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Quality assurance standards: comparison between IAEA 50-C/SG-Q and ISO 9001:1994

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FOREWORD

The International Atomic Energy Agency (IAEA) and the International Organization for Standardization (ISO) agreement regarding the scope and coverage of documents published by both organizations points out that 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 ISO are complementary technical documents emphasizing industrial application and contractual aspects. Regarding the quality assurance topic, the IAEA standards 50-C/SG-Q are mostly used directly or indirectly to establish the nuclear safety requirements at the utility–regulatory interface. The industrial ISO 9001 standards have progressively been used to implement the quality assurance requirements at the interface utility–supplier.

The relationship between both standards is growing in significance owing to the impact upon the owners/operators of nuclear facilities and their contractors/suppliers. The relationship between the IAEA and ISO standards is considered critical, in particular regarding suppliers with a small range of nuclear supplies. These organizations are not always willing to prepare special quality assurance programmes based on nuclear safety standards. On the other hand, these organizations may be qualified on the basis of the ISO quality assurance standards. In any case, for delivering nuclear items and services the quality assurance programme must comply with the requirements established in the nuclear safety regulatory standards. This implies that the utility–supplier will have to demonstrate that the acceptable degree of quality assurance in relation to nuclear safety is accomplished. This may be achieved by imposing additional requirements on the supplier over and above those contained within the ISO.

In order to provide a description of the differences between the IAEA and ISO standards when applied in nuclear installations, and to support the practical way of fulfilling nuclear safety, the IAEA established a project for producing a guidance report. Valuable contributions from the European Atomic Forum (FORATOM) were committed and contractual arrangements made, with the target of finalizing the report in the shortest feasible timeframe commensurable with available resources.

The issue as to which ISO 9001 standard should be used for the comparison, i.e. the current version 1994 or future version 2000, was discussed quite extensively by the members of the initial consultants meeting held in Vienna in January 1999. The consultants recommended proceeding with the use of ISO 9001 version 1994 on the grounds that some time would still be needed before the next version 2000 is adopted and effectively implemented. In the meantime guidance based upon the ISO 9001 version 1994 was considered to be applicable and the efforts expended in the preparation of the guidance report worthwhile. The report will subsequently be updated to include the new ISO 9001 version 2000 standard.

In thanking the contributors to this report, the IAEA wishes to acknowledge the efforts and assistance provided by FORATOM and by the participants at the preparatory and review meetings, who are listed at the end of the report. Special acknowledgement is due to K.-P. Kleinert (Germany), E. Glauser (Switzerland), M. Hille (Germany) and N. Redman (United Kingdom) for their contributions. The IAEA officer responsible for this work was N. Pieroni 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 the Safety Series No. 50-C/SG-Q [1] define basic quality assurance requirements, which must be considered to ensure safety, and provides recommendations on how to fulfil these basic requirements. The IAEA 50-C/SG-Q standard reflects the 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 9001:1994 [2] specifies quality system requirements for use where any supplier's capability to design and supply a conforming product needs to be demonstrated. The requirements specified are aimed primarily at achieving customer satisfaction by preventing non-conformity at all stages from design through to servicing. The ISO 9001:1994 standard is sometimes used at the nuclear utility–supplier interface.

1.2. Objective

The objective of this report is to compare the requirements of IAEA 50-C/SG-Q (1996) [1] with ISO 9001:1994 [2] in order to identify the main differences and additional requirements contained within [1]. The report also provides information and guidance, which may be considered when ISO 9001:1994 is utilized by the nuclear industry.

1.3. Scope

The comparison is made with the following publications:

IAEA Safety Series No. 50-C/SG-Q (1996), Quality Assurance for Safety in Nuclear Power Plants and other Nuclear Installations, Code and Safety Guides Q1–Q14 [1].

ISO 9001:1994, Quality Systems — Model for Quality Assurance in Design, Development, Production, Installation and Servicing [2].

ISO 9002:1994, Quality Systems — Model for Quality Assurance in Production, Installation and Servicing [3].

