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Use of a Graded Approach in the Application of the Management System Requirements for Facilities and Activities

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USE OF A GRADED APPROACH IN THE APPLICATION OF THE MANAGEMENT SYSTEM REQUIREMENTS FOR FACILITIES AND ACTIVITIES

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INTERNATIONAL ATOMIC ENERGY AGENCY
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FOREWORD

IAEA Safety Standards Series No. GS-R-3, The Management System for Facilities and Activities, defines the requirements for establishing, implementing, assessing and continually improving a management system that integrates safety, health, environmental, security, quality and economical elements. It details the need to grade the application of the management system requirements to ensure that resources are deployed and appropriate controls are applied on the basis of the consideration of: the significance and complexity of each product or activity; the hazards and the magnitude of the potential impact (risks) associated with the safety, health, environmental, security, quality and economical elements of each product or activity; and the possible consequences if a product fails or an activity is carried out incorrectly. The grading of the application of the requirements detailed in IAEA Safety Standards Series No. GS-R-3 is especially essential when they are implemented in smaller facilities and activities. The grading is done to ensure that the management system for smaller facilities and activities are suitably tailored to the hazards and the magnitude of the potential impact of the facilities and activities.

Detailed guidance on how the grading requirements of IAEA Safety Standards Series No. GS-R-3 can be met and how to ensure that grading is performed in a consistent manner can be found in IAEA Safety Standards Series No. GS-G-3.1, Application of the Management System for Facilities and Activities. In addition, it contains guidance on systematic grading methods which will reduce the likelihood and consequences of improper grading.

This publication provides an overview of grading fundamentals, the grading process, the role of classification in the process and the typical controls that can be graded. It also provides practical guidance and examples of grading as required by IAEA Safety Standards Series No. GS-R-3 to develop and apply a method of grading appropriate to the organization. This publication will be beneficial to users who are in the process of implementing or improving their current management system based on the IAEA Safety Requirements. This publication is not intended to prescribe an approach to grading the application of management system requirements, but instead provides guidance based on practical examples of grading currently used in Member States.

The IAEA wishes to thank the contributors to this publication for their efforts and valuable assistance. The IAEA officers responsible for this publication were J. Majola and J.P. Boogaard of the Division of Nuclear Power.

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1. INTRODUCTION

1.1. BACKGROUND

This publication supersedes Technical Reports Series No. 328 [1], which refers to the Code on the Safety of Nuclear Power Plants: Quality Assurance, IAEA Safety Series 50-C-QA (Rev. 1) [2] and was published to provide guidance on the use of graded approach in the application the quality assurance requirements and was only applicable nuclear power plant activities.

Since 1991, 50-C-QA has been superseded twice and the current IAEA Safety Requirements No. GS-R-3: The Management System for Facilities and Activities [3] defines the requirements for establishing, implementing, assessing and continually improving a management system that integrates safety, health, environmental, security, quality and economical aspects. GS-R-3 is significantly different in two respects: it adopts an integrated management system approach to safety; and it applies to a broader range of users, encompassing nuclear facilities and activities (not just nuclear power plants); activities using sources of ionizing radiation; radioactive waste management; the transport of radioactive material; and radiation protection activities.

To ensure that an integrated management system based on the GS-R-3 [3] requirements is commensurate to the risks, complexity and significance of activities, GS-R-3 includes a requirement to grade the application of the management system requirements and the deployment of resources appropriately.

Grading the application of management system requirements should be applied to the product, item, system, structure or components, services, activities or controls of each process.

The IAEA fundamental objective and associated fundamental safety principles [4] incorporate the requirement for a graded approach, particularly in respect to the assessment of safety and the assessment of radiation risks.

1.2. OBJECTIVES

The objective of this publication is to provide practical guidance to assist users of GS-R-3 to develop and apply a grading method appropriate to the risks, complexity and significance of activities of an organization.

This publication is not intended to prescribe an approach to grading of the application of management system requirements, but provides guidance based on practical examples of grading that are currently used in IAEA Member States.

1.3. SCOPE

In addition to GS-G-3.1 “Application of the Management System for Facilities and Activities” [5] this publication provides practical guidance and examples on the use of a graded approach in the application of the management system requirements as required by GS-R-3, including the application of appropriate resources and controls, necessary for an effective and efficient implementation of the management system.

1.4. USERS

This publication is intended to be used by organizations directly responsible for:

— Nuclear facilities;
— Activities using sources of ionizing radiation;
— Radioactive waste management;
— The transport of radioactive material;
— Radiation protection activities;
— Any other practices or circumstances in which people may be exposed to radiation from naturally occurring or artificial sources.

