (b) to identify any problems and propose necessary actions. <p>Participants in such reviews shall include representatives of functions concerned with the design and development stage(s) being reviewed. Records of the results of the reviews and any necessary actions shall be maintained (see 4.2.4).</p>	<p>IAEA GS-R-3 contains generic requirements for all processes, including design processes. The requirements are therefore addressed.</p>
7.3.5	<p><i>Design and development verification</i> Verification shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the design and development outputs have met the design and development input requirements. Records of the results of the verification and any necessary actions shall be maintained (see 4.2.4).</p>	<p>IAEA GS-R-3 contains generic requirements for all processes, including design processes. The requirements are therefore addressed.</p>

TABLE 2. ISO 9001:2008 REQUIREMENTS NOT CONTAINED IN IAEA GS-R-3 (cont.)

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Clause	ISO 9001:2008 requirements	Notes to aid users of GS-R-3 in meeting the ISO 9001:2008 requirements
7.3.6	<p><i>Design and development validation</i> Design and development validation shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where known. Wherever practicable, validation shall be completed prior to the delivery or implementation of the product. Records of the results of validation and any necessary actions shall be maintained (see 4.2.4).</p>	<p>IAEA GS-R-3 contains generic requirements for all processes, including design processes. The requirements are therefore addressed.</p>
7.3.7	<p><i>Control of design and development changes</i> Design and development changes shall be identified and records maintained. The changes shall be reviewed, verified and validated, as appropriate, and approved before implementation. The review of design and development changes shall include evaluation of the effect of the changes on constituent parts and product already delivered. Records of the results of the review of changes and any necessary actions shall be maintained (see 4.2.4).</p>	<p>IAEA GS-R-3 contains generic requirements for all processes, including design processes. The requirements are therefore addressed.</p>
7.4 Purchasing		
7.4.1	<p><i>Purchasing process</i> The organization shall ensure that purchased product conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on subsequent product realization or the final product. The organization shall evaluate and select suppliers based on their ability to supply product in accordance with the organization's requirements. Criteria for selection, evaluation and re-evaluation shall be established. <i>Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained (see 4.2.4).</i></p>	<p>IAEA GS-R-3 includes requirements for the control of records. It is the responsibility of the process owner to define the records required as part of the process documentation (see para. 5.6 of IAEA GS-R-3). The process should include records of the results of evaluations of suppliers and any necessary actions arising from the evaluation.</p>

TABLE 2. ISO 9001:2008 REQUIREMENTS NOT CONTAINED IN IAEA GS-R-3 (cont.)

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Clause	ISO 9001:2008 requirements	Notes to aid users of GS-R-3 in meeting the ISO 9001:2008 requirements
7.4.2	<p><i>Purchasing information</i> Purchasing information shall describe the product to be purchased, including where appropriate (a) requirements for approval of product, procedures, processes and equipment, (b) requirements for qualification of personnel, and (c) quality management system requirements. The organization shall ensure the adequacy of specified purchase requirements prior to their communication to the supplier.</p>	<p>IAEA GS-R-3 does not specifically address purchasing information; rather, it uses the expression ‘procurement documents’ and requires purchasing requirements to be developed and specified in the procurement documents.</p>
7.4.3	<p><i>Verification of purchased product</i> The organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements. Where the organization or its customer intends to perform verification at the supplier’s premises, the organization shall state the intended verification arrangements and method of product release in the purchasing information.</p>	<p>IAEA GS-R-3 does not specifically require that intended verification arrangements and the method of product release be addressed in the procurement documents. Verification of products, including purchased products, is covered in para. 5.15 of IAEA GS-R-3.</p>
7.5 Production and service provision		
7.5.2	<p><i>Validation of processes for production and service provision</i> The organization shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement and, as a consequence, deficiencies become apparent only after the product is in use or the service has been delivered. Validation shall demonstrate the ability of these processes to achieve planned results. The organization shall establish arrangements for these processes including, as applicable (a) defined criteria for review and approval of the processes, (b) approval of equipment and qualification of personnel, (c) use of specific methods and procedures, (d) requirements for records (see 4.2.4), and (e) revalidation.</p>	<p>IAEA GS-R-3 provides requirements on validation but does not provide details of the validation process. Validation of processes is covered in paras 5.3 and 5.8 of IAEA GS-R-3.</p>

TABLE 2. ISO 9001:2008 REQUIREMENTS NOT CONTAINED IN IAEA GS-R-3 (cont.)

