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Quality Standards: Comparison between IAEA 50-C/SG-Q and ISO 9001:2000

International Atomic Energy Agency, Vienna, 2002

QUALITY STANDARDS: COMPARISON BETWEEN IAEA 50-C/SG-Q AND ISO 9001:2000

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

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QUALITY STANDARDS: COMPARISON BETWEEN IAEA 50-C/SG-Q AND ISO 9001:2000

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FOREWORD

The International Atomic Energy Agency (IAEA) has the statutory mandate to seek to accelerate and enlarge the contribution of atomic energy to peace, health and prosperity throughout the world. As part of the activities to achieve its objectives, the IAEA is authorized to establish standards of safety for the protection of health and the minimization of danger to life and property. The standards of safety developed by the IAEA are recommendations for use by its Member States in the framework of national regulations for the safe utilization of nuclear energy. Such standards should be considered as nuclear safety regulatory documents. The standards developed by the International Organization for Standardization (ISO) are complementary technical documents emphasizing industrial application and contractual aspects. Regarding the quality assurance topic, the IAEA developed the publication Safety Series No. 50-C/SG-Q, Quality Assurance for Safety in Nuclear Power Plants and other Nuclear Installations, which is mostly used directly or indirectly to establish the nuclear safety requirements at the nuclear utility–regulator interface. The ISO 9001:2000 standard, Quality Management Systems — Requirements, is often used to define the quality management system requirements at the utility–supplier interface.

The relationship between the IAEA and ISO quality standards is growing in significance owing to their increasing impact upon utilities (owners/operators of nuclear facilities) and their contractors/suppliers. The relationship between the IAEA and ISO standards is considered critical in particular with respect to contractors/suppliers with a small range of nuclear supplies. These contractors/suppliers are not always willing to prepare special quality assurance programmes based on nuclear safety standards. On the other hand, these contractors/suppliers may be qualified on the basis of the ISO quality standard. In any case, for delivering nuclear items and services the contractors/suppliers' quality assurance programme must comply with the nuclear safety requirements. The utility/owner/operator has the ultimate responsibility to ensure that an acceptable degree of quality assurance in relation to nuclear safety has been achieved. This can be done by imposing additional requirements on the contractors/suppliers over and above those contained within the ISO 9001:2000 standard.

In order to provide a description of the differences between the IAEA and ISO quality standards when applied in nuclear installations, and to support practical measures for achieving nuclear safety, the IAEA established a project for producing a guidance report. A first effort to compare the IAEA and ISO quality standards was conducted during the years 1999 and 2000. The comparison was made using the 1994 edition of the ISO:9001 standard despite the fact that the ISO 9000:2000 series of standards was in its final phase of discussion and approval. This effort was considered

to be worth while and remains valid since the two versions will co-exist during the period from 15 December 2000 to 15 December 2003, during which ISO users will have to upgrade their quality management systems to meet the requirements of ISO 9001:2000. The result of the first comparison was published in IAEA-TECDOC-1182, Quality Assurance Standards: Comparison between IAEA 50-C/SG-Q and ISO 9001:1994.

After the publication of ISO 9001:2000 a new effort was initiated in 2001 to update the comparison mentioned above. The result is presented in this publication, which provides information and guidance that may be considered when ISO 9001:2000 and also ISO 9004:2000 are utilized by the nuclear industry.

In thanking the contributors to this Safety Report, who are listed at the end of this publication, the IAEA wishes to especially acknowledge the efforts and valuable assistance of the FORATOM Quality Management Working Group. The Scientific Secretary responsible for the preparation of this publication was C.R. Clark of the Division of Nuclear Power.

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1. INTRODUCTION

1.1. BACKGROUND

The International Atomic Energy Agency (IAEA) Code and Safety Guides contained in Safety Series No. 50-C/SG-Q [1] define basic quality assurance requirements (in the Code) which must be considered to ensure safety, and provide recommendations (in the Safety Guides) on how to fulfil these basic requirements. The IAEA 50-C/SG-Q Code and Safety Guides reflect a performance based approach to quality assurance covering all aspects of plant safety, economics and efficiency. The IAEA requirements and recommendations are generally used at the nuclear utility–regulator interface.

The International Organization for Standardization (ISO) International Standard ISO 9001:2000 [2] specifies quality management system requirements where a supplier needs to:

(a) Demonstrate its ability to consistently provide a product that meets customer and applicable regulatory requirements;
(b) 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 regulatory requirements.

The ISO 9001:2000 standard is sometimes used at the nuclear utility–supplier interface. The earlier version, ISO 9001:1994, was used in a previous comparison with IAEA 50-C/SG-Q, and the results were issued as IAEA-TECDOC-1182 [3].

1.2. OBJECTIVE

The objective of this Safety Report is to compare the requirements of IAEA 50-C/SG-Q with ISO 9001:2000 in order to identify the main differences between the ISO quality standards and the additional requirements and guidance contained within the IAEA standard. This report also provides information and guidance that may be considered when ISO 9001:2000 and ISO 9004:2000 [4] are utilized by the nuclear industry.

1.3. SCOPE

The comparison is made between the following publications:

— IAEA Safety Series No. 50-C/SG-Q, Quality Assurance for Safety in Nuclear Power Plants and other Nuclear Installations, Code and Safety Guides Q1–Q14 [1];
— ISO 9001:2000, Quality Management Systems — Requirements [2].

The guidelines contained in ISO 9004:2000 [4] and the fundamentals and vocabulary contained in ISO 9000:2000 [5] were considered where appropriate.

1.4. USERS

This Safety Report is intended for use by nuclear utilities, regulatory bodies, suppliers, and research and development organizations. They could use the information provided when procuring items and services for use in the nuclear industry. Also, they could use this report as a source of guidance on specifying additional quality management system requirements to their suppliers when their quality management systems comply with ISO 9001:2000.

2. STANDARDS USED IN THE COMPARISON

2.1. IAEA 50-C/SG-Q CODE AND SAFETY GUIDES ON QUALITY ASSURANCE

2.1.1. IAEA Code 50-C-Q

The IAEA Safety Series includes one Code on quality assurance, 50-C-Q, and 14 related Safety Guides, 50-SG-Q1 to Q14. The quality assurance Code 50-C-Q establishes the basic requirements that must be met to ensure adequate safety of nuclear power plants and other nuclear installations. The Code consists of ten basic requirements (BRs) as the foundation for establishing and implementing a comprehensive quality assurance programme related to the safety of nuclear power plants. The basic requirements are presented in three functional categories:

I. Management
   BR 1: Quality assurance programme
   BR 2: Training and qualification
   BR 3: Non-conformance control and corrective actions
   BR 4: Document control and records

II. Performance
BR 5: Work
BR 6: Design
BR 7: Procurement
BR 8: Inspection and testing for acceptance
III. Assessment
BR 9: Management self-assessment
BR 10: Independent assessment

The Code includes an Annex, which provides guidance to aid in the understanding and implementation of the basic requirements. The content of this Annex was also taken into account in this comparison.

2.1.2. IAEA Safety Guides 50-SG-Q1 to Q14

The IAEA Safety Guides 50-SG-Q1 to Q14 provide detailed and comprehensive guidance and recommendations on how to implement the basic requirements of the IAEA Code. The Safety Guides also describe acceptable methods of implementing particular parts of the Code. The Safety Guides 50-SG-Q1 to Q14 are of two types:

— Basic requirement related Safety Guides,
— Stage related Safety Guides.