However it could also be beneficial for the grading of the management systems of regulatory bodies, designers, manufacturers, constructors, contractors and suppliers.

1.5. STRUCTURE

This publication consists of five sections. Section 2 describes the fundamentals of grading. Section 3 describes a methodology for grading, including a process for classification and a process for grading. Section 4 describes the specification and application of graded controls to various activities. Section 5 introduces the examples of methodologies for grading and examples of grading that are given in the Annexes.

2. GRADING FUNDAMENTALS

The IAEA Safety Glossary [6] defines the ‘graded approach’ as follows:

1. For a system of control, such as a regulatory system or a safety system, a process or method in which the stringency of the control measures and conditions to be applied is commensurate, to the extent practicable, with the likelihood and possible consequences of, and the level of risk associated with, a loss of control.

   An example of a graded approach in general would be a structured method by means of which the stringency of application of requirements is varied in accordance with the circumstances, the regulatory systems used, the management systems used, etc. For example, a method in which:

   (1) The significance and complexity of a product or service, activity or controls are determined;
   (2) The potential impacts of the product or service on health, safety, security, the environment, economical aspects and the achieving of quality and the organization’s objectives are determined;
   (3) The consequences if a product fails or if a service is carried out incorrectly are taken into account.

2. An application of safety requirements that is commensurate with the characteristics of the practice or source and with the magnitude and likelihood of the exposures.

In practical terms, a graded approach applies to management system requirements of a product, item, system, structure or component, service, activity or controls of a process

commensurate with its relative importance, complexity, variability, maturity, potential impact on safety, health, environmental, security, quality and economical aspects.

By the application of a graded approach, the controls, measures, training, qualification, inspections, detail of procedures, etc. might be adapted to the level of risk or importance for safety, health, environmental, security, quality and economical aspects. In evaluating these aspects the system is to be considered holistically.

The graded approach will result in an effective application of appropriate resources (time, money, staff, etc.) with regard to defined requirements. For each specific product, item, system, structure or component, service, activity or controls the graded approach will affect the type and level (extent and depth) of controls applied, for example:

— the type and level of planning and analysis;
— the type and level of verification, inspection and testing;
— the review and approval requirements of activities, documents and records;
— the detail of documentation and records;
— the type and level of qualification and training for individuals; and
— the type and level of evaluation of suppliers.

The type and level of controls can change from organization to organization, with time and with the state or the life cycle stage of the facility or activity.

Risk is a fundamental consideration in determining the detailed description of procedures and the extent to which controls and measures are to be applied. A graded approach is applicable to all stages of the lifetime of a nuclear facility including siting, design, construction, commissioning, operation and decommissioning and to all activities. IAEA Safety Standards Series, Safety Guide No. GS-G-3.5 [7] provides guidance on developing a structured approach to grading the application of management system requirements. During the lifetime of a facility, any grading that is performed should ensure that safety functions are preserved, that the license and the operational limits and conditions[1] (OLC) are not challenged and there are no negative effects on the safety of the facility staff, the public, or the environment.

The grading of a product, service, activity or controls of a process is based on analyses, regulatory requirements, license conditions, the OLC and engineering judgment. The grading of product, item, system, structure or components and activities will take into account the safety function and the consequences of failure to perform their functions, in general covered by the classification of structures systems and components (SSCs), the complexity and maturity level of the technology, operating experience associated with the activities and the lifecycle stage of the facility.

The management system requirements should be applied in such a way that the level of application of the requirements are commensurate with the potential risk associated with the facility or activities or with the consequences of losing knowledge (e.g., losing records or drawings, or knowledge of staff due to retirement), without adversely affecting safety.

[1] The terms ‘safety specifications’, ‘technical specifications (tech specs) for safe operation’, ‘limiting conditions of operation’ and ‘general operating rules’ are sometimes used in place of operational limits and conditions (OLCs).

Grading should be performed by competent individuals using established and controlled processes, procedures and/or instructions. Grading is not to exclude any management system requirements but to apply them at a level commensurate with functionality and significance of the item or activity and potential impact on safety.

The main benefits of grading are improvements in efficiency and effectiveness in achieving the organization's objectives through the deployment of appropriate controls and resources.

An approach to grading involves:

— identifying the product, item, system, structure or component, service, activity or controls to be graded;
— determining the significance of and/or hazard associated with the above in relation to safety, health, environmental, security, quality and economical aspects;
— determining the degree of the associated risk (probability and consequence) if the item, system, structure or component fails in service or if the work is incorrectly conceived or executed, that affects public, worker, or environment;
— determining the controls required to mitigate the risk.

To facilitate the grading process, organizations typically group the controls into a number of grading levels. The grading levels are based on significance of impact: the higher the grading level, the more stringent the controls.

