ISO 9001 or IAEA GS-R-3?

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Abstract: This article identifies, characterises and analyses International Organisation for Standardisation (ISO) and International Atomic Energy Agency (IAEA) normative requirements for the development and implementation of quality management systems in nuclear organisations. The applicable standards are identified and their requirements are characterised and reviewed. The correspondence and correlation between the applicable standards' requirements are presented.

Keywords: ISO 9001; IAEA GS-R-3; management systems; nuclear organisations; nuclear technology; quality; safety.

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1 Introduction

Publication IAEA GS-R-3 (IAEA, 2006) defines the requirements for establishing, implementing, assessing and continually improving a management system. A management system designed to fulfill these requirements integrates safety, health, environmental, security, quality and economic elements. Safety is the fundamental principle upon which the management system is based. These requirements must be met to ensure the protection of people and the environment.

Publication ISO 9001:2008 (ISO, 2008) specifies the requirements for a quality management system where an organisation needs to demonstrate its ability to consistently provide a product that meets customer and applicable statutory and regulatory requirements and aims to enhance customer satisfaction through the effective application of the system, including processes for the continual improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements.
2 Identification of the applicable standards

According to the information obtained in the International Atomic Energy Agency (IAEA) and International Organisation for Standardisation (ISO) databases, the following applicable standards will be studied in this paper:

- IAEA GS-R-3 – The management system for facilities and activities: safety requirements

3 Characterisation of the applicable standards

3.1 IAEA GS-R-3 – The management system for facilities and activities: safety requirements

IAEA GS-R-3 – The management system for facilities and activities: safety requirements, published in 2006, defines the requirements for establishing, implementing, assessing and continually improving a management system that integrates safety, health, environmental, security, quality and economic elements and ensures that safety is properly taken into account in all the activities of an organisation.

The management system is a set of interrelated or interacting elements (system) for establishing policies and objectives and enabling these objectives to be achieved in an efficient and effective way.

Publication IAEA GS-R-3 replaces Code IAEA 50-C-Q (IAEA, 1996) – Quality assurance for safety in nuclear power plants and other nuclear installations, which was published in 1996. It makes use of the expression ‘management system’ instead of the expression ‘quality assurance’. The expression ‘management system’ reflects and includes the concept of ‘quality control’ (quality control of products) and its evolution to the concepts of ‘quality assurance’ (the system to assure the quality of products) and ‘quality management’ (the system to manage quality).

IAEA GS-R-3 is applicable to the establishment, implementation, assessment and continual improvement of management systems for nuclear facilities, activities using sources of ionising radiation, radioactive waste management, the transport of radioactive material, radiation protection activities, any other practices or circumstances in which people may be exposed to radiation from naturally occurring or artificial sources and the regulation of such facilities and activities.

This publication is applicable throughout the lifetime of facilities and for the entire duration of the activities in normal, transient and emergency situations.

The structure of IAEA GS-R-3 consists of six sections:

1 Introduction
2 Management system
   • General requirements
   • Safety culture
   • Grading the application of management system requirements
   • Documentation of the management system
3 Management responsibility
   • Management commitment
   • Satisfaction of interested parties
   • Organisational policies
   • Planning
   • Responsibility and authority for the management system

4 Resource management
   • Provision of resources
   • Human resources
   • Infrastructure and the working environment

5 Process implementation
   • Developing processes
   • Process management
   • Generic management system processes: control of documents, control of products, control of records, purchasing, communication, managing organisational change

6 Measurement, assessment and improvement
   • Monitoring and measurement
   • Self assessment
   • Independent assessment
   • Management system review
   • Non-conformances and corrective and preventive actions
   • Improvement.