2.1.2.1. Basic requirement related Safety Guides

The basic requirement related Safety Guides provide recommendations and guidance on how to fulfil the basic requirements of the Code that are relevant in all of the life cycle stages of nuclear power plants and other nuclear installations. The basic requirement related Safety Guides are:

50-SG-Q1: Establishing and Implementing a Quality Assurance Programme
50-SG-Q2: Non-conformance Control and Corrective Actions
50-SG-Q3: Document Control and Records
50-SG-Q4: Inspection and Testing for Acceptance
50-SG-Q5: Assessment of the Implementation of the Quality Assurance Programme
50-SG-Q6: Quality Assurance in Procurement of Items and Services
50-SG-Q7: Quality Assurance in Manufacturing

2.1.2.2. Stage related Safety Guides

The stage related Safety Guides provide specific recommendations and guidance on how to implement the Code during the different life cycle stages of nuclear power plants and other nuclear installations. The stage related Safety Guides are:

50-SG-Q8: Quality Assurance in Research and Development
50-SG-Q9: Quality Assurance in Siting
50-SG-Q10: Quality Assurance in Design
50-SG-Q11: Quality Assurance in Construction
50-SG-Q12: Quality Assurance in Commissioning
50-SG-Q13: Quality Assurance in Operation
50-SG-Q14: Quality Assurance in Decommissioning

2.2. ISO 9000:2000 STANDARDS ON QUALITY MANAGEMENT SYSTEMS

The ISO 9000:2000 family includes three primary standards:

ISO 9000: Quality Management Systems — Fundamentals and Vocabulary
ISO 9001: Quality Management Systems — Requirements
ISO 9004: Quality Management Systems — Guidelines for Performance Improvement

The ISO 9001:2000 and ISO 9004:2000 standards were developed as a 'consistent pair' of standards. ISO 9001:2000 addresses the quality management system requirements that an organization must fulfil to demonstrate its capability to meet customer requirements and enhance customer satisfaction. ISO 9004:2000 gives guidance on a wider range of objectives of a quality management system than does ISO 9001:2000. These objectives include the satisfaction of interested parties, in addition to customers, and improving the performance of the organization.

The ISO 9001:2000 and 9004:2000 standards are based on eight quality management principles that reflect good management practices. These eight principles are:

— Customer focus,
— Leadership,
— Involvement of people,
— Process approach,
— System approach to management,
— Continual improvement,

— Factual approach to decision making,
— Mutually beneficial supplier relationships.

3. APPLICATION OF IAEA 50-C-Q AND ISO 9001:2000 STANDARDS

Figure 1 illustrates where IAEA 50-C-Q and ISO 9001:2000 are applicable at the interfaces between the regulator, utility and suppliers.

A nuclear utility has two different interfaces where quality management system standards are applied. The primary interface is between the utility and the regulator, and in this case the regulator has the expectation (in some Member States it is specified as a licensing requirement) that the utility will develop and implement a quality management system which satisfies the IAEA 50-C-Q requirements.

The utility also has a secondary interface with the suppliers of items and services. In some cases the utility requires its suppliers to have developed and implemented a quality management system for the supply and delivery of items and services that satisfies the requirements of IAEA 50-C-Q.

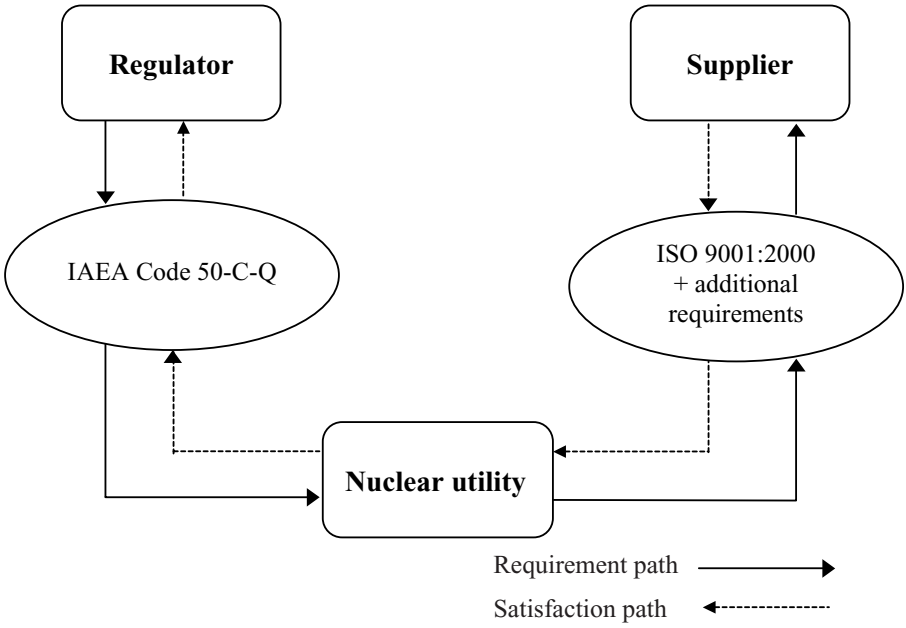

FIG. 1. Application of IAEA 50-C-Q and ISO 9001:2000.

Where a supplier has developed a management system that complies with ISO 9001:2000, it may be necessary for the utility to consider including additional quality management system requirements to address nuclear safety issues as part of the specification to the supplier. Guidance on the additional quality management system requirements is contained in this publication.

4. MAJOR DIFFERENCES AND CORRELATIONS

4.1. STRUCTURE AND FOCUS

Figure 2 highlights the similarities of structure and the differences of focus between IAEA 50-C-Q and ISO 9001:2000. Both standards show a process structure the elements of which are overlapping in scope. The IAEA standard distinguishes between management, performance and assessment, the ISO standard between management responsibility, resource management, product realization, and measurement, analysis and improvement.

The focus of IAEA 50-C-Q is on achieving nuclear safety, the focus of ISO 9001:2000 on achieving customer satisfaction.

In IAEA 50-C-Q the terms 'quality assurance' and 'quality assurance programme' are used. The term 'quality assurance' is no longer used in ISO 9001:2000. The term 'quality management system' used in ISO 9001:2000 is equivalent to the term 'quality assurance programme' as used in IAEA 50-C-Q.

IAEA 50-C-Q and ISO 9001:2000 both utilize a quality management system approach. Both IAEA 50-C-Q and ISO 9001:2000 require that the quality management system shall focus on continual improvement.

4.2. MAJOR CHANGES IN ISO 9001:2000 WITH RESPECT TO ISO 9001:1994

The ISO 9001:1994 version was used in a previous comparison with IAEA 50-C/SG-Q [3]. The major changes in ISO 9001:2000 with respect to ISO 9001:1994 are the increased focus on top management commitment, and an emphasis on the process approach within the organization, on continual improvement and on enhancing satisfaction for customers.

(a) Quality management principles

Eight quality management principles were introduced by the ISO to form the basis for ISO 9001:2000 and 9004:2000. These principles are listed in Section 2.2.