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Clause	ISO 9001:2008 requirements	Notes to aid users of GS-R-3 in meeting the ISO 9001:2008 requirements
7.5.4	<p><i>Customer property</i> The organization shall exercise care with customer property while it is under the organization’s control or being used by the organization. The organization shall identify, verify, protect and safeguard customer property provided for use or incorporation into the product. If any customer property is lost, damaged or otherwise found to be unsuitable for use, the organization shall report this to the customer and maintain records (see 4.2.4).</p>	<p>This requirement should be integrated into a management system based on IAEA GS-R-3; this could be done in the section dealing with requirements for processes regarding the control of products.</p>
<p>7.6 Control of monitoring and measurement equipment</p>		
7.6	<p>The organization shall determine the monitoring and measurement to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity of product to determined requirements. <i>The organization shall establish processes to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements.</i> <i>Where necessary to ensure valid results, measuring equipment shall</i> (a) <i>be calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded (see 4.2.4);</i> (b) <i>be adjusted or re-adjusted as necessary;</i> (c) <i>have identification in order to determine its calibration status;</i> (d) <i>be safeguarded from adjustments that would invalidate the measurement result;</i> (e) <i>be protected from damage and deterioration during handling, maintenance and storage.</i></p>	<p>IAEA GS-R-3 requires the tools and equipment used for these activities to be of the proper range, type, accuracy and precision, but does not provide details relating to ‘control of monitoring and measurement devices’. The ISO 9001:2008 requirements in this area should be integrated into a management system based on IAEA GS-R-3, with the appropriate adaptation or changes to the ISO 9001:2008 terminology to harmonize it with IAEA GS-R-3 language.</p>

TABLE 2. ISO 9001:2008 REQUIREMENTS NOT CONTAINED IN IAEA GS-R-3 (cont.)

(ISO 9001:2008 requirements are reproduced in unedited form; notes to aid users in meeting the requirements relate to the text in italics.)

Clause	ISO 9001:2008 requirements	Notes to aid users of GS-R-3 in meeting the ISO 9001:2008 requirements
7.6 (cont.)	<p><i>In addition, the organization shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. The organization shall take appropriate action on the equipment and any product affected.</i></p> <p><i>Records of the results of calibration and verification shall be maintained (see 4.2.4).</i></p> <p><i>When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application shall be confirmed. This shall be undertaken prior to initial use and reconfirmed as necessary.</i></p>	
<p>8.1–8.5 Measurement, analysis and improvement</p>		
<p>8.2 Monitoring and measurement</p>		
8.2.1	<p><i>Customer satisfaction</i></p> <p>As one of the measurements of the performance of the quality management system, the organizations shall monitor information relating to <i>customer perception</i> as to whether the organization has met <i>customer requirements</i>. The methods for obtaining and using this information shall be determined.</p>	<p>Customers are included among interested parties. Therefore these requirements are addressed in IAEA GS-R-3.</p>
8.2.2	<p><i>Internal audit</i></p> <p>The organization shall conduct internal audits at planned intervals to determine whether the quality management system</p> <p>(a) conforms to the planned arrangements (see 7.1), to the requirements of this International Standard and to the quality management system requirements established by the organization, and</p> <p>(b) is effectively implemented and maintained.</p> <p>An <i>audit programme</i> shall be planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods shall be defined. The selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work.</p>	<p>IAEA GS-R-3 assessments include audits. The management system should include an audit programme as part of independent assessment.</p> <p>IAEA GS-R-3 focuses on processes, but it does not specify the processes to be documented. It gives the authority and responsibility for documenting processes to management.</p>

TABLE 2. ISO 9001:2008 REQUIREMENTS NOT CONTAINED IN IAEA GS-R-3 (cont.)

(ISO 9001:2008 requirements are reproduced in unedited form; notes to aid users in meeting the requirements relate to the text in italics.)

Clause	ISO 9001:2008 requirements	Notes to aid users of GS-R-3 in meeting the ISO 9001:2008 requirements
8.2.2	<p><i>A documented procedure shall be established to define the responsibilities and requirements for planning and conducting audits, establishing records and reporting results.</i></p> <p>Records of the audits and their results shall be maintained (see 4.2.4).</p> <p>The management responsible for the area being audited shall ensure that any necessary corrections and corrective actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities shall include the verification of the actions taken and the reporting of verification results (see 8.5.2).</p>	<p>There should be a documented procedure that defines the responsibilities and requirements for planning and conducting audits, establishing records and reporting results.</p>
8.2.4	<p><i>Monitoring and measurement of product</i></p> <p>The organization shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at appropriate stages of the product realization process in accordance with the planned arrangements (see 7.1). <i>Evidence of conformity with the acceptance criteria shall be maintained. Records shall indicate the person(s) authorizing release of product for delivery to the customer (see 4.2.4).</i></p> <p>The release of product and delivery of service to the customer shall not proceed until the planned arrangements (see 7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.</p>	<p>IAEA GS-R-3 does not have explicit requirements for the maintenance of evidence of conformity, nor does it require the explicit recording of the identity of the person(s) authorizing the release of product for delivery to the customer.</p> <p>However, there are IAEA GS-R-3 requirements relating to non-conformances and corrective and preventive actions that address products and processes not conforming to specified requirements. Evidence of conformity with the acceptance criteria should be maintained. Records should indicate the person(s) authorizing release of product for delivery to the customer.</p>

TABLE 2. ISO 9001:2008 REQUIREMENTS NOT CONTAINED IN IAEA GS-R-3 (cont.)