Section 1 is introductory and describes the background, objective, scope and structure of IAEA GS-R-3.
Section 2 establishes the general requirements for the management system, including those related to safety culture, grading and documentation.
Section 3 establishes the management’s responsibility and requirements for the development and implementation of a management system, including the requirements for management commitment, satisfaction of interested parties, organisational policies, planning, responsibility and authority for the management system.
Section 4 establishes the requirements for resource management, including the requirements for the provision of resources, human resources, infrastructure and the working environment.
Section 5 establishes the requirements for the specification, development and management of the core processes of the organisation and the requirements for generic management system processes: control of documents, control of products, control of records, purchasing, communication and managing organisational change.
Section 6 establishes the requirements for the measurement, assessment and improvement of the management system. The requirements for monitoring and measurement, self-assessment, independent assessment, management system review, nonconformances, corrective and preventive actions, and improvement for the management system are also established.

3.2 ISO 9001:2008 – Quality management systems – requirements

ISO 9001:2008 – Quality management systems – Requirements, published in 2008, is a generic management system standard that means that all the requirements of this international standard are generic and are intended to be applicable to all organisations regardless of the type, size and product provided. This standard is focused on the processes that influence the quality of products and is not directly focused on the products themselves. The quality management system requirements specified by this standard are complementary to the requirements of products.

This international standard specifies the requirements for a quality management system where an organisation needs to demonstrate its ability to consistently provide a product that meets customer and applicable statutory and regulatory requirements and aims to enhance customer satisfaction through the effective application of the system, including processes for the continual improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements.

ISO 9001:2008 has the following structure:

0 Introduction
1 Scope
2 Normative reference
3 Terms and definitions
4 Quality management system
   • General requirements
   • Documentation requirements: general, quality manual, control of documents, control of records
5 Management responsibility
   • Management commitment
   • Customer focus
   • Quality policy
   • Planning: quality objectives, quality management system planning
   • Responsibility, authority and communication: responsibility and authority, management representative, internal communication
   • Management review: general, review input, review output
6 Resource management
   • Provision of resources
- Human resources: general, competence, training, and awareness
- Infrastructure
- Work environment

7 Product realisation
- Planning of product realisation
- Customer-related processes: determination of requirements related to the product, review of requirements related to the product, customer communication
- Design and development: design and development planning, design and development inputs, design and development outputs, design and development review, design and development verification, design and development validation, control of design and development changes
- Purchasing: purchasing process, purchasing information, verification of purchased product
- Production and service provision: control of production and service provision, validation of processes for production and service provision, identification and traceability, customer property, preservation of product
- Control of monitoring and measuring devices

8 Measurement, analysis and improvement
- General
- Monitoring and measurement: customer satisfaction, internal audit, monitoring and measurement of processes, monitoring and measurement of product
- Control of nonconforming product
- Analysis of data
- Improvement: continual improvement, corrective action, preventive action.

ISO 9001:2008 Sections 0 to 3 are merely introductory. Section 0 introduces the concept of a quality management system, Section 1 presents the standard objective, Section 2 indicates the normative reference used and Section 3 refers to the terms and definitions used.

Section 4 describes the general requirements for an organisation to establish, document, implement and maintain a quality management system and continually improve its effectiveness.

Section 5 describes the organisation’s responsibility, its commitment to the quality management system, the satisfaction of customer requirements, the quality policy elaboration, the quality management system planning and the definition of responsibilities, authorities and communication in the organisation.

Section 6 deals with resource management, personnel competence, infrastructure and the work environment. The organisation should determine and supply the necessary resources to implement, maintain and continually improve the quality management system and increase customer satisfaction.
Section 7 describes the product realisation process and its planning, the customer-related processes, design and development stages, purchasing process, production and service provision and control of monitoring and measuring devices.

Section 8 deals with measurement, analysis and improvement requirements. The organisation should plan and implement the necessary processes of monitoring, measurement, analysis and improvement to demonstrate the conformance of products, ensure the conformance of the quality management system and continually improve its effectiveness.

4 Review of the applicable standards’ requirements

4.1 Objectives

IAEA GS-R-3 is intended to help an organisation 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 organisation. The implementation of a strong safety culture is the main focus of the management system.

ISO 9001:2008 allows an organisation to demonstrate its ability to meet the customer and statutory and regulatory requirements applicable to a product (in addition to its own organisational requirements) and to enhance customer satisfaction.