ISO 9003:1994, Quality Systems — Model for Quality Assurance in Final Inspection and Test [4].

Throughout this report, the comparison discussed is the comparison against ISO 9001:1994 only, as it contains all the requirements contained in ISO 9002:1994 and ISO 9003:1994.

Suppliers, utilities, regulatory bodies, as well as research and development organizations could use this report when considering using ISO 9001:1994 to procure items and services for use in the nuclear industry.

2. STANDARDS USED IN THE COMPARISON

2.1. IAEA Code and Safety Guides on Quality Assurance 50-C/SG-Q

The IAEA Safety Series includes one Code 50-C-Q on quality assurance and 14 related Safety Guides 50-SG-Q1 to Q14 [1].

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 10 basic requirements (BR) to be adopted by the responsible organization 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 the understanding and implementation of the basic requirements. The content of this annex is included in this comparison.

The Safety Guides describe acceptable methods of implementing particular parts of the Code.

The Safety Guides 50-SG-Q1 to Q14 are one of two types:

- **Basic requirement related Safety Guides**

These 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 BR related guides are:

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

- **Stage related Safety Guides**

These 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 guides are:

Safety Guide Q8: Quality Assurance in Research and Development
Safety Guide Q9: Quality Assurance in Siting
Safety Guide Q10: Quality Assurance in Design (this specific guide may also be used as a BR related Guide when the design activities are carried out in any stage).
Safety Guide Q11: Quality Assurance in Construction
Safety Guide Q12: Quality Assurance in Commissioning
Safety Guide Q13: Quality Assurance in Operation
Safety Guide Q14: Quality Assurance in Decommissioning

2.2. Quality System Standard ISO 9001:1994

The ISO 9001:1994 standard defines the requirements for a quality management system in clauses 4.1 to 4.20. The clauses are sequentially numbered to reflect the sequence of events and activities supporting production, from developing the quality policy to the after sales service.

The clauses of ISO 9001:1994 are:

4.1 Management Responsibility
4.2 Quality System
4.3 Contract Review
4.4 Design Control
4.5 Document and Data Control
4.6 Purchasing
4.7 Control of Customer-Supplied Product
4.8 Product Identification and Traceability
4.9 Process Control
4.10 Inspection and Testing
4.11 Control of Inspection, Measuring and Test Equipment
4.12 Inspection and Test Status
4.13 Control of Nonconforming Product
4.14 Corrective and Preventive Action
4.15 Handling, Storage, Packaging, Preservation and Delivery
4.16 Control of Quality Records
4.17 Internal Quality Audits
4.18 Training
4.19 Servicing
4.20 Statistical Techniques

These 20 clauses have a relationship with and are comparable to the 10 basic requirements of the IAEA Code 50-C-Q. The ISO 9001:1994 standard, however, does not give any guidance or recommendations on how the defined requirements can be implemented.

3. MAJOR DIFFERENCES AND LINKAGES

3.1. IAEA Code 50-C-Q basic requirements 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 topics and life-cycle stages. An overview showing how each Safety Guide addresses the basic requirements is given in the Appendix: Matrix 1.

3.2. IAEA Code 50-C-Q basic requirements and clauses of ISO 9001:1994

The linkages between the ten basic requirements of the IAEA Code 50-C-Q and the 20 clauses of ISO 9001:1994 are provided in the Appendix: Matrix 2. In general the basic requirements of the IAEA Code 50-C-Q are addressed by one or more clauses of ISO 9001:1994. However the IAEA Safety Guides provide more detailed and comprehensive guidance and recommendations on how to implement the basic requirements of the IAEA Code.

Each basic requirement of the IAEA Code 50-C-Q addresses one or more of the clauses of ISO 9001:1994. However there are some significant differences in the approaches, identification of the customer and additional requirements.

3.2.1. Underlying approaches

The IAEA Code 50-C-Q provides the basic requirements to be adopted for establishing and implementing quality assurance programmes related to the safety of nuclear power plants and other nuclear installations. These basic requirements apply to the overall quality assurance programme 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 programmes 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 continuously improving the methods employed to achieve quality. The Code recognizes that all work is a process that can be planned, performed, assessed and improved.

