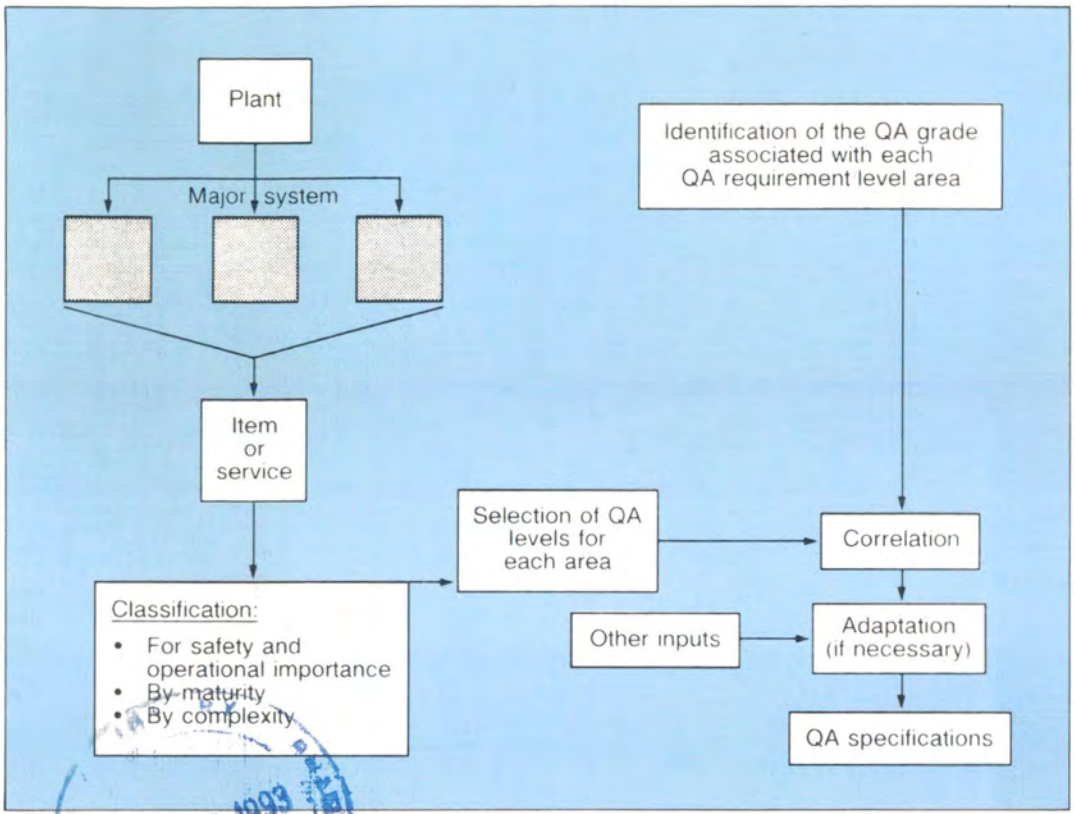

TECHNICAL REPORTS SERIES No. 328

Grading of Quality Assurance Requirements

A Manual

INTERNATIONAL ATOMIC ENERGY AGENCY, VIENNA, 1991

GRADING OF QUALITY ASSURANCE REQUIREMENTS

A Manual

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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".

Printed by the IAEA in Austria
October 1991

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GRADING OF QUALITY ASSURANCE REQUIREMENTS: A MANUAL
IAEA, VIENNA, 1991
STI/DOC/10/328
ISBN 92-0-155291-2
ISSN 0074-1914

FOREWORD

The items and services of a nuclear power plant differ in their relative importance to the safety, reliability and economics of plant performance. In order to take these differences into consideration it is necessary to implement the activities established in the corresponding quality assurance programme in a manner that ensures that the significant items and services have more stringent control and verification measures than items or services of lesser significance whilst at the same time conformance to the required technical specifications is achieved.

The present Manual provides guidance and illustrative examples for applying a method by which graded quality assurance requirements may be determined and adapted to the items and services of a nuclear power plant in conformance with the requirements of the IAEA Nuclear Safety Standards (NUSS) Code and Safety Guides on quality assurance. The Manual replaces the previous publication IAEA-TECDOC-303 on the same subject.

Various methods of grading quality assurance are available in a number of Member States. During the development of the present Manual it was not considered practical to attempt to resolve the differences between those methods and it was preferred to identify and benefit from the good practices available in all the methods. The method presented in this Manual deals with the aspects of management, documentation, control, verification and administration which affect quality.

The endeavours undertaken to develop this Manual are part of the continuing IAEA programme on the preparation of User's Manuals to provide practical assistance in implementing quality activities. In the preparation of this Manual the IAEA received the support of many Member States in the form of expert advice and material. The various drafts were prepared by specialists having extensive experience with the establishment and implementation of quality assurance programmes. The main authors of the document were M. Massicotte (Canada), J. Deckers (Germany), E. Nicoloso (Italy), A. Sayers (UK) and J. Spraul (USA). The drafts for the Manual were critically reviewed and assessed by representatives from nuclear utilities, regulatory bodies and suppliers. In this way all the partners commonly involved in a nuclear power project participated in the development of the Manual and it is expected that the final result will serve as a workable basis for all those involved in the grading of quality assurance programme activities within the nuclear industry.

CONTENTS

1. INTRODUCTION

1.1. BACKGROUND

The Code on the Safety of Nuclear Power Plants: Quality Assurance (IAEA Safety Series No. 50-C-QA (Rev. 1)), hereafter referred to as the 'Code', provides, in para. 205, the requirement that "items, services and processes to which the quality assurance (QA) programmes will apply shall be identified. Appropriate methods or levels of control and verification shall be assigned to those items, services and processes. All programmes shall provide control and verification over activities affecting the quality of the identified items to an extent consistent with their importance to safety".

This requirement is further elaborated in the Safety Guide 50-SG-QA1, which provides specific recommendations on the selection of appropriate QA requirements and their application to items and services to implement the requirements of the Code.

Not all the requirements of Safety Guide 50-SG-QA1 need be applied to all items and services which are to be provided. Efficient QA programmes should be developed to satisfy the necessary requirements and to ensure the required level of confidence in quality without unnecessary stipulations. This can be done by grading QA requirements according to the items and services concerned and taking into account industry experience.

1.2. OBJECTIVES

This Manual has been prepared to provide users (owners, designers, purchasers, manufacturers, constructors, operators and regulators) with a practicable and convenient method of grading QA requirements and determining QA requirements applicable to nuclear power plant items and services. The method presented is not intended to indicate a preferred approach in grading QA but rather to offer examples of grading which are similar to methods and techniques currently in use.

1.3. SCOPE

The grading method presented in this Manual deals with those aspects of organization, management and administration which affect quality. It does not apply to the technical requirements relating to quality, which are determined on the basis of engineering judgement and evaluation.

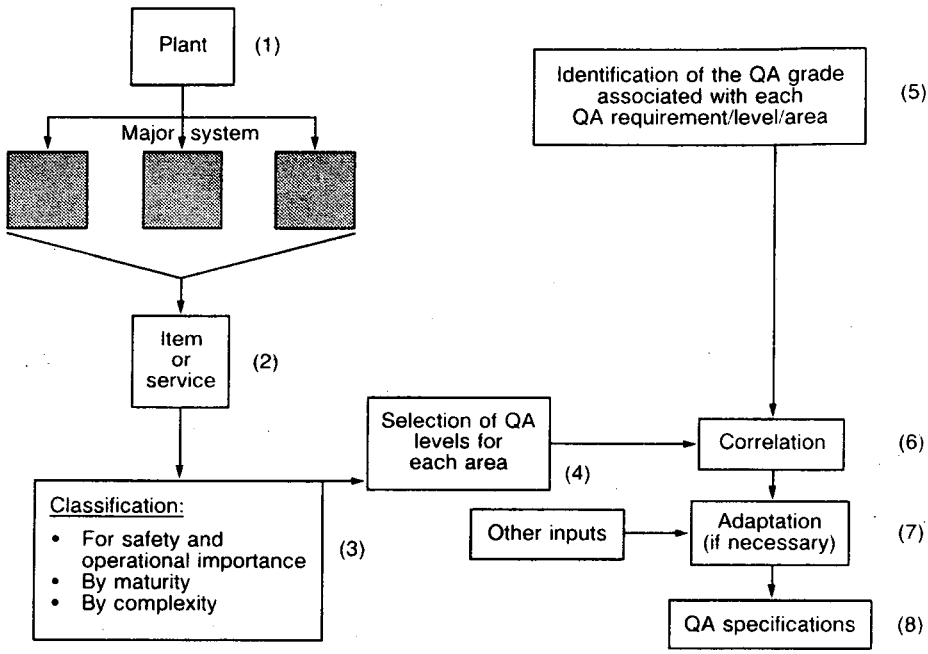

FIG. 1. Flow chart of QA grading method.