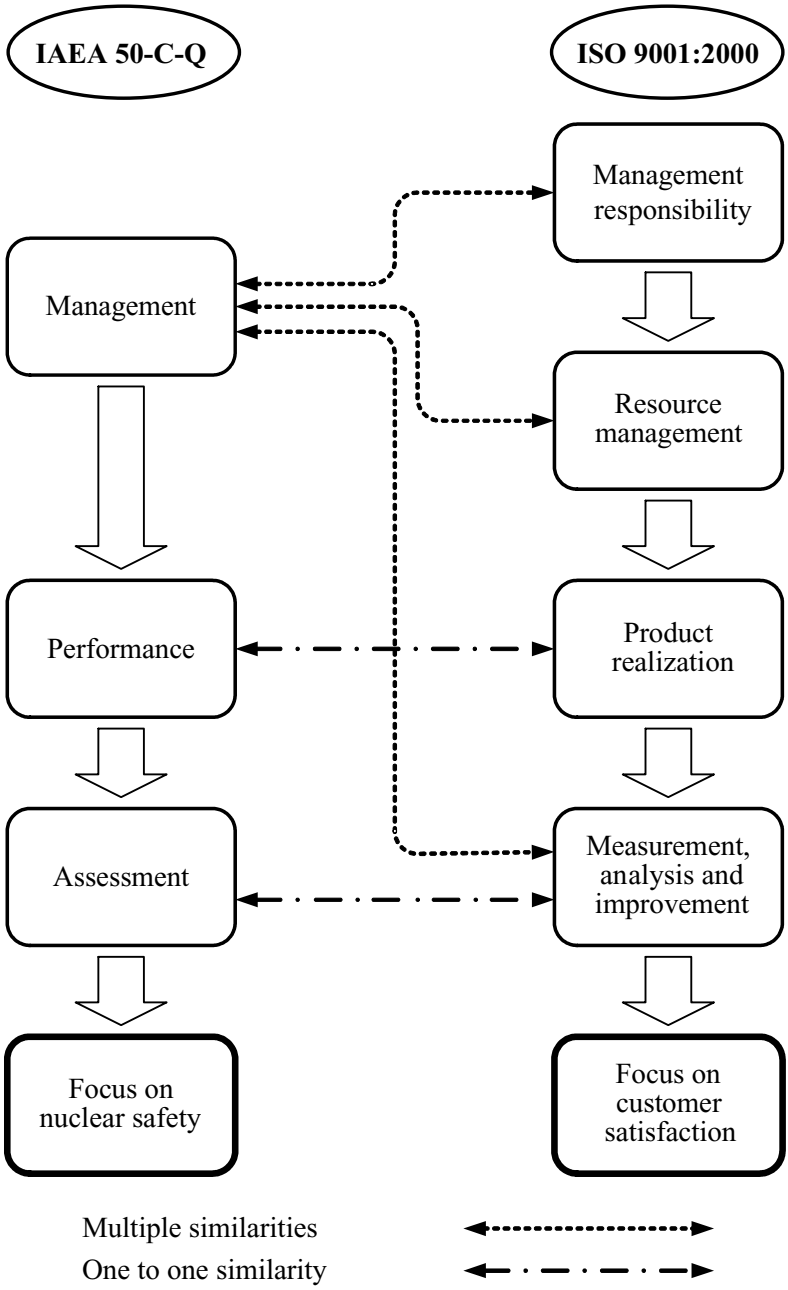

FIG. 2. Similarities of structure and differences of focus between IAEA 50-C-Q and ISO 9001:2000.

(b) Structure

The ISO 2000 version of the ISO quality management system standards includes a radical change to the structure of ISO 9001 and ISO 9004. While retaining the essence of the original requirements, the ISO 2000 version has repositioned the 20 elements of ISO 9001:1994 into five main chapters:

— Quality management system,
— Management responsibility,
— Resource management,
— Product realization,
— Measurement, analysis and improvement.

(c) Process approach

The standard promotes the adoption of a process approach as opposed to the procedural approach described in the 1994 version.

(d) Top management role

More emphasis is placed on the role of top management, which includes its commitment to the development, implementation, improvement and review of the quality management system. In addition, emphasis is also placed on customer focus, consideration of statutory and regulatory requirements, and the establishment of measurable objectives for relevant functions and levels.

(e) Continual improvement

An enhanced requirement for continual improvement is introduced into ISO 9001:2000, defining a complete cycle to improve the effectiveness of the quality management system.

(f) Application

The concept of exclusions to the requirements of ISO 9001:2000 is introduced as a way to cope with the wide spectrum of organizations and activities using the standard.

(g) Customer satisfaction

An item introduced into ISO 9001:2000 is the requirement for the organization to monitor information on customer satisfaction as a measure of system performance.

(h) Resources

Emphasis is placed on top management commitment to making the necessary resources available. Requirements now relate to evaluation of the effectiveness of training and other actions taken, provision of relevant information, internal and external communication, infrastructure and work environment.

(i) Terminology

There are also changes in terminology. The most important changes concern the use of the term 'organization' instead of 'supplier', and the use of the term 'supplier' instead of 'subcontractor'. These changes respond to the need for greater consistency and compatibility with the normal use and meaning of the words.

(j) Documentation

The number of requirements for documented procedures has been reduced in ISO 9001:2000, and the emphasis has been placed on the organization demonstrating effective operation.

4.3. CORRELATION BETWEEN THE BASIC REQUIREMENTS OF THE IAEA CODE 50-C-Q AND IAEA SAFETY GUIDES 50-SG-Q1 TO Q14

While the IAEA Code 50-C-Q specifies the ten basic requirements for quality assurance in nuclear power plants and other nuclear installations, the Safety Guides provide recommendations relative to the fulfilment of these basic requirements for different life cycle stages. An overview showing how each Safety Guide addresses the basic requirements is given in Appendix I.

4.4. CORRELATION BETWEEN THE BASIC REQUIREMENTS OF THE IAEA CODE 50-C-Q AND THE REQUIREMENTS OF ISO 9001:2000

The correlation between the ten basic requirements of the IAEA Code 50-C-Q and the requirements of ISO 9001:2000 is shown in Appendix II.

In general the basic requirements of the IAEA Code 50-C-Q are addressed by one or more clauses of ISO 9001:2000. The following clauses of ISO 9001:2000 are not specifically addressed within IAEA 50-C-Q:

— Clause 5.2: Customer focus
— Clause 5.5.3: Internal communication
— Clause 7.5.4: Customer property
— Clause 8.2.1: Customer satisfaction

4.4.1. Underlying approaches

The IAEA Code 50-C-Q provides the basic requirements to be adopted for establishing and implementing quality assurance programmes/quality management systems related to the safety of nuclear power plants and other nuclear installations. These basic requirements apply to the overall quality assurance programme/quality management system of the responsible organization, i.e. the organization having overall responsibility for the nuclear power plant, as well as to any other separate quality assurance programme/quality management system in each stage of the life of a nuclear power plant.

The objective of the IAEA Code is to establish basic requirements for quality assurance in order to enhance nuclear safety by continually improving the methods employed to achieve quality. The Code recognizes that all work is a process that can be planned, performed, assessed and improved.

ISO 9001:2000 specifies requirements for a quality management system that can be used for internal application by organizations, or for certification or contractual purposes. It focuses on the effectiveness of the quality management system in meeting customer requirements.

In summary, the IAEA Code 50-C-Q is focused on meeting the overall safety requirements for the plant, personnel and society in general, whilst ISO 9001:2000 is focused on satisfying the requirements of the customer.

4.4.2. Additional conceptual requirements of the IAEA Code 50-C-Q

4.4.2.1. Grading

The IAEA Code 50-C-Q recommends a graded approach for the application of quality assurance during the various stages of a nuclear power plant life cycle. All items, services and processes require various controls to ensure that they perform correctly. The grading process is a means of determining the types and extent of controls to be applied to specific items, services and processes. Safety Guide 50-SG-Q1 explains what the graded approach means in relation to nuclear safety.