ISO 9001:2008 does not include requirements that are specific to other management systems, such as those particular to environmental management, occupational health and safety management, financial management or risk management. However, this publication enables an organisation to align or integrate its own quality management system with related management system requirements.

4.2 Focus, scope and level of application

IAEA GS-R-3 is a nuclear industry-specific standard and has its focus on achieving and enhancing safety while enhancing the satisfaction of interested parties.

ISO 9001:2008 is a generic standard and has its focus on customer satisfaction while assuring the conformity to customer and applicable statutory and regulatory requirements.

IAEA GS-R-3 integrates the requirements of all the factors affecting activities: customer, supplier, regulator, employee, shareholder and society requirements. ISO 9001:2008 does not include requirements that are specific to other management systems; it includes only those established in the quality management system: customer, supplier and regulator requirements.

IAEA GS-R-3 requires proactive strategic thinking, while ISO 9001:2008 is at the operational level.

Figure 1 shows the scope of application of IAEA GS-R-3 and ISO 9001:2008.
4.3 Structure

There are similarities in the applicable standards’ structures:

- management system
- management responsibility
- resource management
- process implementation or product realisation
- measurement, assessment or analysis and improvement.

However, there are differences in the emphasis and details within these main categories or chapters of requirements. Figure 2 shows the similarities of the applicable standards’ structure.
Figure 2  The similarities of IAEA GS-R-3 and ISO 9001:2008’s structures
4.4 Vocabulary


4.5 Management system

The promotion of and support for a strong safety culture is an integral part of IAEA GS-R-3. Safety culture is not a requirement of ISO 9001:2008. The graded application of requirements is an integral feature of IAEA GS-R-3, while in ISO 9001:2008, it is not a stated requirement.

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

ISO 9001:2008 provides, in the scope of application, for the exclusion of requirements within Section 7 – Product Realisation, where such exclusions do not affect the organisation’s ability or responsibility to provide a product that meets customer and applicable statutory and regulatory requirements.

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

- the policy statements
- a description of the management system
- a description of the structure of the organisation
- a description of the functional responsibilities, accountabilities, levels of authority and interactions of those managing, performing and assessing work
- a description of the processes
- records, specified in the process documentation, that are required to demonstrate that the process results have been achieved.

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

1. quality policy and quality objectives
2. a quality manual
3. documented procedures for:
   - control of documents
   - control of records
   - internal audit
   - control of nonconforming products
   - corrective action
   - preventive action
4. documents needed to ensure effective planning, operation and control of processes and records.
IAEA GS-R-3 requires considering the expectations and satisfaction of interested parties in the processes of its management system. The focus in IAEA GS-R-3 is on safety, but with due consideration of the expectations of interested parties.

ISO 9001:2008 focuses only on customers; it includes customer satisfaction as part of the monitoring and measurement of the performance of the quality management system.

4.6 Management responsibility

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

- developing individual values, institutional values and behavioural expectations
- communicating to the individuals the need to adopt these values and expectations
- fostering the involvement of the individuals
- establishing and developing the goals, strategies, plans and objectives of the organisation.

4.7 Resource management

IAEA GS-R-3 states that senior management shall determine the amount of resources necessary and provide the resources to carry out the activities of the organisation.

ISO 9001:2008 states that the organisation shall determine and provide the resources needed to enhance customer satisfaction by meeting customer requirements.

Both applicable standards have the following similarities about human resources:

- to determine the necessary competence for personnel performing work
- to provide training or take other actions to achieve the required level of competence.

In IAEA GS-R-3, training shall ensure that individuals are aware of how their activities contribute to safety, whereas in ISO 9001:2008, the individuals shall be aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives.

IAEA GS-R-3 does not set detailed requirements regarding infrastructure.

ISO 9001:2008 contains requirements for the infrastructure needed to achieve the desired product requirements.

4.8 Process implementation

Both applicable standards adopt the process approach, based on the concept that work may be structured and interpreted as a set of interacting processes.