The quality assurance model set out in ISO 9001:1994 provides the framework for the quality assurance programme of a supplier, which enables the supplier to demonstrate the capability to produce a quality product and provides a vehicle for assessment by external parties. The requirements specified are aimed primarily at achieving customer satisfaction by preventing non-conformity at all stages from design to servicing. They are generic and independent of any specific industry sector.

The comparison suggests that the IAEA Code 50-C-Q is a top-down approach focused on meeting the overall safety requirements for the plant, personnel and the society in general whilst ISO 9001:1994 is a bottom-up approach focusing on satisfying the specific requirements of the immediate customer.

3.2.2. Identification of the customer

The nuclear utility in meeting national regulatory requirements satisfies the safety requirements of its customer: society at large. The regulator, representing the customer in this

case, utilizes the IAEA Code 50-C-Q to define the requirements for the quality assurance programme of its supplier, the nuclear utility. The nuclear utility also fulfils the role of the customer utilizing, where appropriate, ISO 9001:1994 plus any additional requirements to define the quality assurance programme of its suppliers of items and services. The supplier satisfies the nuclear utility (the customer) by supplying a quality product. (See Figure 1)

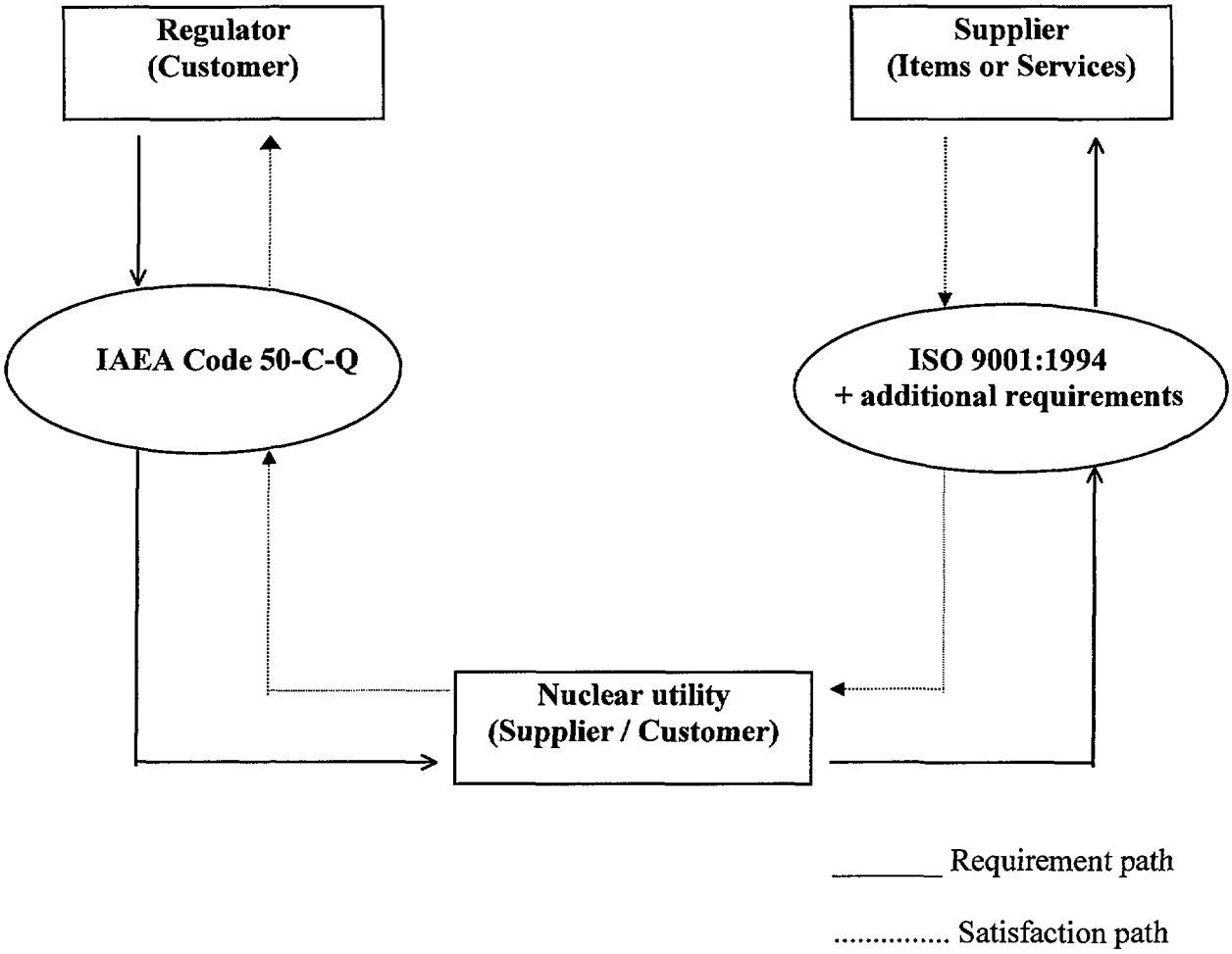

Fig. 1: Application of IAEA Code 50-C-Q and ISO 9001:1994.

3.2.3. Additional requirements

3.2.3.1. Management self-assessment

The IAEA Code 50-C-Q defines specific requirements for "Management self-assessment", an activity not required by ISO 9001:1994.

> *"Management at all levels shall regularly assess the processes for which it is responsible. Management shall determine its effectiveness in establishing, promoting and achieving nuclear safety objectives. Management process weaknesses and barriers that hinder the achievement of the nuclear safety objectives shall be identified and corrected."* (Section 401)

This statement in the Code is further clarified in the Annex:

> *"The thrust of management self-assessment is to identify, correct and prevent management problems that hinder the achievement of the organization's objectives. This Code establishes the requirement for a routine and continuing assessment of the management system by the organization's managers.*
>