1.4. STRUCTURE

The grading method described herein contains the following sections:

— Concepts and basis of a grading method
— Classification of items and services
— Selection of QA level
— Grading of QA requirements
— Correlation of items and services with applicable QA requirements
— Adaptation of applicable QA requirements
— Specifying applicable QA requirements.

The grading method is shown schematically in the flow chart of Fig. 1.

2. CONCEPTS AND BASIS OF A GRADING METHOD

2.1. GENERAL CONSIDERATIONS ON THE QUALITY ASSURANCE GRADING METHOD

Quality assurance can be graded using a number of different methods. The method described in this Manual considers: (1) the safety and operational importance of the item or service; (2) the maturity of the involved areas (design, procurement, manufacturing, construction, operation and management); and (3) the complexity of the involved areas. The implementation of this method requires sound engineering judgement to establish the extent of application for each of the activities of the QA programme.

2.2. BASIS OF THE QUALITY ASSURANCE GRADING METHOD

The QA grading method is illustrated in Fig. 1 and consists of the following eight stages:

(1) First, the plant is divided into its major systems. (Section 3.1).
(2) Next, a particular item or a particular service associated with a major system is identified. (Section 3.1).
(3) The safety and operational importance, the maturity and the complexity of the identified item or service are considered, evaluated and classified. The maturity and complexity of the organization involved are also evaluated. (Section 3.2).
(4) Following classification, one of three different QA levels is selected for each area. Level I identifies a set of graded QA requirements providing the most stringent controls. Level II identifies a set of requirements providing less stringent controls than level I but more than level III to produce adequate confidence. (Section 4).
(5) Each of the QA requirements for each level in each area is identified and graded. (This has already been achieved in some national standards and QA specifications.) Grades 1, 2 and 3 are used such that grade 1 requires full implementation of the defined QA requirements and is the most stringent. Grade 2, for the same QA requirements, is less stringent than grade 1 but more stringent than grade 3. A grade indicated by a 'dash' shows that good commercial practice is acceptable with no additional QA requirements to provide adequate confidence. (Section 5).
(6) The applicable QA requirements corresponding to each grade, for each QA requirement/level/area, are determined. (Section 6).
(7) If necessary, an adaptation is made to special circumstances. (Section 7).
(8) A QA specification or requirements document is prepared. (Section 8).

3. CLASSIFICATION OF ITEMS AND SERVICES

3.1. IDENTIFICATION OF ITEMS AND SERVICES

A meaningful method of classification should begin by dividing the plant into its major systems (e.g. primary circuit, emergency core cooling system, containment system, etc.). This may already have been accomplished for a similar plant. Further division and subdivision of these systems into basic units should follow until each unit is identified as a discrete item or service.

3.2. CLASSIFICATION METHOD AND TECHNIQUES

3.2.1. Classification in terms of safety and operational importance

The method of classification should allow each item or service to be characterized with respect to the importance of the function each performs in the overall safe and satisfactory operation of the nuclear plant. Annex I presents such a classification system.

3.2.2. Classification by maturity

Items or services are classified in a way that reflects the maturity and experience available in each area. The maturity is a measure of the availability of experienced organizations and staff and proven designs and processes.

(1) Design maturity

The maturity of the design is based on the availability of an equivalent design which has proved effective by performance tests and field experience.

(2) Procurement maturity

The maturity of procurement activities is based on the experience of the organizations involved in the procurement process.

(3) Manufacturing and construction maturity

The maturity of manufacturing and construction activities is based on the availability of relevant experience in the manufacture or construction of items or services required to meet similar or equivalent requirements. Proven performance, processes and qualifications should be taken into account.

(4) Operation maturity

The maturity of operation activities is based on factors such as plant personnel qualifications, experience and knowledge of systems and components, proven practices and procedures and equipment operational history. Whenever available, plant performance indicators can provide valuable indications of operation maturity.

(5) Management maturity

The maturity of the management can be determined by factors such as the experience of the organization in performing the required tasks (for example, an organization expressly established for a specific task or contract cannot be considered mature) and the stability of the management systems.

3.2.3. Classification by complexity

Items or services can also be classified in a way that reflects the complexity of the organization, functions and activities involved in the various areas.

(1) Design complexity

The classification of the complexity of design is based on the difficulties likely to be encountered in the effective implementation of the design process. This classification reflects the complexity of the design process and not the complexity of the item or its function. It takes into account, for example, cases where a supplier carries out reviews of designs by other organizations prior to production. The evaluation of the complexity of design should also consider other factors, such as safety, seismic and stress analyses, material selection and environmental analysis.

(2) Procurement complexity

The complexity of the procurement activities relates to the complexity of the organizations involved and the complexity of the item or service to be procured.

(3) Manufacturing and construction complexity

The complexity of manufacturing and construction activities is based on the processes involved and the degree of difficulty associated with each process in the achievement and verification of quality characteristics. Account should be taken of other aspects such as the number of close tolerances and the number of moving parts.

(4) Operation complexity

The complexity of operation is based on the number and the interrelations of the controls required for the operational activities, the extent to which radioactive materials have to be handled, the reliability of the systems and components and their accessibility for maintenance, inspection, test and repair.

(5) Management complexity

The complexity of management can be determined by factors such as the size of the organization, the number of functions involved and the multiplicity of organizational interfaces encountered.

4. SELECTION OF QUALITY ASSURANCE LEVEL

4.1. QUALITY ASSURANCE PROGRAMME ACTIVITIES

The QA requirements described in the Code and elaborated further in the associated Safety Guides can be related to activities for an overall QA programme and also for the constituent QA programmes. Annex II shows how the activities of the constituent QA programmes are grouped into areas (design, procurement, manufacture, construction, operation and management) with respect to the overall QA programme and to each other.

4.2. CRITERIA FOR QUALITY ASSURANCE LEVEL SELECTION

4.2.1. Level selection for design

The criteria to be used in establishing the different QA levels for design are the function of the item or service, the safety considerations, the complexity of the design and the maturity of the technology.

Level I requirements should be selected if the design is intended for a critical application and inadequate control of design activities could result in a failure or malfunction leading to an undue risk to the health and safety of the operating personnel or the public. Level I should also be considered if the design effort is extensive or complex or if the design is new or is made from first principles.

Level III requirements can be selected if the application is non-critical, if there is no risk to the health and safety of the operating personnel and the public and if a proven design is available.

For intermediate degrees of criticality of application, importance of malfunction, complexity and maturity, level II should be selected.

4.2.2. Level selection for procurement

The criteria to be used in establishing the different QA levels for procurement relate to the relevant contracted activities in design, manufacturing, construction and operation. Factors to be taken into consideration are the function of the contracted item or service in terms of safety and operational importance, the complexity of the processes used and the maturity of the technology to be employed in designing, manufacturing and constructing the item or service.

Level I requirements should be selected if the contracted items are intended for a critical application and a malfunction could result in an undue risk to the health and safety of the operating personnel or the public, if the items or services require a large number of complex processes, or if suppliers are inexperienced in the design, manufacture or construction of similar items or services.

Level III requirements can be selected if the application of the items or services is non-critical and there is no risk to the health and safety of the operating personnel and the public should a failure or malfunction occur, if the technology is proven and if the supplier has a proven record of supplying equivalent items or services.

For intermediate degrees of criticality of application, importance of malfunction, complexity of processes and maturity of technology, level II should be selected.

The same process for the level selection of QA requirements is applicable to each lower tier in the procurement process.