3. GRADING METHODOLOGY

3.1. GRADING METHOD

Establishing a systematic method for grading is essential. This will assure consistency in grading, minimize subjectivity and reduce the likelihood and consequence of improper grading.

To establish the method for grading the organization should:

a. Determine the criteria for grading appropriate to the organization's objectives and activities
   — Identify the areas where significant impacts might be anticipated, e.g. safety, health, environmental, security, quality and economical aspects and stakeholder confidence;
   — Develop criteria in each area to determine relative significance in case the activity be inadequately conceived or performed or the item, system, structure or component fails in service. An already established classification scheme and/or external requirements should be taken into account. The safety classification of the structures, systems and components dictates the classification scheme for the grading process related to the systems, structures and components;
   — Evaluate the level of complexity of activity or item, system, structure or component.
b. Determine the optimum number of grading levels that encompass the identified criteria (typically, organizations find that 3–4 grading levels are sufficient). It is a general practice that grade 1 is the highest and grade 4 the lowest.
c. Determine the applicable controls appropriate to each grading level (Section 4 describes typical controls).

3.2. CLASSIFICATION PROCESS

Classification[2] is a specific type of grading applied to Structures, Systems and Components (SSCs) or to activities. It is a method of grouping items with similar characteristics or functions for the purpose of identifying appropriate requirements, codes, and standards to be applied to their design, manufacture, construction, operation and maintenance. For example, SSCs and items are classified based on technical considerations pertaining to safety function and safety significance.

Classification can be applied to all nuclear facilities (SSR-2/1) [8], radioactive waste (GSG-1) [9], research reactors (SSG 22) [10], transport (TS-G-1.4) [11], and working areas and access control (NS-G-2.7) [12].

Classification facilitates grading of controls or activities because it includes an assessment of inherent risk. For example, a variety of activities, each with differing potential consequences, may be performed on a classified SSC, and grading will help to determine the appropriate level of control for each activity.

The method of classification will allow each item or activity to be characterized with respect to the importance of the function each performs in the overall safe and satisfactory operation.

For the majority of nuclear installations, a formal safety classification for the structures, systems and components is in place. If no formal classification is defined (e.g., small installations or non-technical applications), classification may be aided by considering maturity and complexity.

Classification by maturity and complexity facilitates grading since it includes an assessment of inherent risk. For example, a highly complex activity of low maturity would require higher rigor in applying controls.

3.2.1. Classification by maturity

Products, items, systems, structures or components or services may be classified in a way that reflects the maturity, including experience, available in each area. The maturity is a measure of 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 including the maturity of suppliers.

(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 are normally being taken into account.

[2] A classification process is in principle also a grading process.

(4) Operation maturity
The maturity of operation activities is based on factors such as plant personnel qualifications, experience and knowledge of structures, systems and components (SSC), 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 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.

3.2.2. Classification by complexity

Products, item, system, structure, component, or services can also be classified in a way that reflects the complexity of the products, item, system, structure or component, 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. Other factors, such as safety, seismic and stress analyses, material selection and environmental impact analysis are essential in the evaluation of the complexity of design.

(2) Procurement complexity
The complexity of the procurement activities relates to the number and 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. Other aspects such as the number of close tolerances and the number of moving parts are also important in this case.

(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.

3.3. GRADING PROCESS

It is important to establish a process to apply the grading method and it should include determination of the competencies required to use the process. The grading process contains the following steps:

1. Assess the significance of the process, including the significance of the product, service, activity and controls of the process, using the criteria for grading (paragraph 3.1)
2. Identify the classification (paragraph 3.2), if applicable;
3. Identify a grade based on the assessment (preliminary grade);
4. Consider other factors that may change the preliminary grade level, such as:
   - external requirements: contracts, codes, regulations, standards
   - significant adverse impacts on safety, health, environmental, security, quality and economical aspects
   - high probability of an adverse incident
   - complexity
   - process and organizational interfaces
   - variability
   - novelty
   - uniqueness
   - performance history
   - operating experience
   - accessibility (e.g., for test, inspection, maintenance, during normal operation)
   - ability to prove functionality or reliability after installation
   - extent of use of contractors
   - workforce diversity, human factors, man machine interface control (MMIC)
   - replacement cost
5. Assign a grade (final grade) and as appropriate, verify that the most appropriate grade has been assigned
6. Allocate/specify controls appropriate to the grade
7. Apply controls (Section 4 describes typical controls)

The grading process and in particular the criteria and the respective controls, are reviewed from time to time to ensure the accuracy of the basis that supports the final grade.

This grading process is illustrated in Figure 1.