ISO 9001:2000 does not specifically address a graded approach for applying the controls specified in the quality system.

4.4.2.2. Independence of inspection and testing personnel

The IAEA Code 50-C-Q requires that inspection and testing of specified items, services and processes shall be conducted using established acceptance and performance criteria. The level of inspection and testing and the degree of independence of personnel shall be established.

ISO 9001:2000 does not specifically cover the independence of inspection and testing personnel.

5. GUIDANCE FOR THE USE OF ISO 9001:2000

Through the process of grading its management system requirements, the utility should be able to identify where in the procurement of items and services it requires a supplier's management system to meet specific requirements.

In cases where the supplier has a management system which meets the requirements of ISO 9001:2000, the utility should consider whether any additional requirements need to be included to satisfy the requirements of IAEA 50-C-Q. These additional management system requirements should be included in procurement documentation.

Sections 5.1 and 5.2 identify management system requirements and guidance in the IAEA documents that are not contained within ISO 9001:2000 and provide recommendations on what requirements additional to those of ISO 9001:2000 might need to be specified. No recommendations are provided in cases where the implications of the guidance within the Safety Guides are considered to be self-explanatory. Section 5.3 identifies clauses of the ISO standards that do not have corresponding requirements and guidance in the IAEA documents.

5.1. IAEA-50-C-Q REQUIREMENTS NOT CONTAINED IN ISO 9001:2000

A comparison was made between the ten basic requirements of the IAEA Code 50-C-Q and ISO 9001:2000, Chapters 4–8. The table below presents the requirements not covered in the ISO document, along with recommendations for satisfying these requirements.

Section	IAEA 50-C-Q requirements	Recommendations
101–108	**Introduction**	
104	The responsible organization has to demonstrate the effective fulfilment of the quality assurance requirements to the satisfaction of the regulatory body.	The utility should require its suppliers to apply any additional requirements in order to satisfy the utility, who has the responsibility to satisfy the regulatory body, where necessary.
201–205	**BR 1: Quality assurance programme**	
204	Nuclear safety shall be the fundamental consideration in the identification of the items, services and processes to which the quality assurance programme applies. A graded approach based on the relative importance to nuclear safety of each item, service or process shall be used. The graded approach shall reflect a planned and recognized difference in the applications of specific quality assurance requirements.	The graded approach is described within the utility quality system documentation as part of quality planning and procurement activities. The utility should ensure that any grading requirements are included within procurement documents. It may be necessary to ensure that the supplier understands the safety significance of the procured items and services.
206	**BR 2: Training and qualification**	
206	Personnel shall be trained and qualified so that they are competent to perform their assigned work and understand the safety consequences of their activities.	The utility should ensure that suppliers identify personnel concerned with safety matters. The supplier should be required to ensure that these personnel are

Section	IAEA 50-C-Q requirements	Recommendations
206 (cont.)		properly trained. In some cases the utility can provide training to supplier staff.
304–305	**BR 6: Design**	
305	The adequacy of design, including design tools and design inputs and outputs, shall be verified or validated by individuals or groups other than those who originally performed the work. Verification, validation and approval shall be completed before implementation of the design.	The utility should require that supplier staff involved in safety related design verification and validation be different from those performing the work. Design verification and approval should be performed before implementation of the design.
Annex	Design inputs include all requirements for the design, such as the technical bases for the design (design basis), performance requirements, reliability requirements, and safety and security requirements. Computer programs used in design are validated through testing or simulation prior to use if not proven through previous use.	The utility should require the design organization to validate the computer codes used for safety design prior to use.
309–310	**BR 8: Inspection and testing for acceptance**	
309	Inspection and testing of specified items, services and processes shall be conducted using established acceptance and performance criteria. The level of inspection and testing and the degree of independence of personnel shall be established.	The utility should specify the required degree of independence for supplier personnel involved in inspection and test activities.

5.2. ADDITIONAL GUIDANCE IN IAEA SAFETY GUIDES 50-C-SG1 TO SG14 NOT COVERED IN ISO 9001:2000

A comparison was made between the additional guidance in the IAEA Safety Guides 50-SG-Q1 to Q14 and ISO 9001:2000. The following table presents the guidance not covered in the ISO document, along with recommendations for additional requirements that might need to be specified.

Safety Guide 50-SG-Q1: Establishing and Implementing a Quality Assurance Programme

Section	Additional guidance	Recommendations
209–211	**Grading**	
209	Whilst the quality assurance (QA) principles remain the same, the extent to which the QA requirements are to be applied shall be consistent with the importance to nuclear safety of the item, service or process. A graded approach which can satisfy the necessary requirements and ensure the required quality and safety shall be used.	The suppliers' quality systems should meet the QA requirements notified by the utility, including provisions for grading their own QA requirements to their own sub-suppliers where necessary. The suppliers' graded approach should be acceptable to the utility.
211	When items, processes or services are modified, the assigned grade of QA requirements could become more stringent or less stringent depending on whether a change in nuclear safety significance has occurred.	Self-explanatory.
301–319	**Documentation of the quality assurance programme**	
307	The QA programmes should take account of the details contained in the corresponding Safety Guides and should also recognize that the planning and	The utility should ensure that any requirements for subsequent stages are identified and communicated to suppliers. Also see clause 313 of Safety Guide Q3.

Section	Additional guidance	Recommendations
307 (cont.)	development of the later stage QA programmes commences during the early stages of a project, for example design review requires consideration of inspectability, constructability, operability, maintainability and ALARA requirements before finalization of the design. To do this effectively, the advice of constructors and operators should be sought early in the design stage.	The utility should identify where suppliers are required to document and work to specific procedures/instructions. The QA programme for a supplier appointed as principal designer for a nuclear power plant is required to be developed in accordance with the requirements of IAEA 50-C-Q.
308	The requirements and needs of the QA programme for a particular stage should be considered during earlier stages so that they are fully established prior to the commencement of the stage. For example, establishing the QA programme for operations includes: providing fully documented detailed working documents; having a trained and qualified workforce; and ensuring that workshops, facilities, tools and suitable working environments are in place.	Self-explanatory.
312	The following should be included in the QA programme description: (1) Management's quality policy statement; (2) The mission and objective of the organization;	This is basically equivalent to the requirements of ISO 9001:2000, but it may be useful to consider if any of the guidance is helpful to the supplier.

Section	Additional guidance	Recommendations
312 (cont.)	(3) The organizational structure and outline of the management procedures; (4) The level of authority and the responsibilities and accountabilities of persons and organizational units; (5) The lines of internal and external communications and interface arrangements; (6) The responsibilities of each organization involved in the work; (7) Requirements for training, facilities and working environment; (8) Requirements for the development of detailed working documents for the performance and assessment of work; (9) The arrangements for establishing a graded approach to nuclear safety; (10) The arrangements for measuring effectiveness and management self-assessment of the QA programme.	
401–413	**Implementing the quality assurance programme**	Plans mentioned in the Safety Guide should be handled through quality planning.

Section	Additional guidance	Recommendations
301–313	**Non-conformance control**	
303	Non-conformances may be discovered during regulatory inspections.	Utilities should include the requirement for the right of access for regulatory bodies' representatives for inspection where applicable.
305	On being advised of a non-conformance, the line management should promptly inform the regulatory body and other nuclear power plants if necessary.	The utility should establish criteria with the supplier for identifying non-conformances that should be brought to the attention of the regulator via the utility representative.
308	Non-conformances should be reviewed as soon as practicable by appropriate personnel who should be selected by taking the following into account: — The QA grade or classification of the affected item, service or process; — The need for the safety implications of the non-conformance to be independently reviewed; — The need to involve the regulatory body.	A formal process related to review and acceptance of the non-conformance which affects design intent, by utility representatives or by the regulatory body, should be established.
309	The review should determine: — The cause of the identified non-conformance, which could include failures, malfunctions, incorrect materials, tools, equipment, procedures,	Self-explanatory.