4.2.3. Level selection for manufacturing

The criteria to be used in establishing the different QA levels for manufacturing are the function of the item or service in terms of safety and operational importance, the complexity of the manufacturing processes and the maturity of the manufacturing technology.

Level I requirements should be selected if the manufactured item is intended for a critical application and inadequate control of the manufacturing processes could lead to a malfunction resulting in an undue risk to the health and safety of the operating personnel or the public. Level I should also be considered if the items or services require a large number of complex processes, if the items have a large number of close tolerances or moving parts or if the manufacturing processes are new.

Level III requirements can be selected if the application is non-critical and there is no risk to the health and safety of the operating personnel or the public should a failure or malfunction occur, if items or services require only a few simple processes and have few close tolerances and moving parts, and if the technology is proven.

For intermediate degrees of criticality of application, importance of malfunction, manufacturing complexity and maturity of technology, level II should be selected.

4.2.4. Level selection for construction

The criteria to be used in establishing the different QA levels for construction are the function of the item in terms of safety and operational importance, the complexity of the construction processes and the maturity of the construction technology.

Level I requirements should be selected if the item is intended for a critical application and there would be an undue risk to the health and safety of the operating personnel and the public should a failure occur. Level I should also be considered if the item is unusual or difficult to construct or if the contractor has little experience in the field.

Level III requirements can be selected if the item is intended for a non-critical application and if there would be no risk to the health and safety of the operating personnel or the public should a failure occur, if the construction processes are simple and if the contractor is experienced in the field.

For intermediate degrees of criticality of application, importance of malfunction and average contractor experience, level II should be selected.

4.2.5. Level selection for operation

A number of activities during operation involve servicing of plant items. To establish the QA levels for operation, engineering judgement is used to determine the consequences of inadequate performance or inadequate control of an activity or service. As a result of this evaluation, levels I, II or III may be attributed to the activity or service even though the items to which they pertain are safety and operationally significant and are defined as level I for design, manufacture and construction.

Level I requirements should be selected when inadequate control of activities during operation could result in undue radiological risk to the health and safety of operating personnel or the public. Level I should also be considered when the organization and facility are new or when a given operation is complex.

Level III requirements can be selected when only minor safety or environmental impact risks exist and when insignificant cost penalties are incurred as a result of failure, when the organization and facility are mature and when the operations are not complex.

For intermediate degrees of safety or operational importance, complexity and maturity of operations, level II should be selected.

4.2.6. Level selection for management

The main criterion to be used in establishing the different QA levels required for management is the extent to which the work of the organization affects safety and operational importance. The organizational maturity and complexity should also be considered.

Level I requirements should be selected when the work of the organization can directly affect the safety of operating personnel or the public or the continued operation of the plant. Level I should also be considered when the organization is large or complex, when the management or operating experience is limited, when there are many organizational interfaces and functions or when the assigned tasks involve complex or novel activities.

Level III requirements can be selected when the work of the organization cannot directly affect the safety of operating personnel or the public or the continued operation of the plant, when the organization is small and mature, when the organization can operate properly with uncomplicated management practices and when there are few interface relationships.

For intermediate degrees of impact on safety or operational importance, complexity and maturity of organization, level II should be selected.

Owing to the direct connection between the management area and all the other areas, it is advisable that the level selection for management be made after that for the other areas. The selected management level should be consistent with the highest level selected for the other areas.

4.2.7. Examples of level selection

Annex III gives examples of selected QA levels for the procurement of plant items.

5. GRADING OF QUALITY ASSURANCE REQUIREMENTS

Section 4 has shown how one of three specific QA levels is selected for each of the areas following consideration of factors such as safety and operational importance, maturity and complexity.

The next stage is to identify specific grades for each of the QA requirements corresponding to an area for each of the three QA levels.

The criteria used in identifying the grades and related requirements for each of the QA programme activities should be developed to achieve varying degrees of control, verification, measurement and records and still maintain confidence that items or services satisfy given requirements for quality. Annex IV gives the graded QA requirements for different areas.

Some referenced standards, regulations and contractual specifications have already established the association between QA levels and grades. This simplifies the selection process and it is only necessary to review the established grades to verify that the requirements are appropriate for the selected levels.

If the association between QA levels and grades is not established, the less stringent QA requirements associated with levels II and III should be determined for each of the related QA requirements (level I corresponds to the full requirements stated in the Code and related Safety Guides or equivalent). The determination should take account of the industrial situation, the state of the art and the organizational arrangements within which the grading is being made.

Engineering judgement must be applied to ensure that the less stringent QA requirements are acceptable and do not impair confidence in the final quality. Optimum results are achieved when the engineering judgement is made by experts knowledgeable about both the relevant technology and QA methodology.

6. CORRELATION OF ITEMS AND SERVICES WITH APPLICABLE QUALITY ASSURANCE REQUIREMENTS

After the appropriate QA levels for each area have been selected (Section 4) and the QA requirements for each of the QA levels graded (Section 5), a set of applicable QA requirements is determined. Annex V gives examples of the QA requirements associated with grades 1, 2 and 3 for some of the QA requirements listed in Annex IV. Such examples have been derived from established grading methods.

Section g of Annex V shows how, for maintenance control, the identification of grades is not totally dependent on the safety and operational significance of the item because it is a service of the item and not the item itself that is being considered.

These requirements, subject to review and, if necessary, adapation (Section 7), should be incorporated into a final specification or, as appropriate, a QA requirements document (Section 8).

7. ADAPTATION OF APPLICABLE QUALITY ASSURANCE REQUIREMENTS

The next step is to adapt the applicable QA requirements to any unique factors related to the specific items or services. Some of the factors which should be considered are listed below.

7.1. ACTIVITIES PERFORMED UNDER COMMERCIAL LICENCE

These activities normally imply a division of responsibilities. As a consequence, it may be acceptable to adapt less stringent QA requirements (taking into account the 'licensor' experience) or more stringent QA requirements (in the area of licensor–licensee interface).

7.2. ECONOMIC ASPECTS AND COST EFFECTIVENESS CONSIDERATIONS

These elements can influence the adaptation of the QA requirements or lead to alternative QA methods which still provide adequate assurance of quality. For example, this can be the case whenever the quality of an item or service can be fully verified by final inspection or test.

7.3. QUALITY ASSURANCE PROGRAMMES ALREADY IN USE

The status of the QA programme adopted by an organization can also influence the adaptation of the QA requirements. The experience already acquired by a supplier in the nuclear field, the regular implementation of the programme and the management policy and attitude are all elements to be considered.

7.4. COMMERCIAL GRADE ITEMS

Commercial grade materials or components may be accepted for use as safety or reliability related items if their technical characteristics have been reviewed and found acceptable by the responsible engineer. In this case, specific QA requirements may be relaxed in the contract, but acceptability must be verified.

7.5. AUTOMATED PRODUCTION LINES

If an item is produced directly from an automated production line, it may be more productive to concentrate attention on the control of the manufacturing processes rather than the product characteristics.

7.6. CONFIDENCE IN REGULAR SUPPLIERS

Favourable quality history and trends in previous experience may provide sufficient evidence to reduce the QA verification activities. This confidence may permit limiting the scope of surveillance, auditing and inspection.

7.7. SERVICES BY INDIVIDUALS OR A SMALL NUMBER OF PERSONS

Contracting services to individuals or a small number of persons may allow the integration of their activities into the purchaser's QA programme, identifying only the requirements necessary to fulfil such integration.

7.8. LOWER TIER PROCUREMENT

Under certain conditions, the assignment of QA activities to some lower tier programme participants may be inappropriate. In such cases, it may be more cost effective for the purchaser to perform certain QA programme activities. For instance, if the item being furnished is a standard mass produced item, it may be more effective for the purchaser to perform receiving inspection to screen out inferior items rather than requiring the supplier to perform additional activities.

7.9. RADIATION EXPOSURE

During operation, consideration of radiation exposure may result in adaptation of the QA requirements. For example, enhanced training to keep personnel radiation exposure as low as reasonably achievable may allow reduced verification.

8. SPECIFYING APPLICABLE QUALITY ASSURANCE REQUIREMENTS

The final step of the method for grading QA is the incorporation of the requirements into a final QA specification or, as appropriate, QA requirements document.