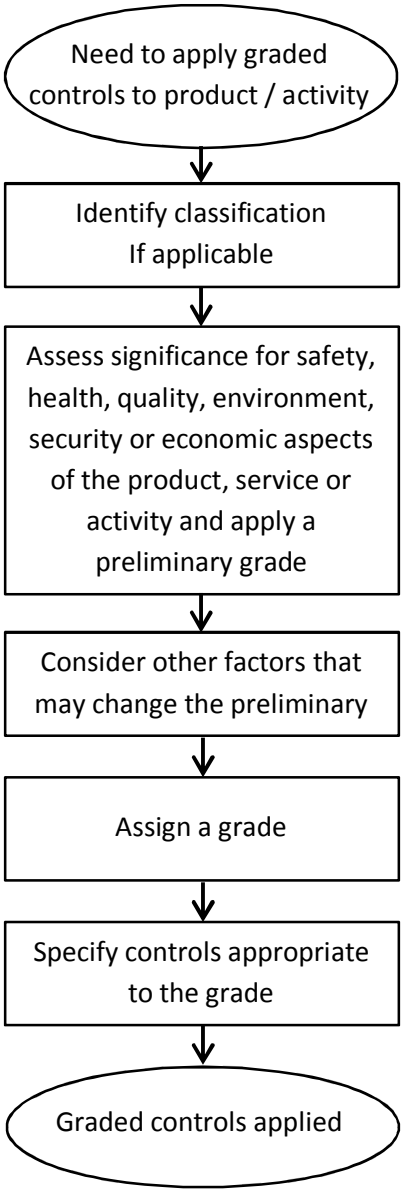

FIG. 1. Process for grading of a product, service or activity. A product is an item, system, structure or component.

4. SPECIFYING AND APPLYING A GRADED APPROACH

4.1 APPLICATION OF GRADING

The management system requirements are primarily related to the management and verification for safety, design, organizational control, training, qualification, operating procedures, records and reports.

4.1.1. Application of grading to inspection activities

The scope and frequency of inspection programmes (e.g., audits, assessments, tests and inspections) are determined based on many different aspects. One of the most important considerations is to be proportionate to the potential safety, occupational health, environmental and security risk posed by the nuclear facility or activity and during particular situations such as organizational changes or personnel turnover. For internal oversight, and external oversight, of safety related activities inspections are often concentrated on areas of safety significance and that the internal or external inspection authority or inspection unit pre-establishes a graded approach in responding to unforeseen circumstances. Guidance on graded approach in regulatory oversight is provided in Ref. [13].

Corrective/preventive actions should also be graded since the severity and impact on safety of non-compliance with the requirements may vary. A graded approach for oversight of safety allows that resources and enforcement actions or methods can be allocated commensurate with the seriousness of a possible non-compliance, escalating them as needed to bring about compliance with requirements. A graded approach with respect to the corrective action process for non-conformances will facilitate that problems of the highest significance are afforded the most evaluation, see also Ref. [5].

Some of the factors to consider in the grading of an inspection programme and of the associated corrective actions are, among others:

(a) Potential safety, occupational health, environmental, security risk or hazard;
(b) The safety significance or seriousness in case of a deficiency;
(c) Timeliness of corrective actions to restore compliance with the requirements;
(d) The frequency of deficiencies;
(d) Who identified and reported the non-compliance, i.e., whether the non-compliance was self-reported or identified during an independent inspection;
(e) The complexity of the remedial, corrective or preventive action needed.

4.1.2. Application of grading to the management for safety

A well-established and implemented Management System is essential in the verification and management of safety for an operating organization and other authorised parties. Grading of the scope and content of activities making up the elements of management of safety is possible while still meeting the requirement that they be comprehensive.

For example, in item (c) grading is clearly essential in defining the human resources required (both number of staff as well as the qualification) for activities, such as operations and maintenance, but also in other areas such as radiation protection, inspections, auditing, assessment, education and training. It is recommended that staff education, training and competence requirements are based on the operating schedule and the complexity of the facility. The latter is determined in particular by the reactor power level, extent of isotope production and scope of experimental facilities. In addition, grading is possible in the depth, frequency and type of safety assessments, in-service inspections and auditing of all safety related matters.

Items to be considered for grading include:

(a) Type and content of training;
(b) Amount of detail and degree of review and approval of operating procedures;

(c) Need for and detail of inspection plans;
(d) Depth of operational safety reviews and controls;
(e) Type and frequency of safety assessments;
(f) Records to be generated and retained;
(g) Level and detail of operating procedures;
(h) Reporting level and authorities of non-conformances and corrective actions;
(i) Testing, surveillance, maintenance and inspection activities;
(j) Equipment to be included in plant configuration control;
(k) Control applied to the storage and records of spare parts;
(l) Need to analyse events and equipment failure data.