(ISO 9001:2008 requirements are reproduced in unedited form; notes to aid users in meeting the requirements relate to the text in italics.)

Clause	ISO 9001:2008 requirements	Notes to aid users of GS-R-3 in meeting the ISO 9001:2008 requirements
8.3 Control of nonconforming product		
8.3	<p>The organization shall ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. <i>A documented procedure shall be established to define the controls and related responsibilities and authorities for dealing with nonconforming product.</i></p> <p>Where applicable, the organization shall deal with nonconforming product by one or more of the following ways:</p> <ul style="list-style-type: none"> (a) by taking action to eliminate the detected nonconformity; (b) by authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer; (c) by taking action to preclude its original intended use or application; (d) by taking action appropriate to the effects, or potential effects, of the nonconformity when nonconforming product is detected after delivery or use has started. <p>When nonconforming product is corrected it shall be subject to re-verification to demonstrate conformity to the requirements.</p> <p>Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained (see 4.2.4).</p>	<p>IAEA GS-R-3 does not specify the processes that are required to be documented, because it is up to each organization to determine the processes that are needed to achieve organizational goals, to provide the means to meet all requirements and to deliver the products of the organization. Control of non-conformities should be defined in a documented procedure.</p>
8.4 Analysis of data		
8.4	<p><i>The organization shall determine, collect and analyse appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the effectiveness of the quality management system can be made. This shall include data generated as a result of monitoring and measurement and from other relevant sources.</i></p>	<p>IAEA GS-R-3 does not have specific requirements on collection and analysis of data to monitor the effectiveness of the management system.</p>

TABLE 2. ISO 9001:2008 REQUIREMENTS NOT CONTAINED IN IAEA GS-R-3 (cont.)

(ISO 9001:2008 requirements are reproduced in unedited form; notes to aid users in meeting the requirements relate to the text in italics.)

Clause	ISO 9001:2008 requirements	Notes to aid users of GS-R-3 in meeting the ISO 9001:2008 requirements
8.4	<p><i>The analysis of data shall provide information relating to:</i></p> <ul style="list-style-type: none"> (a) <i>customer satisfaction (see 8.2.1),</i> (b) <i>conformity to product requirements (see 8.2.4),</i> (c) <i>characteristics and trends of processes and products including opportunities for preventive action (see 8.2.3 and 8.2.4), and</i> (d) <i>suppliers (see 7.4).</i> 	<p>Paragraph 6.1 of IAEA GS-R-3 does in general terms require that the effectiveness of the management system be monitored and measured. The detailed or specific ISO 9001:2008 requirements should be integrated into a management system based on IAEA GS-R-3, as necessary.</p>
8.5 Improvement		
8.5.2	<p><i>Corrective action</i></p> <p>The organization shall take action to eliminate the causes of nonconformities in order to prevent recurrence. Corrective actions shall be appropriate to the effects of the nonconformities encountered. <i>A documented procedure shall be established to define requirements for</i></p> <ul style="list-style-type: none"> (a) <i>reviewing nonconformities (including customer complaints),</i> (b) <i>determining the causes of nonconformities,</i> (c) <i>evaluating the need for action to ensure that nonconformities do not recur,</i> (d) <i>determining and implementing action needed,</i> (e) <i>records of the results of action taken (see 4.2.4), and</i> (f) <i>reviewing the effectiveness of the corrective action taken.</i> 	<p>Arrangements for corrective action should be documented.</p>

TABLE 2. ISO 9001:2008 REQUIREMENTS NOT CONTAINED IN IAEA GS-R-3 (cont.)

(ISO 9001:2008 requirements are reproduced in unedited form; notes to aid users in meeting the requirements relate to the text in italics.)

Clause	ISO 9001:2008 requirements	Notes to aid users of GS-R-3 in meeting the ISO 9001:2008 requirements
8.5.3	<p><i>Preventive action</i></p> <p>The organization shall take action to eliminate the cause of nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential problems.</p> <p><i>A documented procedure</i> shall be established to define requirements for</p> <ul style="list-style-type: none"> (a) determining potential nonconformities and their causes, (b) evaluating the need for action to prevent occurrences of nonconformities, (c) determining and implementing action needed, (d) records of results of action taken (see 4.2.4), and (e) reviewing the effectiveness of the preventive action taken. 	<p>Arrangements for preventive action should be documented.</p>

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