Annex VI illustrates a typical format for specifying contract QA requirements. In this example, Section 1 of the format identifies the scope of application of the programme, a listing of the codes and standards that must be adhered to, the supplier's contractual responsibilities and the purchaser's right of access to initially assess the supplier's capability to perform the work and to later verify correct implementation of the programme and execution of the work.

Section 2 identifies the specific QA requirements for the relevant areas of activity or, alternatively, it may make reference to recognized standards, codes or guides for the selected QA level for each area.

When applicable QA requirements are defined by stipulating an appropriate reference document, the document reference should be complete and specific, including references to applicable sections, subsections and paragraphs. The requirements should specify any modifications, additions or deletions to the reference document.

Section 3 addresses the purchaser–supplier interfaces to ensure compliance with the contract QA and technical requirements.

9. EXAMPLES OF APPLICATIONS OF THE QUALITY ASSURANCE GRADING METHOD

The implementation of the QA grading method presented in the previous sections requires, as already mentioned, the use of sound engineering judgement in order to establish the extent of application of the QA requirements. Appendix I presents a method based on such engineering judgements while Appendix II gives an example of the conversion of such judgements into numerical ratings and the use of these ratings to select the QA levels.

Appendix I

EXAMPLE OF SELECTION OF QA LEVELS: EMERGENCY DIESEL GENERATOR

I.1. ACQUISITION OF DATA AND INFORMATION RELATIVE TO THE EMERGENCY DIESEL GENERATOR

It is essential to provide the person responsible for the QA grading with as much information as possible to support the choice made. The kind of information listed here should be supplemented by any additional detail considered useful for a clear and complete understanding of the item or service under consideration.

I.1.1. Classification by safety and operational importance

The function of an emergency diesel generator (EDG) is to provide electric power for the operation of selected loads in the event that the power station becomes isolated from external sources, in order to prevent accidents involving the release of radioactive material and/or to minimize the consequences of such accidents, should they occur.

It is assumed that emergency electric power will be normally supplied by three EDGs designed to provide adequate redundancy against possible outages (for failure to start up, failure during operation, unavailability during maintenance, etc.)

It is assumed that the malfunction of a single EDG will not be critical for the plant safety or for the plant availability.

The EDGs have no direct operational importance with respect to the plant availability (although the prevention of accidents may have a great importance in assuring a safe and quick restoration of the power generation). Therefore, the safety function is considered to prevail over the operational importance.

I.1.2. Classification by maturity

It is assumed in this example that the EDGs will be supplied by manufacturers with extended experience in the field, on the basis of a standard design and a standard (catalogue) type. It is also assumed that the installation and testing of the EDG on site will be carried out by expert technicians supported, where necessary, by the supplier office.

The details of the classification by maturity for the different areas are presented in Section 2 of this Appendix.

I.1.3. Classification by complexity

It is assumed that the design, manufacture and installation of the EDGs, and the organizations involved, do not differ, with regard to complexity, from the common practices adopted for this kind of product and that such practices are equivalent or very similar in various countries.

The details of the classification by complexity for the different areas is presented in Section 2 of this Appendix.

I.1.4. Other useful information (assumed)

The scope of the contract for the EDGs will include (and be limited to) the design, procurement, fabrication, shop testing, installation and site testing of the EDG system and the auxiliary systems necessary for its operation.

The EDG manufacturer operates as the main supplier and is responsible for the procurement of raw or semifinished material needed for the EDG and also for the major electrical equipment (generator, excitation control, electrical panels, cables, etc.) from known and experienced suppliers.

The purchaser will not interfere with the responsibilities of the supplier; conversely, the purchaser's surveillance activities will not release the supplier from the responsibility of complying with all requirements related to the complete EDG system.

Each EDG system will include the diesel engine, the synchronous three phase generator and its static excitation system, the diesel engine lubrication oil system, air intake and exhaust system, and electrical control system and panels.

I.2. SELECTING QA LEVELS

I.2.1. Design area

(a) Safety and operational importance

The malfunction of an EDG would be of great importance if reliance had to be placed on only one EDG. However, the emergency system has been conceived with appropriate redundancy (three EDGs, each able to feed all the emergency bus lines) and related connections.

(b) Maturity

The EDG system design process is well established and adequately 'mature' since the system is standard. The experience already gained in the operation of such

EDGs has permitted the resolution of 'infancy' problems and confirmed that the design is sound, mature and proven.

(c) Complexity

The design process in this situation will involve activities of reduced complexity, being essentially limited to the adaptation and/or verification of the compliance of the standard design with the technical requirements. The design process will, nevertheless, require the establishment of a number of interfaces among mechanical, electrical, control and civil design groups within and outside the main contractor organization and also will involve the preparation of specific procurement documents.

(d) Evaluation

On the basis of the above considerations, the QA level for design is judged to be level II.

I.2.2. Procurement area

This section deals with the QA requirements to be contractually imposed on the main supplier for performing its procurement activities. These activities can be either internal or external.

Internal procurement activities are those which are performed using internal procedures which are applicable to any kind of procurement carried out by the supplier. These activities involve, for example, the identification of the requirements, the preparation of the procurement documents, the bid request and tender evaluation steps, the setting up and maintenance of the approved subsupplier list and the drawing up of the contract. All of these activities and interfaces are defined, governed and controlled within the organizational and management 'area', as are all the other internal activities and interfaces. For this reason, the QA requirements related to this area are referred to and included in the management area.

External procurement activities include those directly concerning the specific product or service to be procured and involving interfaces with external organizations. These activities include, for example, the evaluation of subsuppliers for the specific purchases, the establishment of the QA requirements, surveillance activities carried out during the manufacturing stages, the auditing activities and the final acceptance of the products or services. The selection of the QA requirements for these external procurement activities is uniquely related to the product or service that the main supplier has to procure and not to the characteristics of the EDG as a whole or to the main supplier as such.

For each procured product or service, the same selection process for the grading of QA requirements should apply. That is, the method described in this Manual is applicable to each lower tier in the procurement process. In this case, the main supplier (with the concurrence of the purchaser, when contractually established) should select the QA requirements to be contractually imposed, e.g. for the procurement of the electric generator, the lubricating oil heat exchangers, the control panels and so on.

When the main supplier interfaces with a subsupplier in the performance of the QA activities, there should be a correlation that takes into account the complexity, maturity and importance of the products or services. This applies, for example, in the evaluation of the acceptability of the potential subsupplier's QA programme and in establishing the 'extent' of the surveillance activities (such as the number of subsupplier documents to be submitted for information or approval, the number of notification/hold points and the number of audits of the subsupplier's QA programme).

Many products (for example, those which are not essential to the proper functioning of the EDG or the quality of which can be completely verified with final testing/incoming inspections, or which are considered acceptable as standard or catalogue items) will not require any special QA requirements for the subsupplier. The selection of these products would, however, be made by competent and knowledgeable personnel.

In summary, the selection of the QA levels applicable to the procurement area requires a double approach:

— for internal procurement activities, the applicable QA level coincides with the level that will be selected for the management area;
— for external procurement activities, the QA requirements should relate directly to, and be correlated with, the QA levels selected for each procured product or service.

I.2.3. Manufacturing area

(a) Safety and operational importance

The considerations presented in the design area for the evaluation of the importance of any malfunction of the EDG also apply to the manufacturing area.

(b) Maturity

The manufacturing activities required to produce the diesel engine and related auxiliaries can be considered mature. The diesel engine is from a standard production run and will be manufactured in the same shop as other diesels of the same series.

(The manufacturing activities referred to concern only the diesel engine and not the generator, the electrical and control panels and the other auxiliary systems which will be manufactured by subsuppliers. These items should be dealt with separately in the evaluation of the relevant maturity.)

(c) Complexity

The manufacturing activities (including assembly and physical and functional testing) are complex, owing to the essential need for co-ordination and planning, the number of interfaces to be controlled, the variety and number of components and processes, the delicacy and criticality of some manufacturing and control processes, the need for qualified personnel and so on.

(d) Evaluation

The 'complexity' factor in this case overrides all the other factors. The QA level for manufacturing is judged to be level I.

I.2.4. Construction area

The construction area includes all the activities required for the installation and commissioning of the EDG. The installation will be carried out by or on behalf of the main supplier and will normally include the entire system, i.e. the diesel engine (and related auxiliaries such as the startup system, the preheating and cooling system, the water and oil heat exchangers and the piping), the electric generator (and related auxiliaries such as the excitation system and the protection system), the control panel and the electrical panels.