4.1.3. Application of grading to the verification of safety

Verification of safety includes a variety of activities and includes audits, assessments, self-assessments, peer reviews, regulatory inspections, safety and oversight committees, etc. All of these of these activities and the activities of the committees can be graded. Grading is possible in the frequency and scope of the activities. The frequency and scope of the activities and assessments can be graded based on the complexity and potential risk related to safety, occupational health, environment and security.

Grading can be applied to the number, size, composition and frequency of meetings of oversight committees such as reactor advisory groups, safety committees, radiation protection committee, etc.

4.1.4. Application of grading to training and qualification of operating personnel

Training, retraining and qualification requirements for the staff of nuclear facilities and the staff involved in activities should be consistent with the complexity of the design, the hazard potential, the planned utilization of the facility, the available infrastructure and other functions that might be assigned to the operating personnel. The educational level, experience and operational requirements (such as minimum operational activity per year) for the various staff positions and the contents and duration of training may be graded in accordance with the above criteria.

The assessment of the training needs and their fulfilment, including retraining, qualification, and operational experience (such as minimum operational activity per year) of the staff is an important aspect of the assessments in order to evaluate the grading process for training, retraining and qualification. Relevant staff positions to be assessed include key management positions of the nuclear facility, shift supervisors, reactor operators, radiation protection staff, maintenance personnel, quality assurance staff and other key staff. The requirement that there be adequate training and that it be implemented is not gradable. The nature and details of the training is gradable. Reauthorization after absences may be approached in a graded manner with retraining, requalification and examinations commensurate with the duration of the absence, the complexity of the facility, and the changes to the facility and its operation during the absence of the individual.

4.1.5. Application of grading to operating procedures

All nuclear facilities require well established operating procedures in order to ensure safe operation and maintenance. It is important to employ grading in the preparation and implementation of the management system programme which governs the content, development, initial and periodic review and control of procedures.

The number and detail of the procedures depends upon the risk and initial hazard associated with the operation of the facility or with the activity described in the procedure.

Grading can also be applied in the implementation and training of the staff in the use of the procedures. Personnel using the procedures should be thoroughly familiar with them and proficient in their use.

While all procedures have to be prepared, reviewed and approved based on criteria established by the operating organization and regulatory requirements, operating procedures may be graded based on their importance to safety. Several examples are:

a) The procedure for regeneration of an ion-exchange system for the demineralized water inventory of a storage tank supplying domestic heating and cooling will be of low safety significance and will involve mature and non-complex technology associated with water treatment. The safety implications of an error in the regeneration process are low. Consequently, the procedure itself may be simplified.
b) By contrast, an operating procedure that is developed for an application in which an error has the potential for safety significance, causing a violation of the OLCs or of the license, would be more detailed. An example would be the procedure for regeneration of an ion-exchange system for the primary cooling water purification system. While it may involve the same basic technology as under a), the safety implications of an error could be much more significant (e.g., an error which allowed resin to enter the primary cooling water and hence into the reactor core). Therefore the possible greater hazard from miss-operation of this system has to be taken into account for design features and/or procedural arrangements.
c) Procedures required for reactor modifications, utilization of research reactors, special fuel tests programmes, experiments and other special applications are often complex and infrequently used. Since these activities will often impact safety, development, review and approval of procedures for these activities would follow the same course as that for other procedures of safety significance.

4.1.6. Application of grading to records and reports

The requirements for records and reports can be found in many IAEA Safety Standards related to design, commissioning, operation, maintenance, modification and decommissioning. Consistent with the purpose for which reports are prepared and records are kept, a graded approach can be applied for:

— Preparation of documents and records;
— Need for and extent of validation;
— Degree of review and the qualification of individuals involved;
— Level of approval to which documents are subjected;
— Need for distribution lists;
— Types of document that can be supplemented by temporary documents;
— Need to archive superseded documents;
— Need to categorize, register, index, retrieve and store document records;
— Retention time of records;
— Responsibilities for the disposal of records;
— Types of storage medium storage conditions, in accordance with the specified length of time of storage.

4.2 GRADING OF CONTROLS

Management system requirements are implemented through processes, procedures and instruction in order to control a product, service, activity or controls of a process. The controls are designed to ensure consistent and expected outcomes. The degree of application of controls can vary in extent and depth commensurate with the probability and potential consequences. Grading is used to establish the necessary level of control to be applied. They cannot supersede applicable regulatory and code requirements.