> *This self-assessment methodology is in addition to the traditional audit/appraisal that determines the adequacy and extent of the QA programme development, documentation and implementation in accordance with specified requirements. This basic requirement improves on the standard stipulation in many QA programmes, which requires that management regularly assess the adequacy of the portion of the programme for which it is responsible and ensure its effective implementation. This standard requirement is typically achieved, on an annual basis, by an independent consultant or group of consultants on behalf of management, and it addresses compliance issues rather than broad categories of management issues. Management self-assessment goes beyond such matters as conformance to regulations, item standards or established procedures.*
>
> *An effective management self-assessment evaluates issues such as:*
>
> — *mission of the organization*
> — *whether employees understand the mission*
> — *what is expected of the organization*
> — *whether the expectations are being met*
> — *opportunities for improving quality and enhancement safety*
> — *how to make better use of human resources.*
>
> *The results of the management self-assessment are documented. Decisions and related actions resulting from the recommendations are promptly followed up to evaluate their effectiveness.*
>
> *The assessment process involves all levels of management, but senior management retains the overall responsibility for management self-assessments. It is essential that senior management directly participate in this process."*

3.2.3.2. Grading

The IAEA QA 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 have various controls built in to ensure they perform correctly. The grading process is a means of determining what types and extent of controls are applied to specific items, services and processes.

Applying controls costs money, therefore they should be applied and focused where necessary and not applied or applied to a lesser degree for less important activities. Errors in more significant activities can potentially cost huge amounts of money, could shut down a plant or production line and could cause a threat to the staff and the environment. Additional controls that may reduce or eliminate such errors are therefore a good investment.

> *"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.

In general, the highest grade should require the most stringent application of the quality assurance requirements; the lowest grade the least stringent.