(a) Safety and operational importance, maturity and complexity

The installation activities are fully normal and although involving various elements and disciplines (such as transportation, rigging, aligning, welding, non-destructive testing, flushing and cabling), are generally of little complexity. The functional testing (which can be considered to represent, in a certain way, the final check that the design, fabrication and installation of the EDG system have been successfully accomplished) is not expected to present special difficulties since it involves standard and proven procedures.

(b) Evaluation

The QA level for construction (installation) of the EDG system is judged to be level III.

I.2.5. Management area

The selection of the QA level for this area should be established after the QA level selection for the design, manufacturing and construction areas have been determined because of the close relationship between the areas.

(a) Safety and operational importance

The importance attributed to the management area is evaluated with reference to its impact on the activities required for the supply of the EDG and should be in line with the evaluation of the importance attributed to the design, manufacture and construction of the EDG.

(b) Maturity

It has been assumed that the supplier of the EDG has a well established and experienced organization and so it can be concluded that the management area is mature, i.e. that the responsibilities, internal interfaces and co-ordination among different organizational units not only have been defined but are also operating smoothly.

(c) Complexity

The complexity of the organization and its operating modes, with regard to the QA level to be selected, is assumed to coincide with the highest complexity among the other areas (design, manufacturing and construction). This assumption is based on the correlation which normally exists between the complexity of an activity and the complexity of the related organization. In this case, the highest complexity has been identified in the manufacturing area and the organization required for the design and for the construction activities is relatively simple.

(d) Evaluation

It is clear from the above that the 'complexity' factor plays the most important role. The QA level of the management area is judged to be level I.

I.2.6. Summary of the QA levels

The set of the QA levels that the purchaser of an EDG system should select, under the specified conditions, may be summarized as follows:

— Design area:	Level II
— Procurement area:	See Subsection 2.2
— Manufacturing area:	Level I
— Construction area:	Level III
— Management area:	Level I.

Appendix II

EXAMPLE OF SELECTION OF QA LEVELS AND GRADES: DESIGN AND MANUFACTURING OF A PIPING SYSTEM

The example in this appendix applies a numerical rating method to the selection of the QA levels for a steam line of a BWR inside the containment.

II.1. IDENTIFICATION OF ITEMS (1, 2)[1]

The nuclear steam supply system of the BWR is installed inside the containment with a pressure suppression system. Each steam line can be isolated by valves located on either side of the containment shell. The pipe line has a nominal diameter of 500 mm.

In accordance with Fig. 1, the system is divided into the following items:

— straight tubes, elbows and fittings;
— containment penetration including bellows; and
— isolation valves.

II.2. CLASSIFICATION (3)

In this example, the design and manufacturing areas are addressed for each of the items. The classification criteria used are listed in Table I for safety/operational importance, design maturity and complexity, and manufacturing maturity and complexity. Similar criteria would need to be developed for procurement, construction, operation and management.

II.2.1. Safety and operational importance

The system can fail in different ways. In the most serious case, a loss of coolant accident results in considerable health hazard to plant personnel and the public. Less serious failures lead to exposure to radiation and, therefore, to a health hazard for the plant personnel and the personnel engaged in performing the repair work.

In the event of a system failure the entire plant has to be shut down. The resulting financial consequences are considerable in terms of both the costs of the repair and loss of production.

The safety/operational importance is, therefore, rated as 1 in accordance with Table I.

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[1] Numbers in parentheses correspond to the numbers in Fig. 1.

TABLE I. CLASSIFICATION CRITERIA

Safety/operational importance

1 Results in risk to health and safety of both personnel and public and/or results in total loss of operation
2 Results in risk to health or safety of operating personnel or limited risk to the public and/or seriously downgrades the operation
3 Results in significant risk to safety and/or significantly downgrades the operation
4 Results in limited risk to safety and/or downgrades the operation to a limited extent
5 No risk to health and safety and/or negligible inconvenience and cost

Design maturity

1 New design of a complex product or service
2 Redesign of existing product or service
3 Modification of proven design
4 Combination of proven design elements
5 Proven design available

Design complexity

1 Design effort is extensive and complex
2 Design effort is extensive or complex
3 Design effort presents some complexity
4 Design effort is significant but simple
5 Design effort is minimal and simple

Manufacturing maturity

1 New manufacturing processes
2 Combination of new and proven manufacturing processes
3 Major modification of proven manufacturing processes
4 Minor modifications to proven manufacturing processes
5 Proven manufacturing process available

Manufacturing complexity

1 Large numbers of complex processes
2 Significant numbers of complex processes
3 Few complex processes
4 Significant number of simple processes
5 Few simple processes

II.2.2. Design maturity

Steam supply systems of similar design have been built in great numbers, for conventional power plants as well as nuclear power plants. It is reasonable, therefore, to consider the design of the system as being mature.

The containment penetration is an improved design of already existing penetrations. The valve design, however, is new and experience is available only from valves of some similarity.

Again, using Table I, the following ratings are chosen for design maturity:

— straight tubes, elbows and fittings — 5
— containment penetration including bellows — 2
— isolation valves — 1.

II.2.3. Design complexity

The system is to be designed for different kinds of loads and different load cases. The loads include fluid pressure and temperature, thermal stress as well as vibration caused by valve closing, earthquakes or other effects from outside the plant. All of these are detailed in the specifications.

TABLE II. SUMMARY OF CLASSIFICATION

	Safety and operational importance	Maturity	Complexity	Total	QA level
Design					
Straight tubes, elbows and fittings	1	5	4	10	II
Containment penetrations including bellows	1	2	2	5	I
Isolation valves	1	1	1	3	I
Manufacturing					
Straight tubes, elbows and fittings	1	5	2	8	II
Containment penetrations including bellows	1	1	1	3	I
Isolation valves	1	1	1	3	I

TABLE III. GRADED QA REQUIREMENTS — DESIGN OF STEAM SUPPLY SYSTEM

	QA level	
	I[a]	II[b]
QA requirements	*QA grade*	
Personnel training and qualification	1	2
Specification of design input	1	2
Checking and approval of design inputs	1	—
Design process planning and performance	1	1
Design analyses	1	2
Drawing preparation	1	1
Preparation of specifications and other design documents	1	2
Design interface control during design process	1	1
Communication between design organization and other organizations (feedback)	1	1
Design verification		
Design reviews and/or	1	2
Alternative calculations and/or	1	2
Qualification testing	1	2
Document control		
Document preparation, review and approval	1	1
Document release and distribution	1	1
Document change control	1	1
Control of design changes	1	2

[a] Isolation valves and containment penetrations including bellows.
[b] Straight tubes, elbows and fittings.

In total, the system is quite complex, although the straight tubes, elbows and fittings are of relatively simple design. On the basis of Table I, the following ratings are chosen for design complexity:

— straight tubes, elbows and fittings — 4
— containment penetrations including bellows — 2
— isolation valves — 1.

II.2.4. Manufacturing maturity

There is a proven manufacturing process available for straight tubes, elbows and fittings. The containment penetration, bellows and isolation valves will be manufactured by a new supplier. Again, from Table I, the following ratings are chosen for manufacturing maturity:

— straight tubes, elbows and fittings — 5
— containment penetrations including bellows — 1
— isolation valves — 1.

II.2.5. Manufacturing complexity

A number of complex processes are required for production, inspection and testing of the system. The manufacturing process is complex. The tube material needs quenching and tempering, a number of thick wall items are to be joined by welding followed by subsequent heat treatment, and dimensions are very critical because of the need to minimize displacements resulting from thermal expansion within the entire system. On the basis of Table I, the following ratings are chosen for manufacturing complexity:

— straight tubes, elbows and fittings — 2
— containment penetrations including bellows — 1
— isolation valves — 1.

Tables II and III summarize the ratings and give the totals for each in each area.

II.3. SELECTION OF QA LEVEL (4)

Using the totals shown in Table II, the QA levels are selected as follows:

Total	Level
3–6	I
7–11	II
12–15	III

The resultant QA levels are also shown in Table II.