In IAEA GS-R-3, process implementation addresses all management system requirements: safety, health, environmental, security, quality and economic elements, including risk management. A designated individual, named ‘process owner’, is responsible and accountable for each process. The organisation retains overall responsibility when contracting any 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. It does not specify or rely on a particular process model to present process implementation requirements, but provides generic requirements for developing and managing processes, focusing on a number of generic management system processes for the control of documents, products, records, purchasing and communication and managing organisational change.

ISO 9001:2008 considers the processes needed for product realisation and focuses mainly on product quality. It 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 continual improvement based on objective measurement. The model emphasises the responsibility of management to manage resources, establish product realisation processes and monitor process effectiveness in delivering a conforming product.

IAEA GS-R-3 regards design as one of the processes to be developed and implemented. ISO 9001:2008 includes specific requirements to control design and development planning, the determination of design inputs and outputs, design review, verification and validation and the control of design changes.

IAEA GS-R-3 has specific requirements for evaluating and classifying organisational changes according to their importance to safety, justifying each change and planning, communicating, monitoring, tracking and recording the implementation of such changes to ensure that safety is not compromised. ISO 9001:2008 has no explicit requirements for managing organisational change.

4.9 Measurement, assessment and improvement

IAEA GS-R-3 only provides high-level requirements for monitoring and measuring the effectiveness of the management system. ISO 9001:2008 offers more detailed requirements, especially on customer satisfaction.

IAEA GS-R-3 requires senior management and management at all other levels in the organisation to carry out self-assessment. ISO 9001:2008 has no equivalent requirement.

5 Correspondence between IAEA GS-R-3 and ISO 9001:2008’s requirements

Table 1 presents the correspondence between IAEA GS-R-3 and ISO 9001:2008’s requirements.

Table 1 was structured with topics referred to in IAEA GS-R-3 to permit a correlation with the topics referred to in ISO 9001:2008. The formatting of the topics presented in Table 1 follows the formatting of text that appears in IAEA GS-R-3.

The following symbols were adopted in Table 1:

- ‘-o-’: topic with no direct correlation, but with some correlation in its subtopics
- ‘-x-’: topic with no correlation.

The topics between parentheses refer to ISO 9001:2008 topics with no correspondence in IAEA GS-R-3.
Table 1 The correspondence between IAEA GS-R-3 and ISO 9001:2008’s requirements