Section	Additional guidance	Recommendations
309 (cont.)	information, training or human error. Root cause analysis techniques should be utilized. — Any safety implications of the non-conformance.	
311	During the review additional information about the nature of the non-conformance and restrictions to be imposed on further processing or operation should be made available to involved organizations, including the regulatory body and other nuclear power plants if required.	Self-explanatory.
313	Relevant information on the status of non-conformances should be reported to management and the regulatory body, where required.	Self-explanatory.
401–406	**Corrective actions**	
406	Implementation of preventive actions may proceed in stages. In such cases each stage should be clearly defined and specify the means of verification that assures that the actions have been effective. Prior to implementation, all proposed actions should have been agreed, documented and authorized by appropriate personnel and the regulatory body if required.	Self-explanatory.

Section	Additional guidance	Recommendations
301–332	**Document control**	
305	During preparation, activities described by the documents should be assessed using the grading system, so that the appropriate controls are chosen and included.	Supplier documents should include all controls necessary for activities to be properly implemented.
313	Where acceptance by, or approval of, the regulatory body is required, this should be obtained before the document is issued for use.	The utility should ensure that suppliers are aware of any specific documents requiring regulatory acceptance/approval. Suppliers should be made aware of situations where work cannot start until acceptance/approval of the specific documents is obtained. The utility should obtain any acceptance/approval required by the regulatory body.
401–427	**Establishment of a records system**	
408	The method of indexing should be established before receipt of the record. The index should provide sufficient information on both the item and the relevant record.	The utility should specify record requirements.
425	The responsible organization should identify who is responsible for transferring or disposing of records.	The utility should specify responsibilities for transfer and disposal of records.

Section	Additional guidance	Recommendations
301–323	**Inspection and testing**	
302	Items and services, including input material to be processed, should not be used, nor processing commenced, until they have been checked for conformance to specified requirements. Such checks should be in accordance with inspection and testing plans or procedures. Receiving inspection and/or testing activities should be carried out in conjunction with a review of the corresponding documents.	An Inspection and Test Plan (ITP)/Quality Plan (QP) should be prepared by suppliers and approved by the utility. See also BR 7.
305	Arrangements should be established to hold the item or stop further work until the required inspections and tests have been completed and the corresponding reports have been received and verified by designated personnel.	The utility should establish, where applicable, hold points (HPs) or witness points (WPs) in ITPs, and communication for HPs or WPs and releasing activities related to these points should be established in the procurement documents.
310	Items and services should not be dispatched or brought into service until all the activities specified in the inspection and testing plan have been satisfactorily completed. The associated documents and records should be available and approved as specified.	The utility or supplier responsibilities for acceptance inspection and testing should be clearly identified.
319	Testing should demonstrate that the safety function of an item or service has been maintained.	Self-explanatory.

Section	Additional guidance	Recommendations
501–514	**Plant inspections and testing**	
501	Systematic inspection and testing following installation of major plant systems is an essential element during the commissioning stage.	Suppliers may need to be involved in this activity.
508	In-service inspection and testing should be an integral part of preventive maintenance aimed at the early detection of the potential failure of items. It also provides data on which to base judgements related to the continued operation and life extension of the plant.	Self-explanatory.
509	In-service inspection and testing should be concentrated on items that may affect safety to ensure that operation has not resulted in an unacceptable degradation or deviation from the design intent.	Self-explanatory.
510	In-service inspection and testing during operation will comprise both routine checks and periodic examination that may require the plant to be shut down. Both activities should be defined.	Self-explanatory.
511	Routine in-service inspection and testing activities should confirm the availability and reliability of systems and should indicate the current plant status.	Self-explanatory.

Section	Additional guidance	Recommendations
512	For evaluation purposes, the results of in-service inspection and tests during plant shutdown should be recorded using appropriate media such as photographs, videos, instrumentation printouts and computer records.	Self-explanatory.
513	Results of in-service inspections and tests should be promptly reviewed. Non-conformances should be investigated to determine their root cause. The resulting data should be analysed for trends using statistical methods.	Self-explanatory.
514	Plant management should be periodically appraised of all in-service inspection and testing performed on the operating plant. Plant management should also be provided with summary reviews of the results. Issues requiring attention, such as problems that could jeopardize the safe operation of the plant, should be highlighted.	Self-explanatory.

Safety Guide 50-SG-Q5: Assessment of the Implementation of the Quality Assurance Programme

Section	Additional guidance	Recommendations
201–214	**General considerations**	
201	Assessments are carried out to determine that requirements are met and that processes are adequate and effective, and to encourage managers to implement improvements, including safety improvements.	The internal audits of suppliers should assist continual improvement.
202	The assessment activity falls into two broad categories: (1) Management self-assessment, which is an ongoing process conducted by management in order to evaluate the effectiveness of performance in all areas of their responsibility. (2) Independent assessment, which is usually conducted by an independent organizational unit in order to determine the effectiveness of management processes, the adequacy of work performance and the quality of items and services.	Self-explanatory.
211	Managers should make arrangements to ensure that all personnel performing assessment activities, including themselves, have appropriate qualification, training and experience.	Supplier auditors should be trained properly in auditing practices and techniques.

Section	Additional guidance	Recommendations
501–509	**Management self-assessment**	
501	The purpose of management self-assessment should be to evaluate known performance issues, identify contributing management aspects and make improvements.	Careful consideration should be given to imposing this requirement on suppliers as self-assessment is only used as guidance in ISO 9004.
502	Management self-assessment should be regarded as an ongoing process that determines how well leadership is being provided to meet requirements and expectations.	Self-explanatory.
503	Management at all levels (for example senior, line and supervisory managers) perform these self-assessments with an emphasis on the allocation of human and financial resources to achieve organizational goals and objectives.	Self-explanatory.
601–620	**Independent assessment**	
601	Independent assessment, such as internal audits, external audits, surveillance, peer evaluation and technical review, should be focused on safety aspects and areas where problems have been found. Assessment objectives should be reviewed periodically to reflect current management concerns and performance activities. Appropriate combinations of various types of assessment should be used to provide the best	Self-explanatory.

Section	Additional guidance	Recommendations
601 (cont.)	balanced evaluation of performance.	
602	A system for internal audits should be established by the assessment unit and agreed with the management of the organization.	Self-explanatory.
606	External audits of suppliers should be managed by the assessment unit on behalf of management, who agree the schedule of audits to be performed. The frequency of audits should be determined by factors such as the importance of items and the performance of the supplier.	Self-explanatory.
608	Surveillance of work performance is considered to be the best technique for assessing and reporting on a specific area, or an ongoing activity. It is flexible and less formal than audits and can be performed in a relatively short period of time with limited preparation.	Self-explanatory.
613	Peer evaluation is a critical examination of specific nuclear safety related subjects by senior staff from one or more other nuclear power plants to seek improvements and to promote good practices. The evaluation team should consist of experts in all areas of evaluation in order to promote the sharing of	Self-explanatory.

Section	Additional guidance	Recommendations
613 (cont.)	experience and to develop relationships between the peers and the people at the nuclear power plants.	
617	Senior management may arrange for a review of the technical content of activities and processes, with a view to improving the effectiveness of these activities or processes.	Self-explanatory.