TABLE IV. GRADED QA REQUIREMENTS — MANUFACTURING OF STEAM SUPPLY SYSTEM

	QA level	
	I[a]	II[b]
QA requirements	*QA grade*	
Personnel training and qualification	1	2
Manufacturing process planning and change control		
Identification of requirements	1	1
Identification of processes	1	1
Process qualification	1	1
Plans and procedures	1	2
Change control	1	2
Document control	1	1
Procurement control	1	1
Item identification control	1	1
Inspection and test control		
Procedures and instructions	1	2
Inspection	1	2
Testing	1	2
Results, evaluation and reporting	1	2
Measuring and test equipment control	1	1
Handling, storage and shipping		
Handling	1	1
Storage	1	2
Shipping	1	2
Non-conformance control		
Identification and documentation	1	1
Segregation	1	1
Review and disposition	1	2

[a] Isolation valves and containment penetrations including bellows.

[b] Straight tubes, elbows and fittings.

II.4. GRADING OF QA REQUIREMENTS (5)

The graded QA requirements can be taken from Annex IV or derived from national standards or QA specifications. The present example uses Annex IV Section a for design and Annex IV Section c for manufacturing. Tables III and IV show the results.

II.5. DETERMINING, ADAPTING, AND SPECIFYING GRADED QA REQUIREMENTS (6–8)

The QA requirements for each level and grade should be derived as described in Section 6. Sections 7 and 8 describe the adaptation and specification of these QA requirements.

Annex I

CLASSIFICATION OF ITEMS AND SERVICES FOR SAFETY AND OPERATIONAL IMPORTANCE

Category	Definition	Description
I	Permanent plant — safety related	Structures, systems and components that prevent or mitigate the consequences of postulated accidents that could cause undue risk to the health and safety of the public (e.g. primary heat transport system components).
II	Permanent plant — operationally significant	Structures, systems and components not covered in category I but whose failure to function at full design rating will affect the ability of the plant to function at its design rating and which are not essential for a safe shutdown or shutdown heat removal. Failure of the items in this category would not endanger public safety (e.g. turbine generator and associated service equipment).
III	Permanent plant — non-operationally related	Structures, systems and components used to support normal plant operations whose failure to function would not cause damage to safety related structures, systems or components, and which are not essential to the ability of the plant to function at its design rating. These items do not contain radioactive material and their failure could not result in the release of radioactive material (e.g. administrative building, yard drains, parking lot).
IV	Non-permanent plant related	Non-permanent plant structures, systems and components which are required for plant construction activities but which do not become part of the permanent plant. This category includes site preparation and improvement (e.g. temporary construction equipment and buildings).

Annex II

STRUCTURE AND ACTIVITIES OF QA PROGRAMME

Overall programme				
Programme management				
Quality assurance programme Organization Document control		Audits and reviews Non-conformance control Corrective action		Reporting Records Personnel training
Design	Procurement	Manufacturing	Construction	Operation
Design input requirements Design process planning and performance Design verification Design change control	Planning Procurement document preparation, review and change control Selection of procurement sources Bid evaluation and award Purchaser evaluation of supplier performance Verification activities by purchaser Non-conformance control and corrective action Acceptance of items and services	Manufacturing process planning and change control Document control Procurement control Item identification control Inspection and test control Results evaluation and reporting Measuring and test equipment control Manufacturing equipment control Handling, storage and shipping Non-conformance control	Planning Receiving, storage and handling Measuring and test equipment control Change control In-process inspection and testing Final inspection and tests Inspection and test data analysis and evaluation Non-conformance control	Planning Document control Operational control Maintenance control Modification control Material control Equipment control Inspection and testing Calibration control Non-conformance control

Annex III

EXAMPLES OF SELECTED QA LEVELS FOR THE PROCUREMENT OF PLANT ITEMS

Item	Design	Manufacture	Construction	Management
	QA level[a]			
Reactor pressure vessel	I	I	II	I
Reactor internals	II	I	II	I
Primary circuit piping	I	I	II	I
Primary circuit pipe supports	II	II	—[b]	II
Primary circuit thermal insulation	III	III	III	III
ECCS heat exchangers	I	I	—	I
ECCS cooling water pipes	II	II	III	II
ECCS cooling water valves	—	III	—	III
Emergency cooling towers	II	—	II	II
Hydrogen recombiners	I	I	—	I
Spent fuel racks	I/III[c]	II	III	I/II
Fuel building air treatment	I/II	II	II	I/II
Emergency diesel generators	II	I	III	I
Emergency generator	II	I	—	I
Electrical penetration	I/III	II	—	I/II
Class 1E electrical panel	II	III	—	II

[a] The proposed QA levels are based on common industrial and contractual situations encountered in the procurement of the listed items.

[b] When the site installation of an item is normally carried out by a contractor (and not by the supplier of the item), no indication is provided for the construction area.

[c] When more then one QA level is shown, the related industrial and contractual situations have not been already consolidated. For example, the QA levels for the spent fuel rack design may vary from I to III; the choice will depend upon whether the supplier adopts a standardized and proven design (QA level III) or develops a new design (QA level I).

Annex IV

GRADED QA REQUIREMENTS

Section a: Design

	QA level		
	I	II	III
QA requirements		*QA grade*	
Personnel training and qualification	1	2	3
Specification of design input	1	2	—
Checking and approval of design inputs	1	—	—
Design process planning and performance	1	1	3
Design analyses	1	2	—
Drawing preparation	1	1	3
Preparation of specifications and other design documents	1	2	—
Design interface control during design process	1	1	—
Communication between design organization and other organizations (feedback)	1	1	—
Design verification			
Design reviews and/or	1	2	3
Alternative calculations and/or	1	2	3
Qualification testing	1	2	3
Document control			
Document preparation, review and approval	1	1	3
Document release and distribution	1	1	3
Document change control	1	1	3
Control of design changes	1	2	—

Note: For management of design, the graded QA requirements should be in accordance with Section f.

Section b: Procurement

	QA level		
	I	II	III
QA requirements		*QA grade*	
Personnel training and qualification	1	2	3
Planning for procurement	1	1	—
Procurement document preparation review and change control	1	2	3
Content of procurement documents	1	2	3
Procurement document control	1	1	—
Selection of procurement sources	1	2	3
Review of past performance	1	2	—
Evaluation of facilities and personnel	1	2	—
Evaluation of quality assurance programme	1	2	3
Bid evaluation and award	1	2	—
Purchaser evaluation of supplier performance			
Responsibility assignment	1	2	3
Purchaser and supplier co-ordination	1	2	3
Control of supplier generated documents	1	2	—
Control of changes in procurement documents	1	2	—
Verification activities by the purchaser			
Planning of verification activities (procedure)	1	2	—
Planning of verification activities (responsibility assignment)	1	—	—
Implementation of verification activities	1	2	—
Reporting of verification activities	1	1	—
Non-conformance review and disposition	1	2	3
Corrective action	1	2	—
Acceptance of items and services	1	2	3

Note: For management of procurement, the graded QA requirements should be in accordance with Section f.

Section c: Manufacturing

	QA level		
	I	II	III
QA requirements	*QA grade*		
Personnel training and qualification	1	2	3
Manufacturing process planning and change control			
Identification of requirements	1	1	1
Identification of processes	1	1	1
Process qualification	1	1	3
Plans and procedures	1	2	3
Change control	1	2	3
Document control	1	1	3
Procurement control	1	1	3
Item identification control	1	1	3
Inspection and test control			
Procedures and instructions	1	2	3
Inspection	1	2	3
Testing	1	2	3
Results, evaluation and reporting	1	2	3
Measuring and test equipment control	1	1	3
Handling, storage and shipping			
Handling	1	1	1
Storage	1	2	3
Shipping	1	2	3
Non-conformance control			
Identification and documentation	1	1	3
Segregation	1	1	1
Review and disposition	1	2	3

Note: For management of manufacturing, the graded QA requirements should be in accordance with Section f.