The following are examples of topic areas where grading should be applied:

- *Type and content of training*
- *Amount of detail and degree of review and approval of instructions*
- *Need for and detail of inspection plans,*
- *Degree of in-process reviews and controls,*
- *Requirements for material traceability*
- *Type of assessment,*
- *Records to be generated and retained. (Section 210).*

When items, processes or services are modified, the assigned grade of quality assurance requirements could become more stringent or less stringent depending on whether a change in nuclear safety significance has occurred." (Section 211)

Safety Guide 50-SG-Q1 explains what the "graded approach" in relation to nuclear safety means:

> *"Whilst the quality assurance principles remain the same, the extent to which the quality assurance 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."* (Section 209)

ISO 9001:1994 does not specify or define a graded approach for applying the controls specified in the quality system.

3.2.3.3. 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 9001:1994 does not specifically cover the independence of inspection and testing personnel.

3.3. Linkages between the IAEA Safety Guides 50-SG-Q1 to Q14 and clauses of ISO 9001:1994

The linkages between the content of the IAEA Safety Guides and the ISO clauses are presented in the Appendix: Matrix 3.

Matrix 3 supports the following observations:

- The IAEA Safety Guides do not directly consider the customer-related requirements of ISO 9001 defined in Clauses 4.3 Contract Review, 4.7 Control of Customer-Supplied Product and 4.19 Servicing.
- Similar requirements defined under the clauses 'management responsibility' and 'quality system' in ISO 9001 can be found in all of the Safety Guides.
- Stage related Safety Guides in general address the majority of subjects in the ISO clauses.

4. GUIDANCE WHEN USING ISO 9001:1994

A detailed comparison of the IAEA Code 50-C-Q and BR related Safety Guides with ISO 9001:1994 to identify all additional requirements and guidance was carried out. In this comparison the annexes of the IAEA publications 50-C/SG-Q have not been considered as they contain examples illustrative of how the guidance could be implemented. The stage related Safety Guides, with exception of the Safety Guide "Quality Assurance in Design" (50-SG-Q10), were not included in this comparison as they provide specific recommendations for the content of the quality systems at each of the life-cycle stages. The Safety Guide 50-SG-Q10 was included as it provides guidance that may be relevant to the design activity of all stages.

The detailed results of the comparison are included in Sections 4.1 and 4.2. These sections identify additional requirements or guidance found in the IAEA publications 50-C/SG-Q that are not found in ISO 9001:1994. Where the additional requirement or guidance is not self-explanatory some additional notes on application to suppliers are provided.

The application of additional requirements or guidance from the IAEA Code and Safety Guides 50-C/SG-Q should be considered by the nuclear utility from two points of view:

— Should the nuclear power plant/utility address this difference within its own quality assurance programme?
— Should the nuclear power plant/utility require its suppliers to address the difference as an additional requirement in the procurement documents?

The consideration should also take into account the regulatory requirements of each Member State.

4.1. Additional requirements of the IAEA Code 50-C-Q

The following table identifies additional or more detailed requirements in the IAEA Code 50-C-Q that are not contained within ISO 9001:1994.

Section	Additional Requirement	Notes to aid application
101 to 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 demonstrate that its quality programme takes account of and incorporates any requirements from the regulatory body. The utility should require its suppliers to apply any of these specific requirements where necessary.
201 to 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 for activities and items, including procurement, should be described within the utility quality programme. The application of grading to supplier activities should be clarified. The utility should consider whether its supplier should adopt complimentary grading and provide guidance.