Safety Guide 50-SG-Q6: Quality Assurance in Procurement of Items and Services

Section	Additional guidance	Recommendations
201–206	**Arrangements for procurement**	
201	The responsible organization shall ensure that procured items and services meet established requirements and perform as specified and that selected suppliers continue to provide acceptable items and services during the fulfilment of their procurement obligations. The responsible organization may delegate procurement activities to other organizations, but shall retain the responsibility for the overall effectiveness of these activities.	The utility should ensure that management system and product requirements are contained within procurement documents. This includes any additional management system requirements necessary to meet IAEA 50-C-Q requirements.
204	Nuclear safety shall be the fundamental consideration in the identification of the items, services and processes to which the QA programme applies. A graded approach based on the relative importance to nuclear safety of each item, service or process shall be used. The graded approach shall reflect a planned and recognized difference in the applications of specific QA requirements.	The graded approach is described within the utility quality system documentation as part of quality planning and procurement activities. The utility should ensure that any grading requirements are included within procurement documents. It may be necessary to ensure that the supplier understands the safety significance of the procured items and services.
205	This graded approach should be applied throughout the supply chain.	Self-explanatory.

Section	Additional guidance	Recommendations
501–503	**Evaluation of quotations and award of contract**	
501	Submitted quotations (bids or tenders) from prospective suppliers should be evaluated in a logical manner to ensure that they conform to the requirements of the procurement documents.	Conformance to requirements can include evaluating the totality of specified management system requirements. ISO 9001:2000 no longer contains a requirement for contract review but emphasizes customer satisfaction through determining and meeting requirements.
502	The evaluation of quotations carried out by the responsible organization should be a team effort involving the organizational units responsible for the technical and procurement activities. The size of the team undertaking the evaluation should be determined by the size and complexity of the item or service to be purchased.	Self-explanatory.
601–607	**Evaluation of supplier performance**	
603	The extent and necessity of pre- and post-award communication depends on the uniqueness of the product, its complexity, the procurement frequency with the same supplier and past performance in the supply of similar items or services.	Self-explanatory.
801–802	**Commercial grade items**	
801	Certain items with a proven record may be available from commercial stock. Procurement documents should provide	Self-explanatory.

Section	Additional guidance	Recommendations
801 (cont.)	sufficient information from catalogues and suppliers' specifications to enable the correct item to be supplied. All relevant technical data and trial information should be requested. These items may require confirmatory analysis or testing to demonstrate the adequacy of the item to perform its intended function.	
802	When a commercial grade item is proposed for any safety function, a thorough technical evaluation of the complexity of the item and its safety significance should be carried out. The critical characteristics required for that function should be included as acceptance criteria in the procurement documents.	Self-explanatory.
901	**Procurement of spares**	
901	The plant management may arrange to obtain spares of plant items at the time of procurement of the original items. The spares should meet the same QA requirements as the originals, with additional requirements to assure protection during long term storage.	Self-explanatory.

Section	Additional guidance	Recommendations
201–205	**General**	
202	The responsibility for the effectiveness of the overall QA programme of the nuclear power plant remains with the responsible organization without prejudice to the manufacturer's obligations and the legal requirements imposed on the manufacturer.	Self-explanatory.
301–311	**The manufacturing process**	
303	The manufacturer shall be made aware of the requirements of the responsible organization and regulatory body (see the Code 50-C-G (Rev. 1)) for sampling points, hold points and witness points.	The utility should ensure that the supplier has incorporated utility and regulatory sampling points, hold points and witness points within documents such as quality plans.

Section	Additional guidance	Recommendations
201–223	**Management**	
207	The responsible organization shall identify the principal designer who has responsibility for specifying the design requirements and for approving the design output on its behalf.	Self-explanatory.
208	The responsibilities of the principal designer should include: — Defining the base requirement/specification — Involvement in design reviews — Involvement in design verification — Approval of detail design — Review and approval of design changes during all stages — Control of interfaces — Review of relevant non-conformance applications — Review and approval of the QA programme.	Self-explanatory.
213	Training and development for technical personnel should supplement previous training, education and experience to prepare individuals to perform their work.	IAEA 50-C-Q is more specific. It should be ensured that the requirement is specified and applied where necessary.

Section	Additional guidance	Recommendations
301–336	**Performance**	
329	Design validation shall be carried out to confirm by examination and provision of objective evidence that the particular requirements for a specific intended use are fulfilled, and that the item conforms to defined requirements.	IAEA 50-C-Q is more specific. It should be ensured that the requirement is specified and applied where necessary.

5.3. ISO 9001:2000 CLAUSES WITH NO CORRESPONDING REQUIREMENTS AND GUIDANCE IN THE IAEA DOCUMENTS

The following table identifies the clauses of the ISO standards which do not have corresponding requirements and guidance in the IAEA 50-C/SG-Q Code and Safety Guides. The utility should be aware of these differences to help understand what additional activities a supplier using ISO 9001:2000 would be implementing.

Clause	ISO 9001:2000 additional requirements	Comments
4.	**Quality management system**	
4.1	**General requirements** Control of outsourced processes is defined.	There are no requirements on outsourcing of processes in the Code and Safety Guides. Utilities should ensure that they are notified of any outsourcing activities. The utility may require prior approval of these processes.
4.2	**Documentation requirements** The ISO intends to reduce the 'documentation load' to organizations.	In the Code and Safety Guides there are defined requirements on documentation control. Safety Guide Q3 gives detailed guidance on documentation control and all the stage related Safety Guides (Q10–Q14) define the requirements specific to the various stages.
5.	**Management responsibility**	
5.1	**Management commitment** Top management shall provide evidence of its commitment to the development and implementation of the quality management system and continual improvement of its effectiveness by: (a) Communicating to the organization the importance of	The Code, the Safety Guide 50-SG-Q1 and all stage related Safety Guides carefully define the responsibilities and commitment of the management. The IAEA documents do not separate top management and management in general. In every

Clause	ISO 9001:2000 additional requirements	Comments
5.1 (cont.)	meeting customer 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.	place where IAEA documents mention 'management', it should be interpreted as top management. The Code and Safety Guides give delegated responsibilities to different levels of management, e.g. senior management, line management and supervisory management (BR3, Q5, Q13, etc.).
5.2	**Customer focus** Top management shall ensure that customer requirements are determined and are met with the aim of enhancing customer satisfaction.	The IAEA documents do not specifically identify the customer.
5.5.2	**Management representative** Top management shall appoint a member of management who, irrespective of other responsibilities, shall have responsibility and authority that includes: (a) Ensuring that processes needed for the quality management system are established, implemented and maintained; (b) Reporting to top management on the performance of the quality management system and any need for improvement; and (c) Ensuring the promotion of awareness of customer requirements throughout the organization.	In the IAEA documents, 'management representative' is not defined, as the responsibility for this activity is placed with management in general.