Section d: Construction

	QA level		
	I	II	III
QA requirements	*QA grade*		
Personnel training and qualification	1	2	3
General activities			
Engineering	1	1	—
Planning	1	1	—
Preparation of procedures, instructions and drawings	1	1	—
Housekeeping during construction and installation	1	2	—
Receiving, handling and storage of materials and equipment	1	1	3
Cleaning of fluid systems and associated equipment	1	2	—
Protective coatings control	1	2	—
Measuring and test equipment control	1	1	3
Installation, inspection and testing of soil, foundations, concrete and structural steel			
Pre-construction verification	1	2	—
In-process inspection and test	1	1	3
Final inspection	1	2	3
Installation, inspection and test of equipment and systems			
Pre-installation verification	1	2	—
In-process inspection and test	1	1	3
Final inspection and test	1	2	3
Analysis and evaluation of inspection and test results	1	2	—
Non-conformance control			
Identification and documentation	1	1	3
Segregation	1	2	3
Review and disposition	1	2	3

Note: For management of construction, the graded QA requirements should be in accordance with Section f.

Section e: Operation

	QA level		
	I	II	III
QA requirements		*QA grade*	
Personnel training and qualification	1	2	3
Working documents (procedures, instructions, specifications, drawings)			
Review, approval, validation	1	2	3
Document control	1	1	3
Verification of adherence	1	2	—
Operations control	1	2	—
Materials control	1	2	3
Fuel control	1	—	—
Equipment control	1	2	—
Maintenance control	1	2	3
Chemistry control	1	2	—
Housekeeping and cleanliness	1	2	3
Inspection test and surveillance	1	2	—
Calibration control	1	1	3
Modification control	1	2	—
Radiation protection	1	2	—
Emergency control	1	2	—
Security	1	2	2
Non-conformance control	1	2	—
Operational feedback	1	2	—
Corrective action	1	2	—

Note: For management of operation, the graded QA requirements should be in accordance with Section f.

Section f: Management

	QA level		
	I	II	III
QA requirements	*QA grade*		
Personnel training and qualification	1	2	3
Planning and designing QA programme	1	2	—
Developing QA programme procedures	1	1	3
Documenting QA programme	1	2	3/—
Structuring the organization	1	1	—
Documenting the organization structure	1	1	3
Document control system	1	2	—
Preparation, review and approval	1	2	—
Issue and distribution	1	2	—
Change control	1	2	—
Audits and reviews	1	2	—
Management reviews	1	2	—
Non-conformance control	1	1	1
Corrective action	1	2	—
Trend analysis	1	—	—
Reporting quality status	1	2	3
Reporting QA programme status and adequacy	1	1	—
Record management system	1	2	—

Annex V

EXAMPLES OF GRADING OF QA REQUIREMENTS[2]

Section a: Design review

Grade 1

(1) A formal design review shall be carried out by a panel of competent individuals who have not contributed to the design effort under review.

(2) The panel shall be representative of all disciplines (e.g. QA, mechanical, electrical, instrumentation) which could be impacted by the system under review.

(3) An appointed panel president shall distribute to each panel member copies of all the design inputs (performance, functional, environmental, safety requirements), design output (design calculations, analyses, drawings) for review prior to the design review meeting.

(4) The panel members shall review all aspects of the design prior to the meeting and shall provide written comments.

(5) Comments shall be discussed in detail, recorded and resolved in writing at the meeting or later if necessary.

(6) Minutes of the meeting shall be kept and circulated, when finalized, to all members of the panel and to all personnel involved in the design.

(7) The minutes shall form part of the permanent records.

Grade 2

(1) A technical review shall be carried out by a panel of competent individuals who have not contributed to the design under review.

(2) The panel may be composed of personnel from the same department as the designer whose design is under review.

(3) An appointed panel president shall distribute the design inputs and outputs to all panel members.

(4) At the design review meeting, the panel members shall discuss and resolve any points of the design which are in question.

(5) A record of the meeting shall be kept and placed on file as part of the permanent record.

Grade 3

The designer's supervisor, provided this person has not participated in the design effort, shall review all design calculations, analyses and output documentation and shall signify approval/acceptance by signing or initialling the reviewed documentation.

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[2] The various sections of this annex are taken from different sources and therefore differ in style.

Section b: Purchaser and supplier co-ordination

Actions to be performed by purchaser	QA requirements		
	Grade 1	Grade 2	Grade 3
		Management area	
Supplier evaluation	'Direct' evaluation of new suppliers or 'indirect' evaluation of usual suppliers		'Indirect' evaluation except for important technical aspects
Acquisition of QA manual or equivalent document	For concurrence	For information and comments	
Review of supplier's management/ administrative procedures	For concurrence, on procedures involving purchaser–supplier interface		Optional
Verification of the supplier's QA programme implementation	To be performed in conjunction with surveillance activities and, at least annually by audit	To be performed in conjuction with surveillance activities	Optional
		Design area	
Review of design planning documents	For concurrence	For information and comments	Optional
Review of design output documents	For concurrence on documents concerning physical interfaces and concurrence on selected documents		Optional
Review of change proposals	For concurrence on change proposals to technical requirements contractually established by the purchaser		

Section b (cont.)

Actions to be performed by purchaser	QA requirements		
	Grade 1	Grade 2	Grade 3
	Manufacturing and construction areas		
Review of supplier's established contractual QA requirements	For concurrence, on selected items or services		Optional
Review of control of planning documents	For concurrence	For concurrence on selected manuf./const. activities	For information
Review of technical procedures	For concurrence on selected procedures		Optional
Selection of surveillance plans	Required		Optional
Surveillance over manufacturing construction activities	To be performed at the selected points		Optional
Review of non-conformance disposition proposal	For concurrence on 'major' type of non-conformance		
Final or receiving inspection	Required		
Review of supplier's QA record package	Required		

Section c: Document control

Grade 1

Procedures shall be established and implemented to control all technical and administrative documents pertaining to the QA programme.

Each document shall be reviewed and duly approved by authorized personnel prior to issue. The control system shall ensure that appropriate revisions of the documents are available where the related activities are performed and that obsolete documents are promptly removed. Changes to the documents shall be reviewed and approved by the same organization that performed the original review and approval unless other designation is made. Pertinent information shall be available to the designated organization. The nature of the change, where significant, shall be identified and documented. Different revisions of the documents shall be clearly identified and a master list or an equivalent control programme shall be established in order to identify such revisions.

Documents shall be reissued after a practical number of changes have been made.

Grade 2

A documented system shall be adopted to control technical and selected administrative documents concerning the QA programme.

The system shall ensure that these documents are approved by competent persons before their issue, appropriate revisions are available to the users, obsolete documents are removed and changes to the documents are approved by competent and knowledgeable persons.

Grade 3

The technical documents on the QA programme shall be approved before issue.

A control system shall ensure that appropriate revision of inspection and test procedures and other important documents is instituted.

Grade '–'

Good commercial practice shall be used.

Section d: Measuring and test equipment control

Grade 1

(1) A system shall be maintained for selecting, using, calibrating and controlling measuring and test equipment.

(2) Measuring and test equipment shall be:

(a) Of the appropriate range and accuracy for the intended use;
(b) Calibrated before use when first acquired;
(c) Calibrated at appropriate intervals;
(d) Stored and calibrated in a controlled environment to the extent necessary to ensure valid measurements;
(e) Calibrated according to approved procedures using reference standards which are traceable to national standards or which have been derived from accepted values of physical constants;
(f) Identified to indicate its calibration status and the scheduled date of its next calibration and to identify it with its calibration record.

(3) A calibration record shall be maintained for each piece of measuring and test equipment.

(4) A record of issue, use and return of measuring and test equipment shall be maintained.

Grade 3

(1) A system shall be maintained for selecting and calibrating measuring and test equipment.

(2) Measuring and test equipment shall be:

(a) Of the appropriate range and accuracy for the intended use;
(b) Calibrated before each use;
(c) Stored and calibrated in a controlled environment to the extent necessary to ensure valid measurements;
(d) Calibrated using reference standards which are traceable to national standards or which have been derived from accepted values of physical constants;
(e) Identified to relate it to its record of issue, use and return.

(3) A record of issue, use and return of measuring and test equipment shall be maintained.

Section e: Non-conformance control

Grade 1

(1) Identify and hold non-conformances for evaluation.

(2) Define the responsibilities and authority of those assigned to the disposition of non-conforming items and services.

(3) Provide for a review of the non-conformance involving representatives from all relevant functions, including quality assurance.