<table>
<thead>
<tr>
<th>IAEA GS-R-3</th>
<th>Topic</th>
<th>ISO 9001:2008</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Introduction</td>
<td>0</td>
</tr>
<tr>
<td>1.1–1.7</td>
<td>Background</td>
<td>0.1</td>
</tr>
<tr>
<td>1.8–1.9</td>
<td>Objective</td>
<td>1</td>
</tr>
<tr>
<td>1.10–1.13</td>
<td>Scope</td>
<td>1.2</td>
</tr>
<tr>
<td>1.14</td>
<td>Structure</td>
<td>0.2</td>
</tr>
<tr>
<td>2</td>
<td>Management system</td>
<td>4</td>
</tr>
<tr>
<td>2.1–2.4</td>
<td>General requirements</td>
<td>4.1</td>
</tr>
<tr>
<td>2.5</td>
<td>Safety culture</td>
<td>-x-</td>
</tr>
<tr>
<td>2.6–2.7</td>
<td>Grading the application of management system requirements</td>
<td>-x-</td>
</tr>
<tr>
<td>2.8–2.10</td>
<td>Documentation of the management system</td>
<td>4.2</td>
</tr>
<tr>
<td>-x-</td>
<td>(Quality manual)</td>
<td>(4.2.2)</td>
</tr>
<tr>
<td>3</td>
<td>Management responsibility</td>
<td>5</td>
</tr>
<tr>
<td>3.1–3.5</td>
<td>Management commitment</td>
<td>5.1</td>
</tr>
<tr>
<td>3.6</td>
<td>Satisfaction of interested parties</td>
<td>8.2.1</td>
</tr>
<tr>
<td>-x-</td>
<td>(Customer focus)</td>
<td>(5.2)</td>
</tr>
<tr>
<td>3.7</td>
<td>Organisational policies</td>
<td>-o-</td>
</tr>
<tr>
<td>3.8–3.11</td>
<td>Planning</td>
<td>5.4</td>
</tr>
<tr>
<td>3.12–3.14</td>
<td>Responsibility and authority for the management system</td>
<td>5.5.1; 5.5.2</td>
</tr>
<tr>
<td>4</td>
<td>Resource management</td>
<td>6</td>
</tr>
<tr>
<td>4.1–4.2</td>
<td>Provision of resources</td>
<td>6.1</td>
</tr>
<tr>
<td>4.3–4.4</td>
<td>Human resources</td>
<td>6.2</td>
</tr>
<tr>
<td>4.5</td>
<td>Infrastructure and the working environment</td>
<td>-o-</td>
</tr>
<tr>
<td>-x-</td>
<td>(Product realisation)</td>
<td>(7)</td>
</tr>
<tr>
<td>5</td>
<td>Process implementation</td>
<td>-o-</td>
</tr>
<tr>
<td>5.1–5.5</td>
<td>Developing processes</td>
<td>0.2; 7.1; 8.2.3</td>
</tr>
<tr>
<td>5.6–5.10</td>
<td>Process management</td>
<td>-x-</td>
</tr>
<tr>
<td>5.11</td>
<td>Generic management system processes</td>
<td>-o-</td>
</tr>
<tr>
<td>5.12–5.13</td>
<td>Control of documents</td>
<td>4.2.3</td>
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<tr>
<td>5.14–5.20</td>
<td>Control of products</td>
<td>7.2.1; 7.2.2; 7.5.1; 7.5.2; 7.5.3; 7.5.5; 8.2.4</td>
</tr>
<tr>
<td>-x-</td>
<td>(Customer property)</td>
<td>(7.5.4)</td>
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<tr>
<td>5.21–5.22</td>
<td>Control of records</td>
<td>4.2.4</td>
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<td>5.23–5.25</td>
<td>Purchasing</td>
<td>7.4</td>
</tr>
<tr>
<td>5.26–5.27</td>
<td>Communication</td>
<td>5.5.3; 7.2.3</td>
</tr>
<tr>
<td>5.28–5.29</td>
<td>Managing organisational change</td>
<td>-x-</td>
</tr>
</tbody>
</table>
Table 1  The correspondence between IAEA GS-R-3 and ISO 9001:2008’s requirements (continued)

<table>
<thead>
<tr>
<th>IAEA GS-R-3</th>
<th>Topic</th>
<th>ISO 9001:2008</th>
</tr>
</thead>
<tbody>
<tr>
<td>6</td>
<td>Measurement, assessment and</td>
<td>8</td>
</tr>
<tr>
<td></td>
<td>improvement</td>
<td></td>
</tr>
<tr>
<td>6.1</td>
<td>Monitoring and measurement</td>
<td>8.2</td>
</tr>
<tr>
<td>6.2</td>
<td>Self-assessment</td>
<td>-x-</td>
</tr>
<tr>
<td>6.3–6.6</td>
<td>Independent assessment</td>
<td>8.2.3; 8.2.4</td>
</tr>
<tr>
<td>6.7–6.10</td>
<td>Management system review</td>
<td>5.6</td>
</tr>
<tr>
<td>-x-</td>
<td>(Analysis of data)</td>
<td>(8.4)</td>
</tr>
<tr>
<td>6.11–6.16</td>
<td>Nonconformances and corrective and preventive actions</td>
<td>8.3</td>
</tr>
<tr>
<td>6.17–6.18</td>
<td>Improvement</td>
<td>8.5.1</td>
</tr>
<tr>
<td>References</td>
<td></td>
<td>2</td>
</tr>
<tr>
<td>Glossary</td>
<td></td>
<td>3</td>
</tr>
</tbody>
</table>

6  Correlation between the applicable standards’ requirements

As presented in Table 1, the standards that are applicable to our study are correlated in some topics. This means that the requirements of the correlated topics will be satisfied when any of the applicable standards is implemented by an organisation.