Clause	ISO 9001:2000 additional requirements	Comments
5.5.2 (cont.)	NOTE: The responsibility of a management representative can include liaison with external parties on matters relating to the quality management system.	
5.5.3	**Internal communication** Top management shall ensure that appropriate communication channels are established within the organization and that communication takes place regarding the effectiveness of the quality management system.	In the IAEA documents, internal communication is described but not as explicitly as in the ISO standard.
5.6	**Management review** Top management shall review the organization's quality management system at planned intervals to ensure its continuing 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. Records from management reviews shall be maintained.	This requirement is included in the 'management self-assessment' requirement throughout the IAEA documents. The self-assessment in this case is a combination of management review and monitoring and measurement of processes. No economic aspect in the Code and SG-Q5 as an input for self-assessment is considered. The ISO standard gives more details on the review (self-assessment) of outputs. ISO 9004:2000 gives examples of management self-assessment.
7.	**Product realization**	
7.2.3	**Customer communication** The organization shall determine and implement effective	Customer communication is not defined within the IAEA documents. This requirement

Clause	ISO 9001:2000 additional requirements	Comments
7.2.3 (cont.)	arrangements for communicating with customers in relation to: (a) Product information; (b) Enquiries, contracts or order handling, including amendments; and (c) Customer feedback, including customer complaints.	should enhance customer (utility) and supplier relationships.
7.3.1	**Design and development planning** The organization shall plan and control the design and development of the product. During the design and development planning, the organization shall determine: (a) The design and development stages; (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. The organization shall manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility. Planning output shall be updated, as appropriate, as the design and development progresses.	'Principal designer' is a term used in 50-SG-Q10. Utilities may require a principal designer to be nominated within a supplier organization.

Clause	ISO 9001:2000 additional requirements	Comments
7.5.2	**Validation of processes for production and service provision** The organization shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any processes where 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 the 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.	The validation of processes is not a requirement in the IAEA documents. Validation is used as a method of ensuring the accuracy of working level documents.
8.	**Measurement, analysis and improvement**	
8.2.1	**Customer satisfaction** As one of the measurements of the performance of the quality management system, the	The issue of customer focus does not need further explanation.

Clause	ISO 9001:2000 additional requirements	Comments
8.2.1 (cont.)	organization shall monitor information relating to customer perception as to whether the organization has met customer requirements. The methods for obtaining and using this information shall be determined.	

Appendix I

COVERAGE OF IAEA CODE 50-C-Q BASIC REQUIREMENTS IN IAEA SAFETY GUIDES 50-SG-Q1 TO Q14

			Management				Performance				Assessment	
			BR 1	BR 2	BR 3	BR 4	BR 5	BR 6	BR 7	BR 8	BR 9	BR 10
			Quality assurance programme	Training and qualification	Non-conformance control and corrective actions	Document control and records	Work	Design	Procurement	Inspection and testing for acceptance	Management self-assessment	Independent assessment
Basic requirement related Safety Guides	Q1	Establishing and Implementing a Quality Assurance Programme	+									
	Q2	Non-conformance Control and Corrective Actions	+		+			+		+		
	Q3	Document Control and Records	+			+						
	Q4	Inspection and Testing for Acceptance	+	+	+		+		+	+		
	Q5	Assessment of the Implementation of the Quality Assurance Programme	+	+			+	+		+	+	+
	Q6	Quality Assurance in Procurement of Items and Services	+	+	+				+	+		
	Q7	Quality Assurance in Manufacturing	+	+	+		+			+	+	+
Stage related Safety Guides	Q8	Quality Assurance in Research and Development	+	+	+	+		+			+	+
	Q9	Quality Assurance in Siting	+	+	+	+		+	+	+	+	+
	Q10	Quality Assurance in Design	+	+	+	+		+			+	+
	Q11	Quality Assurance in Construction	+	+	+	+	+	+	+	+	+	+
	Q12	Quality Assurance in Commissioning	+	+	+	+	+	+	+	+	+	+
	Q13	Quality Assurance in Operation	+	+	+	+	+	+	+	+	+	+
	Q14	Quality Assurance in Decommissioning	+	+	+	+	+	+	+	+	+	+

Appendix II

CORRELATION BETWEEN THE BASIC REQUIREMENTS OF IAEA CODE 50-C-Q AND THE REQUIREMENTS IN ISO 9001:2000

		Management				Performance				Assessment	
		BR 1	BR 2	BR 3	BR 4	BR 5	BR 6	BR 7	BR 8	BR 9	BR 10
Clause in ISO 9001:2000		Quality assurance programme	Training and qualification	Non-conformance control and corrective actions	Document control and records	Work	Design	Procurement	Inspection and testing for acceptance	Management self-assessment	Independent assessment
4.	**Quality management system (title only)**										
4.1	General requirements	+									
4.2	Documentation requirements (title only)										
4.2.1	General	+			+						
4.2.2	Quality manual	+									
4.2.3	Control of documents				+						
4.2.4	Control of quality records				+						
5.	**Management responsibility (title only)**										
5.1	Management commitment	+		+						+	
5.2	Customer focus										
5.3	Quality policy	+									
5.4	Planning (title only)										
5.4.1	Quality objectives	+		+						+	
5.4.2	Quality management system planning	+									
5.5	Responsibility, authority and communication (title only)										
5.5.1	Responsibility and authority	+		+						+	
5.5.2	Management representative										
5.5.3	Internal communication	+	+								
5.6	Management review (title only)										
5.6.1	General	+		+						+	
5.6.2	Review input	+		+						+	

Clause in ISO 9001:2000		Management				Performance				Assessment	
		BR 1	BR 2	BR 3	BR 4	BR 5	BR 6	BR 7	BR 8	BR 9	BR 10
		Quality assurance programme	Training and qualification	Non-conformance control and corrective actions	Document control and records	Work	Design	Procurement	Inspection and testing for acceptance	Management self-assessment	Independent assessment
5.6.3	Review output	+		+						+	
6.	**Resource management (title only)**										
6.1	Provision of resources	+		+						+	+
6.2	Human resources (title only)										
6.2.1	General	+		+							
6.2.2	Competence, awareness and training		+								
6.3	Infrastructure	+				+					
6.4	Work environment					+					
7.	**Product realization (title only)**										
7.1	Planning of product realization	+				+			+		
7.2	Customer related processes (title only)										
7.2.1	Determination of requirements related to the product					+	+	+	+		
7.2.2	Review of requirements related to the product	+			+	+	+	+	+	+	
7.2.3	Customer communication										
7.3	Design and development (title only)										
7.3.1	Design and development planning						+				
7.3.2	Design and development inputs						+				
7.3.3	Design and development outputs						+				
7.3.4	Design and development review						+				
7.3.5	Design and development verification						+				
7.3.6	Design and development validation						+				
7.3.7	Control of design and development changes						+				
7.4	Purchasing (title only)										

Clause in ISO 9001:2000		Management				Performance				Assessment	
		BR 1	BR 2	BR 3	BR 4	BR 5	BR 6	BR 7	BR 8	BR 9	BR 10
		Quality assurance programme	Training and qualification	Non-conformance control and corrective actions	Document control and records	Work	Design	Procurement	Inspection and testing for acceptance	Management self-assessment	Independent assessment
7.4.1	Purchasing process							+			
7.4.2	Purchasing information							+			
7.4.3	Verification of purchased product							+	+		
7.5	Production and service provision (title only)										
7.5.1	Control of production and service provision					+					
7.5.2	Validation of processes for production and service provision					+					
7.5.3	Identification and traceability			+		+			+		
7.5.4	Customer property										
7.5.5	Preservation of product					+					
7.6	Control of monitoring and measuring devices					+			+		
8.	**Measurement, analysis and improvement (title only)**										
8.1	General	+		+		+			+		
8.2	Monitoring and measurement (title only)										
8.2.1	Customer satisfaction										
8.2.2	Internal audit									+	+
8.2.3	Monitoring and measurement of processes			+		+				+	+
8.2.4	Monitoring and measurement of product					+			+		
8.3	Control of non-conforming product			+							
8.4	Analysis of data			+							
8.5	Improvement (title only)										
8.5.1	Continual improvement	+		+						+	+
8.5.2	Corrective action			+							
8.5.3	Preventive action			+							