(4) Record each non-conformance.

(5) Obtain concurrence of all responsible parties for dispositions.

(6) Tag all non-conforming items and place in a segregated holding area when feasible.

(7) Ensure that reworked and repaired items are reinspected and retested according to the original or approved modified requirements.

(8) Maintain records of all non-conformances, dispositions, results of reinspections and retests.

Grade 2

(1) Identify and hold non-conformances for evaluation.

(2) Contact those individuals assigned to the disposition of non-conforming items or services.

(3) Record each non-conformance.

(4) Tag all non-conforming items.

(5) Maintain records of all non-conformances and dispositions.

Grade 3

(1) Identify and hold non-conformances for evaluation.

(2) Contact those individuals assigned to the disposition of non-conforming items or services.

(3) Tag all non-conforming items.

(4) Release non-conforming items for disposition when instructed.

Grade '–'

Use good commercial practice.

Section f: Records management system (manufacturing and construction)

Grade 1

(a) Maintain quality records as objective evidence that:

(i) The quality assurance programme meets the requirements;
(ii) The product or service and documentation meet specified requirements;
(iii) Personnel, procedures, documentation and equipment for special processes are qualified;
(iv) The requirements for selection, surveillance and audit of subsuppliers are met;
(v) Corrective actions are taken and are effective.

(b) Maintain quality audit records which identify:

(i) Audited procedures, processes, products and services;
(ii) Results obtained;
(iii) Analyses of audit data and resultant corrective actions taken.

(c) Maintain records of management reviews and resultant corrective actions.

(d) Maintain records of verifications, inspections and tests which identify:

(i) The item or service;
(ii) Applicable requirements;
(iii) Specific verifications, inspections, tests performed and results obtained, including the basis of acceptance;
(iv) Non-conformances;
(v) Feedback or corrective actions generated;
(vi) Dates of inspections or tests;
(vii) Verifiers or inspectors;
(viii) Data recording instruments.

(e) Make quality records available to the customer representative for analysis and review.

(f) Identify, index and file quality records for prompt retrieval up to the time of customer acceptance of the product or service and for sure retrieval for the time specified in the contract.

(g) Define and provide the environment needed to minimize deterioration or damage and to prevent loss of records.

Grade 2

(a) Maintain quality records as objective evidence that:

(i) The quality assurance programme meets the requirements;
(ii) The product or service and documentation meet specified requirements;
(iii) Personnel, procedures, documentation and equipment for special processes are qualified;
(iv) Requirements for selection, surveillance and audit of subsuppliers are met.

(b) Maintain inspection and test records which identify:

(i) Item or service;
(ii) Basis of acceptance;
(iii) Non-conformances;
(iv) The dates of inspections or tests;
(v) Verifiers or inspectors;
(vi) Data recording instruments.

Grade '–'

Use good commercial practice.

Section g: Maintenance control of a safety related item (operation)

Requirements	*Grade 1*	*Grade 2*	*Grade 3*
Work authorization	Plant manager and health physicist	Shift supervisor	A supervisor
Procedures	Written, reviewed, approved and validated	Written, reviewed and approved	Written and approved
Training	General training, work specific training and equipment specific training	General and work specific training	General or work specific training
Checklists	Sign-off of key steps, shift changes, verification and hold points	Verification points and final sign-off	Final sign-off
Verification of work	Supervisor, engineer and QA	Supervisor and engineer	Supervisor

Annex VI

TYPICAL FORMAT FOR SPECIFYING CONTRACT QUALITY ASSURANCE REQUIREMENTS

1. General
   - 1.1. Scope
   - 1.2. Codes and standards
   - 1.3. Supplier's responsibilities
   - 1.4. Right of access to supplier premises and documentation

2. Supplier QA programme requirements[a]
   - 2.1. Design area
   - 2.2. Procurement area
   - 2.3. Manufacturing area
   - 2.4. Construction area
   - 2.5. Management area

3. Purchaser-supplier interface[b]
   - 3.1. Purchaser-supplier meeting on QA programme (preliminary, periodic)
   - 3.2. Submittal of supplier documents (type of documents; submittal dates; reason for submittal; approval, comment, information)
   - 3.3. Notification/hold points (type of notification/hold points, advance notice, hold point release)
   - 3.4. Non-conformances and design changes (definition of major/minor; submittals)
   - 3.5. Audit of supplier's QA programme (advance notice, corrective action request)
   - 3.6. Final documentation package (content, submittal, approval)
   - 3.7. Purchaser final inspection and acceptance

4. Appendices

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[a] Section 2 may detail the specific QA requirements for the applicable areas or reference to the adopted QA levels may be made for the applicable areas (quoting the standard/specification which specify the related QA requirements).

[b] The contents of this section should be limited to the extent required to permit the purchaser to carry out the surveillance activities.

CONTRIBUTORS TO DRAFTING AND REVIEW

Appell, P.J.	Electricité de France, France
Bernatowicz, M.	Inspectorate for Nuclear and Radiological Safety, Poland
Chen, C.K.	International Atomic Energy Agency
Deckers, J.	Agency for Safety of Aerospace Products GmbH, Germany
Derbyshire, D.	Nuclear Installations Inspectorate, United Kingdom
Dizadji, F.	Commission of the European Communities
Fischer, J.	International Atomic Energy Agency
Froman, B.	Cogéma, France
Koll, H.	Comisión Nacional de Energía Atómica, Argentina
Massicotte, M.	Atomic Energy Control Board, Canada
Maurer, H.	Commission of the European Communities
Mello, D.G.	Angra Nuclear Power Plant, Brazil
Nevander, O.	Finnish Centre for Radiation and Nuclear Safety, Finland
Nicoloso, E.	ENEL-DCO, Italy
Oliva, T.	Federal Ministry of Fuel and Energy, Czechoslovakia
Pieroni, N.	International Atomic Energy Agency
Rapillo, M.	ENEA-DISP, Italy
Sayers, T.	Nuclear Electric, United Kingdom
Spraul, J.	Nuclear Regulatory Commission, United States of America
Verlaeken, J.G.	AIB Vincotte, Belgium
Vincze, P.	Nuclear Power Plant Paks, Hungary

Consultants Meetings

Vienna, Austria: 27 February–3 March 1989, 7–11 May 1990

Advisory Group Meeting

Vienna, Austria: 16–20 October 1989

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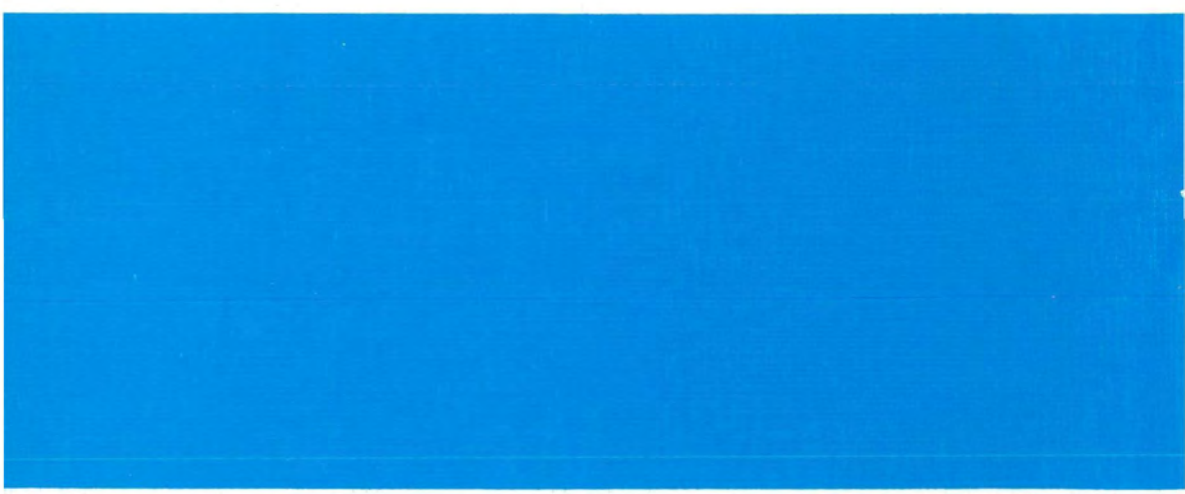

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