An organization with a process based management system has processes defined in order to identify, manage and check work and activities in the most appropriate way in order to meet the objectives of an organization and how the activities are to be documented. No single 'process catalogue' — listing of processes that must be documented – can be applied to every organization. Instead, each organization has to determine which processes are to be documented, on the basis of applicable regulatory and statutory safety requirements, the nature of the organization's activities and its overall strategy. A common understanding of what a process is, how many processes are in place in the organization and how they interrelate is essential for the commitment of the implementation of the processes in an organization.

Sections 4.2.1–4.2.3 illustrate how the aspects used to identify, manage, check and document work and activities could be used to group some typical management system processes/activities where the applied controls can be graded. In each section a table illustrates how the levels of typical controls appropriate to each grade could be applied for some of the processes/activities identified in the specific section. Each table lists typical activities for each process and typical levels of controls. For the purpose of this illustration a four grade process has been used. It must be noted that the actual grade levels and controls are used to address, at a minimum, the regulatory requirements and/or code requirements and the table presents only examples. The grade levels correspond to the highest level of controls needed (i.e. grade 1) to the minimum level of control (i.e. grade 4). Annex 2 presents more examples used in some Member States.

Level 1 requirements have to be selected for critical applications, when inadequate controls of activities or malfunctions could result in a failure leading to an excessive risk to the health and safety of the operating personnel and/or the public.

Level 2 requirements have to be selected for critical applications, when inadequate controls of activities or malfunctions could result in a failure leading to intermediate degrees of impact, on safety of the operating personnel and the public or operation, and excessive consequences in case of loss of knowledge.

Level 3 requirements have to be selected when inadequate controls of activities or malfunctions could result in a failure leading to minor of impact, on safety of the operating personnel and the public or operation and modest consequences in case of loss of knowledge.

Level 4 requirements can be selected if the application is non-critical, if there is no or negligible risk to the health and safety of the operating personnel and the public and limited consequences in case of loss of knowledge.

4.2.1. Processes or activities to perform and manage work

Typical processes/activities that manage work, where applied controls can be graded, include:

— Specification;
— Procedures, documents and records;
— procurement planning;
— change control;
— process qualification;
— resource allocation;
— in-process controls such as hold and witness points;
— handover/turnover (i.e., transition from maintenance to operation, or construction to commissioning; or commissioning to operation);
— reviews;
— approvals;
— authorizations;
— safety analysis;
— chemical analyses;
— calibration processes;
— training and qualification;
— communication.

Examples of how controls applied to activities, perform and manage work may be graded

Procurement of a component that impacts a safety function requires more stringent controls. These controls may include enhanced levels of specification, technical review, supplier qualification, procurement documentation, communication, traceability, inspection and testing, disposition of non-conformance, approval, receipt inspection, and records and their retention. Procurement of a component with no safety implications requires fewer or decreased levels of controls.

A procedure for an activity of high significance would contain more detail, be subject to a higher level of review and approval, and may require verification and validation, both prior to use and in use. Such a procedure may be required to be followed and checked off step-by-step and to be present at the point of work. Procedures for an activity of lower significance may contain less detail, may require decreased levels of control of the activity and may be referenced for information purposes prior to work.

Training for a significant activity may require application of a systematic approach to training, including needs analysis, training design, training development, training delivery and evaluation. Performance of a significant activity may require specific qualification such as welding, non-destructive examination or reactor operations. Training for an activity of lower significance may not require full application of the systematic approach to training or a specific qualification for performance.

TABLE 1. EXAMPLES[3] OF GRADED CONTROLS APPLIED TO PROCUREMENT

Activity	Controls	Grades			
		1	2	3	4
Supplier qualification	Management system certified to appropriate standard(s) and independent audit or inspection evidence of capability	X			
	Management system certified to appropriate standard(s) or independent audit or inspection evidence of capability		X		
	Approved commercial grade dedication process, as applicable	X	X		
	Management system implemented and evidence of satisfactory performance			X	
	Commercial supplier				X
Supplier quality plans	Quality plan required which includes inspection, witness, test and hold points and acceptance criteria	X	X		
	Approval by the purchaser	X	X		
	Flow down of specific requirements			X	
	Not required				X
QA audit	New suppliers audited prior to first use	X	X		
	Subsequent audits undertaken periodically, as determined by the supplier evaluation process	X	X		
	As determined by the supplier evaluation process			X	
	Not required				X
Records provided by the supplier	Records, such as, inspection and test results, material safety data sheets, evidence of calibration and certificates of conformity and any record identified in the quality plan/specification	X	X		
	Operating and maintenance instructions	X	X	X	X
	Certificates of conformity	X	X	X	X
Materials & spares control	Inspection status identified and indicated	X	X		
	Items stored in accordance with inspection status	X	X		
	Items in secure storage	X	X		
	Items physically segregated from those of a different grade	X	X		
	Material traceability as required	X	X		
	Preservation, testing and maintenance in storage as required	X	X		
	Items stored in the required environment (e.g. temperature, humidity, packaging)	X	X	X	X

[3] It must be noted that the tables are only an example and that the actual grade levels and controls have to be based on analyses and have to address at least the regulatory or code requirements

TABLE 1. EXAMPLES OF GRADED CONTROLS APPLIED TO PROCUREMENT (cont.)