Table 1 also identifies IAEA GS-R-3 topics that have no correlation with ISO 9001:2008 topics and vice versa.

6.1 IAEA GS-R-3 topics that have no correlation with ISO 9001:2008

When organisations adopt ISO 9001:2008 as a quality management system standard, the following requirements of IAEA GS-R-3 are not being satisfied:

1. integrated management system – a management system that integrates safety, health, environmental, security, quality and economic elements
2. safety culture – the assembly of characteristics and attitudes in organisations and individuals which establishes that, as an overriding priority, protection and safety issues receive the attention warranted by their significance
3. grading the application of management system requirements – the classification of a product or activity in relation to its significance and complexity, the hazards and potential risks associated with safety, health, environmental, security, quality and economic elements and the consequences if a product fails or an activity is carried out incorrectly
4. organisational policies – the overall intentions and direction of an organisation related to safety, health, environmental, security, quality and economic elements as formally expressed by top management
process management – coordinated activities to manage and control a process, with
the definition of authority and responsibility and the specifications for performance,
verification, acceptance and assessment criteria

managing organisational change – organisational changes shall be evaluated and
classified according to their importance to safety and each change shall be justified

self-assessment – a routine and continuing process conducted by senior management
and management at other levels to evaluate the effectiveness of performance in all
areas of their responsibility.

6.2 ISO 9001:2008 topics that have no correlation with IAEA GS-R-3

When organisations adopt IAEA GS-R-3 as a management system standard, the
following requirements of ISO 9001:2008 are not being satisfied:

- quality manual – the organisation shall establish and maintain a quality manual that
describes the scope, documented procedures and interaction between the processes of
the quality management system

- customer focus – top management shall ensure that customer requirements are
determined and met with the aim of enhancing customer satisfaction

- customer property – the organisation shall exercise care with customer property
while it is under the organisation’s control or being used by the organisation

- analysis of data – the organisation shall determine, collect and analyse appropriate
data to demonstrate the suitability and effectiveness of the quality management
system and evaluate where continual improvement of the effectiveness of the quality
management system can be made.

7 Conclusions

The general objective of this paper was to identify, characterise and analyse IAEA
and ISO normative requirements for the development and implementation of quality
management systems in nuclear organisations.

To obtain the general objective of this paper, the applicable standards were identified
and their requirements were characterised, reviewed and correlated.

The methodology used in the elaboration of this paper consisted of making a review
of and correlation between the applicable standards’ requirements.

A discussion of the noncorrelated requirements was made to enable the understanding
of which requirements would not be considered when one of the applicable standards is
adopted instead of the other by an organisation.

IAEA GS-R-3 introduces the concept of an integrated management system for
nuclear organisations instead of the prior approach to a quality management system.
This publication also considers the implementation of a strong safety culture as the main
focus of the management system. No less important is the approach it makes for grading
the application of management system requirements. It is used between the nuclear
facility or activity and the regulatory interface.
ISO 9001:2008 applies to any industry aiming to implement a quality management system, with its focus on the satisfaction of customer and regulatory requirements. It is used between the nuclear facility or activity and the supplier interface. A supplier that has implemented a quality management system according to ISO 9001:2008 shall include additional requirements to his system to satisfy the nuclear requirements specified by a nuclear facility or activity.

The design and implementation of an organisation’s quality management system is influenced by its organisational environment, its varying needs, its particular objectives, the products it provides, the processes it employs, its size and its organisational structure.

The adoption of a quality management system should be an organisation’s strategic decision. However, it is fundamental for nuclear organisations to implement the requirements of IAEA GS-R-3.

References

Notes
1 From this paragraph on, the reference IAEA GS-R-3 (IAEA, 2006) will appear simply as IAEA GS-R-3.