Section	Additional Requirement	Notes to aid application
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 identify personnel involved with safety matters and provide the related training and qualification programme. The utility should notify its suppliers when their personnel are involved with safety matters and ensure they are trained appropriately.
206 to 208	**BR 3: Non-Conformance Control and Corrective Actions**	Non-conformance (as per IAEA Code 50-C-Q) covers non-conforming product, system and process non-conformity as per the ISO standard.
304 to 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 quality programme addressing design should specify that persons in charge of safety related design verification and validation should be different from those performing the work. The utility should notify the relevant requirements to suppliers when they perform safety related design activities. Any design verification and approval should be performed before implementation of design. Generally design validation is performed through commissioning under defined operating conditions and specific dispositions should be applied for accidental conditions.
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.	—
306 to 308	**BR 7: Procurement**	Suppliers in IAEA terms are equivalent to subcontractors.
308	Requirements for reporting deviations from procurement requirements shall be specified in the procurement documents.	The option contained within ISO 9001:1994 for reporting deviations (non-conforming product) should be identified as being necessary.
309 to 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.	It is recommended that utilities request suppliers to include this requirement in their quality programme, when appropriate.
401	**BR 9: Management Self-Assessment**	Management Self-Assessment is more complex and detailed than the ISO Management-Review. Management Self-Assessment focuses on the achievement of the nuclear safety objectives. Although ISO 9001:1994 covers the management review and internal audit processes it does not cover management self-assessment. (It is therefore recommended that suppliers providing items and services to ISO Standard also include management self-assessment in their quality assurance programme.)

Section	Additional Requirement	Notes to aid application
401	Management at all levels shall regularly assess the processes for which it is responsible. Management shall determine its effectiveness in establishing, promoting and achieving nuclear safety objectives. Management process weaknesses and barriers that hinder the achievement of the nuclear safety objectives shall be identified and corrected.	The management review should include the assessment of nuclear safety related processes. Nuclear safety objectives should be part of the quality objectives, with associated performance indicators. Weaknesses and barriers should be handled through corrective and preventive action. Management assessment should be carried out at all levels.
402 to 405	**BR 10: Independent Assessment**	Independent Assessment includes quality systems internal audits, peer evaluation, technical review, design review, inspection. Utilities should consider expanding the type of assessments that their suppliers perform.

4.2. Additional guidance of the IAEA Safety Guides

The following tables identify guidance and recommendations that are not contained within ISO 9001:1994.

Safety Guide Q1: Establishing and Implementing a Quality Assurance (QA) Programme

Section	Additional guidance/recommendations	Notes to aid application
101 to 108	**Introduction**	
107	This Safety Guide applies to the establishment and implementation of a QA programme by the responsible organization as well as to the establishment and implementation of other separate programmes at all stages of a nuclear power plant project. It covers items, services and processes important to nuclear safety.	The utility quality system is considered as being the quality programme as per the IAEA code.
201 to 211	**Establishing the QA Programme**	
203	The responsible organization shall develop QA programmes for all nuclear power plant stages (siting, design, construction, commissioning, operation and decommissioning) at a time consistent with the schedule for accomplishing stage-related activities.	The utility quality programme should be developed according to the actual stages of the plant.
209	Whilst the 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 its own QA requirements to its 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.	—
301 to 319	**Documentation of the QA 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 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 ensure that any requirements for subsequent stages are identified and communicated to suppliers. Also see clause 313 of Safety Guide Q3. ALARA stands for As Low As Reasonably Achievable.
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.	—

Section	Additional guidance/recommendations	Notes to aid application
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; 3. The organizational structure and outline of the management procedures; 4. The level of the 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.	This list is basically equivalent to the requirements of ISO 9001:1994, but it may be useful to consider if any of the guidance is helpful to suppliers.
401 to 413	**Implementing the QA Programme**	Plans mentioned in the Safety Guide should be handled through quality planning

Safety Guide Q2: Non-conformance Control and Corrective Actions

Section	Additional guidance/recommendations	Notes to aid application
301 to 313	**Non-conformance Control**	
303	Non-conformances may be discovered during regulatory inspections.	Utilities should determine how they address such non-conformances and inform their suppliers that the regulator may wish to conduct inspections.
305	On being advised of a non- conformance, the line management should promptly inform the regulatory body and other nuclear power plants if necessary.	There may also be a need for suppliers to identify 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: 1. The QA grade or classification of the affected item, service or process; 2. The need for the safety implications of the non-conformance to be independently reviewed; 3. The need to involve the regulatory body.	—
309	The review should determine: 1. The cause of the identified non-conformance, which could include failures, malfunctions, incorrect materials, tools, equipment, procedures, information, training, or human error. Root cause analysis techniques should be utilized. 2. 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.	—
313	Relevant information on the status of non-conformances should be reported to management and the regulatory body, where required.	—
401 to 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.	—