	Items identified	X	X	X	X
	Shelf life managed	X	X	X	X
Specification	Physical properties	X	X		
	Inspection and test requirements	X	X		
	Chemical composition requirements	X	X		
	Verification and validation requirements	X	X		
	Functional requirements	X	X	X	
	Codes, standards and special processes	X	X	X	
	Material/performance certification	X	X	X	
	Preservation and handling	X	X	X	
	Product brand and part number			X	X
Receipt inspection	Technical attributes identified in the specification verified	X			
	Documents and records providing evidence of conformity provided by supplier verified	X	X		
	Inspection for damage	X	X	X	X
	Quantitative verification	X	X	X	X
In-process inspection	100 % of items and critical elements inspected/tested by the supplier	X			
	Inspections/ witnessing tests/surveillance/document reviews, as included in the quality plan performed by the purchaser or its representative	X	X		
	Sample of items and critical elements inspected/tested by the supplier		X		
	Inspection in accordance with supplier's process			X	X
Document submission prior to manufacture	Specified documents, such as quality plans, drawings, procedures for test and instructions for special processes and forms that will become records submitted for approval	X	X		
	Specified documents that will become records			X	
	Not required				X
Issue of components from stores	Authorization required	X	X		
	No special requirements			X	X

4.2.2. Processes or activities that check and assess work

Typical processes/activities that check work, where applied controls can be graded, include (but are not limited to):

— verification;
— validation;

— review;
— inspection;
— testing;
— analysis;
— monitoring and measurement;
— assessment;
— oversight.

Examples of how controls applied to activities to check and assess work may be graded

TABLE 2. EXAMPLES OF GRADED CONTROLS APPLIED TO PROCEDURES

Activity	**Controls**	**Grades**			
		1	**2**	**3**	**4**
Preparation of procedures	Includes appropriate quantitative/qualitative acceptance criteria	X	X		
	Includes necessary prerequisites and cautions	X	X		
	Verified/validated to assure expected outcomes are achieved	X	X		
	Prepared to a consistent format	X	X	X	
	Includes a level of detail that allows a competent person to complete the work	X	X	X	
	No formal procedure required				X
Review and approval of procedures	Coverage of interfacing parties	X	X		
	Reviewed by and approved by persons other than the person who prepared the procedure	X	X	X	
	No formal procedure required				X
Use of procedures	Procedure in hand at point of work	X			
	Each step read prior to performance	X			
	Signed off step by step	X			
	Procedure at point of work	X	X		
	Procedure studied prior to start	X	X		
	Signed off as necessary to maintain place keeping	X	X		
	Procedure referred to before start of work			X	
	No formal procedure with independent review required, handwritten instruction is allowed.				X

A significant activity requires a high level of verification. This may include an independent check performed within the organization, an independent check by an external organization, the use of alternative methods of calculation or analysis, or extensive, witnessed inspection and testing. Self-checking or peer-checking may be sufficient verification for a less significant activity.

A significant activity may require a high level of assessment. This may include self-assessment, internal audit, third party audit, peer evaluation, technical review and regulatory review. An activity of lower significance may require less frequent and less extensive, self-assessment and internal audit.

4.2.3. Processes or activities for documentation and records work

Typical processes/activities that record work, where applied controls can be graded, include:

- Documenting results;
- Records management.

Examples of how controls applied to activities for documentation and record work may be graded

Records of significant items or activities require a high level of control. This may include comprehensive record specifications, completion verification, authentication, traceability, retrievability, retention times, secure media, redundant storage and controlled access. An activity of lower significance may require shorter retention time for the records and simple storage requirements.