Appendix III

CORRELATION BETWEEN IAEA SAFETY GUIDES 50-SG-Q1 TO Q14 AND THE REQUIREMENTS IN ISO 9001:2000

Clause in ISO 9001:2000		Basic requirement related Safety Guides							Stage related Safety Guides						
		1	2	3	4	5	6	7	8	9	10	11	12	13	14
		Establishing and Implementing a Quality Assurance Programme	Non-conformance Control and Corrective Actions	Document Control and Records	Inspection and Testing for Acceptance	Assessment of the Implementation of the Quality Assurance Programme	Quality Assurance in Procurement of Items and Services	Quality Assurance in Manufacturing	Quality Assurance in Research and Development	Quality Assurance in Siting	Quality Assurance in Design	Quality Assurance in Construction	Quality Assurance in Commissioning	Quality Assurance in Operation	Quality Assurance in Decommissioning
4.	**Quality management system (title only)**														
4.1	General requirements	+	+	+	+	+	+	+	+	+	+	+	+	+	+
4.2	Documentation requirements (title only)														
4.2.1	General	+		+					+	+	+	+	+	+	+
4.2.2	Quality manual	+		+					+	+	+	+	+	+	+
4.2.3	Control of documents	+		+			+	+	+	+	+	+	+	+	+
4.2.4	Control of quality records	+		+			+	+	+	+	+	+	+	+	+
5.	**Management responsibility (title only)**														
5.1	Management commitment	+	+	+	+	+	+	+	+	+	+	+	+	+	+
5.2	Customer focus														
5.3	Quality policy	+							+	+	+	+	+	+	+
5.4	Planning (title only)														
5.4.1	Quality objectives	+							+	+	+	+	+	+	+
5.4.2	Quality management system planning	+								+	+	+	+	+	+
5.5	Responsibility, authority and communication (title only)														
5.5.1	Responsibility and authority	+	+	+	+	+	+	+	+	+	+	+	+	+	+
5.5.2	Management representative														
5.5.3	Internal communication	+							+	+	+	+	+	+	+

Clause in ISO 9001:2000		Basic requirement related Safety Guides							Stage related Safety Guides						
		1	2	3	4	5	6	7	8	9	10	11	12	13	14
		Establishing and Implementing a Quality Assurance Programme	Non-conformance Control and Corrective Actions	Document Control and Records	Inspection and Testing for Acceptance	Assessment of the Implementation of the Quality Assurance Programme	Quality Assurance in Procurement of Items and Services	Quality Assurance in Manufacturing	Quality Assurance in Research and Development	Quality Assurance in Siting	Quality Assurance in Design	Quality Assurance in Construction	Quality Assurance in Commissioning	Quality Assurance in Operation	Quality Assurance in Decommissioning
5.6	Management review (title only)														
5.6.1	General	+							+	+	+	+	+	+	+
5.6.2	Review input	+							+	+	+	+	+	+	+
5.6.3	Review output	+							+	+	+	+	+	+	+
6.	**Resource management (title only)**														
6.1	Provision of resources	+							+	+	+	+	+	+	+
6.2	Human resources (title only)														
6.2.1	General	+							+	+	+	+	+	+	+
6.2.2	Competence, awareness and training	+	+	+	+	+	+	+	+	+	+	+	+	+	+
6.3	Infrastructure	+						+	+	+	+	+	+	+	+
6.4	Work environment	+						+	+	+	+	+	+	+	+
7.	**Product realization (title only)**														
7.1.	Planning of product realization	+					+	+	+	+	+	+	+	+	+
7.2	Customer related processes (title only)														
7.2.1	Determination of requirements related to the product						+	+	+	+	+	+	+	+	+
7.2.2	Review of requirements related to the product						+	+	+	+	+	+	+	+	+
7.2.3	Customer communication														
7.3	Design and development (title only)														
7.3.1	Design and development planning								+	+	+	+	+	+	+

Clause in ISO 9001:2000		Basic requirement related Safety Guides							Stage related Safety Guides						
		1	2	3	4	5	6	7	8	9	10	11	12	13	14
		Establishing and Implementing a Quality Assurance Programme	Non-conformance Control and Corrective Actions	Document Control and Records	Inspection and Testing for Acceptance	Assessment of the Implementation of the Quality Assurance Programme	Quality Assurance in Procurement of Items and Services	Quality Assurance in Manufacturing	Quality Assurance in Research and Development	Quality Assurance in Siting	Quality Assurance in Design	Quality Assurance in Construction	Quality Assurance in Commissioning	Quality Assurance in Operation	Quality Assurance in Decommissioning
7.3.2	Design and development inputs								+	+	+	+	+	+	+
7.3.3	Design and development outputs								+	+	+	+	+	+	+
7.3.4	Design and development review								+	+	+	+	+	+	+
7.3.5	Design and development verification								+	+	+	+	+	+	+
7.3.6	Design and development validation								+	+	+	+	+	+	+
7.3.7	Control of design and development changes								+	+	+	+	+	+	+
7.4	Purchasing (title only)														
7.4.1	Purchasing process						+	+		+	+	+	+	+	+
7.4.2	Purchasing information						+	+		+	+	+	+	+	+
7.4.3	Verification of purchased product				+		+	+		+	+	+	+	+	+
7.5	Production and service provision (title only)														
7.5.1	Control of production and service provision				+			+		+	+	+	+	+	+
7.5.2	Validation of processes for production and service provision							+	+						
7.5.3	Identification and traceability		+		+		+	+	+	+	+	+	+	+	+
7.5.4	Customer property														
7.5.5	Preservation of product						+	+		+	+	+	+	+	+
7.6	Control of monitoring and measuring devices				+			+	+	+	+	+	+	+	+

Clause in ISO 9001:2000		Basic requirement related Safety Guides							Stage related Safety Guides						
		1	2	3	4	5	6	7	8	9	10	11	12	13	14
		Establishing and Implementing a Quality Assurance Programme	Non-conformance Control and Corrective Actions	Document Control and Records	Inspection and Testing for Acceptance	Assessment of the Implementation of the Quality Assurance Programme	Quality Assurance in Procurement of Items and Services	Quality Assurance in Manufacturing	Quality Assurance in Research and Development	Quality Assurance in Siting	Quality Assurance in Design	Quality Assurance in Construction	Quality Assurance in Commissioning	Quality Assurance in Operation	Quality Assurance in Decommissioning
8.	**Measurement, analysis and improvement (title only)**														
8.1	General	+				+			+	+	+	+	+	+	+
8.2	Monitoring and measurement (title only)														
8.2.1	Customer satisfaction														
8.2.2	Internal audit	+				+			+	+	+	+	+	+	+
8.2.3	Monitoring and measurement of processes	+				+		+	+	+	+	+	+	+	+
8.2.4	Monitoring and measurement of product				+			+		+	+	+	+	+	+
8.3	Control of non-conforming product		+		+			+	+	+	+	+	+	+	+
8.4	Analysis of data	+	+						+	+	+	+	+	+	+
8.5	Improvement (title only)														
8.5.1	Continual improvement	+	+	+	+	+	+	+	+	+	+	+	+	+	+
8.5.2	Corrective action		+						+	+	+	+	+	+	+
8.5.3	Preventive action		+						+	+	+	+	+	+	+

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