Safety Guide Q3: Document Control and Records

Section	Additional guidance/recommendations	Notes to aid application
301 to 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.	QA documents should contain provisions for assuring that document prepared include all/any controls necessary for the activities to be properly implemented. This may apply to suppliers.
313	Where acceptance by, or approval of, a regulatory body is required, this should be obtained before the document is issued for use.	Utilities should ensure suppliers are aware of any specific documents requiring for regulatory approval
401 to 427	**Establishment of a Record System**	
425	The responsible organization should identify who is responsible for transferring or disposing of records.	This is a utility responsibility. The utility must communicate record requirements to suppliers and ensure suitable records are generated and stored in suitable conditions. Ensuring they are transferred to the utility at some point in time.

Safety Guide Q4: Inspection and Testing for Acceptance

Section	Additional guidance/recommendations	Notes to aid application
201 to 208	**General Considerations**	
204	Personnel shall be trained and qualified so that they are competent to perform their assigned work and so they understand the safety consequences of their activities.	see BR2
301 to 323	**Inspection and Testing**	
319	Testing should demonstrate that the safety function of an item or service has been maintained.	—
401 to 410	**Acceptance of Items and Services from Suppliers**	
501 to 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.	—
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.	—
510	In-service inspection and testing during operation will comprise both routine checks and periodic examinations which may require the plant to be shut down. Both activities should be defined.	—
511	Routine in-service inspection and testing activities should confirm the availability and reliability of systems and should indicate the current plant status.	—
512	For evaluation purposes, the results of in-service inspections and tests during plant shutdown should be recorded using appropriate media such as photographs, videos, instrumentation printouts and computer records.	—
513	Results of in-service inspections and tests should be promptly reviewed and evaluated. Non-conformances should be investigated to determine their root cause. The resulting data should be analysed for trends using statistical methods.	—
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.	—

Safety Guide Q5: Assessment of the Implementation of the QA Programme

Section	Additional guidance/recommendations	Notes to aid application
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.	see BR9
202	The assessment activity falls into two broad categories: 1. Management self-assessment, which is an on-going 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.	—
208	Performance indicators should be developed to measure whether performance is satisfactory or not, with particular emphasis on safety.	see BR9
211	Managers should make arrangements to ensure that all personnel performing assessment activities, including themselves, have appropriate qualification, training and experience.	see BR2
501 to 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, grading should help in the determination.
502	Management self-assessment should be regarded as an on-going process that determines how well leadership is being provided to meet requirements and expectations.	—
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.	—
504	At the senior management level it is appropriate to perform a self-assessment to determine if the overall performance effectively focuses on meeting strategic goals, including safety goals. Reports from line management, summaries of both categories of assessment and regulatory feedback are useful sources of information on the overall performance of the organization. It also assists the manager in targeting improvement actions.	—

Section	Additional guidance/recommendations	Notes to aid application
601 to 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 balanced evaluation of performance.	Consideration might be given to recognizing that suppliers may adopt one or more methods of assessment.
602	A system for internal audits should be established by the assessment unit and agreed with the management of the organization.	—
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.	—
608	Surveillance of work performance is considered to be the best technique for assessing and reporting on a specific area, or an on-going activity. It is flexible and less formal than audits and can be performed in a relatively short period of time with limited preparation.	—
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 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.	—

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

Section	Additional guidance/recommendations	Notes to aid application
201 to 206	**Arrangement 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.	—
202	Procurement activities shall conform to the regulatory requirements of the Member State and, as applicable, to the provisions of recognized codes, standards and specifications used in the design, manufacture, installation and operation of items and services.	—
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.	—
205	This graded approach should be applied throughout the supply chain.	—
501 to 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.	—
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.	—
601 to 607	**Evaluation of suppliers 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.	—
801 to 802	**Commercial Grade items**	
801	Certain items with a proven record may be available from commercial stock. Procurement	—

Section	Additional guidance/recommendations	Notes to aid application
	documents should provide 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 the function should be included as acceptance criteria in the procurement documents.	Methods to be used for such technical evaluation should be delineated in the utility quality system and in the supplier quality system when applicable.
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.	—

Safety Guide Q7: Quality Assurance in Manufacturing

Section	Additional guidance/recommendations	Notes to aid application
201 to 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.	see BR1
301 to 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.	—

Safety Guide Q10: Quality Assurance in Design

Section	Additional guidance/recommendations	Notes to aid application
201 to 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.	—
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	—
223	Suitable working environment shall be provided and maintained so that work can be carried out safely and satisfactorily without imposing unnecessary physical and psychological stress on personnel.	—

APPENDIX: CORRELATION MATRICES

MATRIX 1: IAEA CODE 50-C-Q BASIC REQUIREMENTS COVERAGE IN THE IAEA SAFETY GUIDES 50-SG-Q1 TO Q14

Horizontal Axis Basic Requirements BR1 to BR10 of the IAEA Code in Safety Series No. 50-C/SG-Q Vertical Axis Safety Guides Q1 to Q14 of the IAEA Safety Series No. 50-C/SG-Q			Management				Performance				Assessment	
			BR1	BR2	BR3	BR4	BR5	BR6	BR7	BR8	BR9	BR10
			Quality Assurance Programme	Training and Qualification	Non-Conformance Control and Corrective Actions	Document Control and Records	Work	Design	Procurement	Inspection and Testing	Management Self-Assessment	Independent Assessment
Topic 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										
	Q8	Quality Assurance in Research and Development										
Stage Related Safety Guides	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										

MATRIX 2: CORRELATION BETWEEN THE CLAUSES OF ISO 9001:1994 AND THE IAEA CODE 50-C-Q BASIC REQUIREMENTS

Horizontal Axis Clauses in ISO 9001:1994 Vertical Axis Basic Requirements BR1 to BR10 of the IAEA Code in Safety Series No. 50-C/SG-Q			1 Management Responsibility	2 Quality System	3 Contract Review	4 Design Control	5 Document and Data Control	6 Purchasing	7 Control of Customer-Supplied Product	8 Product Identification and Traceability	9 Process Control	10 Inspection and Testing	11 Control of Inspection, Measuring and Test Equipment	12 Inspection and Test Status	13 Control of Nonconforming Product	14 Corrective and Preventive Action	15 Handling, Storage, Packaging, Preservation and Delivery	16 Control of Quality Records	17 Internal Quality Audits	18 Training	19 Servicing	20 Statistical Techniques
Management	BR1	Quality Assurance Programme																				
	BR2	Training and Qualification																				
	BR3	Non-Conformance Control and Corrective Actions																				
	BR4	Document Control and Records																				
Performance	BR5	Work																				
	BR6	Design																				
	BR7	Procurement																				
	BR8	Inspection and Testing for Acceptance																				
Assessment	BR9	Management Self-Assessment																				
	BR10	Independent Assessment																				

MATRIX 3: CORRELATION BETWEEN THE CLAUSES OF ISO 9001:1994 AND THE IAEA SAFETY GUIDES 50-SG-Q1 TO Q14

Horizontal Axis
Clauses of ISO 9001:1994

Vertical Axis
Safety Guides Q1 to Q14 of the IAEA Safety Series No. 50-C/SG-Q

			1 Management Responsibility	2 Quality System	3 Contract Review	4 Design Control	5 Document and Data Control	6 Purchasing	7 Control of Customer-Supplied Product	8 Product Identification and Traceability	9 Process Control	10 Inspection and Testing	11 Control of Inspection, Measuring and Test Equipment	12 Inspection and Test Status	13 Control of Nonconforming Product	14 Corrective and Preventive Action	15 Handling, Storage, Packaging, Preservation and Delivery	16 Control of Quality Records	17 Internal Quality Audits	18 Training	19 Servicing	20 Statistical Techniques
BR 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																				
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