TABLE 3. EXAMPLES OF GRADED CONTROLS APPLIED TO RECORDS AND SENSITIVE INFORMATION

Activity	**Control**	**Grade**			
		1	**2**	**3**	**4**
Creating, copying and editing	Only used on standalone machine and information to be encrypted	X			
	Any company machine, no use of own machine		X		
	Any company machine or own machine connected to network			X	
	Own machine, laptop				X
Storage	Stored in standalone machine, paper to be stored in a secure and approved vault with access control	X			
	Stored on any company machine and paper copy in the approved vault with assigned key-holders		X		
	Information to be encrypted if on a removable device e. g. laptop or USB memory		X	X	
	Stored on any company machine and paper copy in the locked drawer			X	
	Stored on any machine and paper copy in local drawer				X
	Defined retention periods	X	X	X	
Transmission of information	Delivery by hand only conform controlled distribution list. No internal or external email or faxing allowed	X			
	Distribution through controlled distribution lists within closed and sealed envelopes. No external email or faxing allowed.		X		
	Distribution through controlled distribution lists. Email and faxed internally and externally throw defined protocols			X	
	Email or faxed internally or externally without special protocols				X
Disposal of information	Shred only with a specialised shredder	X			
	Shred or dispose in an controlled recycling bin		X		
	Dispose in approved recycle bin			X	
	No disposal requirements				X

TABLE 4. EXAMPLES OF GRADED CONTROLS APPLIED TO OPERATIONS

Activity	**Control**	**Grade**			
		1	**2**	**3**	**4**
Decision to continue operation when abnormal condition is identified	Approval for regulatory body required	X			
	Technical division involved in taking compensatory action and dedicated management team involved in taking decision	X	X		
	Shift Supervisor takes decision and technical division is involved in in taking compensatory action			X	
	Shift Supervisor takes decision and compensatory action				X
Required training	General training, and on the job and specific training required	X	X		
	General training, and on the job training required			X	
	General training required				X
Preparation to perform the work	Read the documentation, have a pre-briefing, a special training and dry run	X	X		
	Read the documentation and have a pre-briefing			X	
	Read the documentation				X
Verification of work	Independent verification	X	X		
	Peer checking	X	X	X	
	Self-checking	X	X	X	X

TABLE 5. EXAMPLES OF GRADED CONTROLS APPLIED TO MAINTENANCE

Activity	Control	Grade			
		1	2	3	4
Identification of the training required to doing a maintenance work	General training (knowledge about the work/job/practices, associated with required qualification)	X	X	X	X
	On the job training (in addition to general training for familiarization with the specific work)	X	X	X	
	Supplementary training required to obtain a specific qualification/ authorization to do the work (shall demonstrated skill and experiences to do the job)	X	X		
Preparation of work	Review work requirements	X	X	X	X
	Pre-briefing – for complex work in order to clarify the expectation for the work and responsibilities of each member in the team and to identify the risk associated with the work and any lesson learned from previous work	X	X	X	
	Possibly using mock-up or special training – especially for complex work which require high skill and which shall be finalized in a certain time	X	X		
	Discuss with supervisor for the understanding the work objectives and expectation it is enough for simple work				X
Verification of work	Independent verification	X	X		
	Peer checking	X	X	X	
	Self-checking	X	X	X	X

TABLE 6. EXAMPLES OF GRADED CONTROLS APPLIED TO RADIATION PROCESSES

Activity	Control	Grade			
		1	2	3	4
Qualification in Radiation Protection	Qualified to assess radiation protection and supervise others when working in radiation field	X			
	Qualified to assess radiation protection for own activities.		X		
	Can work in radiation field only with supervision of a qualified person, and has free access only in controlled zone with only low radiation field.			X	
	No radiation worker qualified. No free access in radiation areas				X

TABLE 7. DEFINITION OF GRADES FOR ORGANIZATIONAL CHANGES

Grade 1[4]	A change that meets the definition of Class B, below, and that will involve a change in organizational structure, resources or functions that will affect the operational limits and conditions or the licensing documentation.
Grade 2	A change in organizational structure, resources or functions which, if incorrectly interpreted or implemented, could jeopardize safe operation or that could compromise fulfilment of the license requirements, the operational limits and conditions or the licensing documentation.
Grade 3	A change in organizational structure or resources which, if incorrectly interpreted or implemented, could reduce the ability of the organization to work safely or could reduce the ability to comply with the license requirements, the operational limits and conditions or the licensing documentation.
Grade 4	All changes with conventional safety aspects for which it has been proved that the nuclear safety is not compromised.

TABLE 8. EXAMPLES OF GRADED CONTROLS APPLIED TO ORGANIZATIONAL CHANGE

Activity	**Control**	**Grade**			
		1	**2**	**3**	**4**
Review	Reactor Safety Committee	X	X		
	Radiation Protection Supervisor	X	X		
	Manager Human Resources	X	X	X	X
	Manager Quality, Health, safety and Environment	X	X	X	X
Approval	Approval of revised Operational Limits and Conditions by Regulatory Body	X			
	Approval of implementation plan by Regulatory Body	X	X		
	Implementation plan to be send to Regulatory Body for information			X	
	Head of Operating Organization	X	X	X	
	Minor change affecting only same practices in organization				X

[4] If the license is affected then a re-licensing process is often required

5. EXAMPLES OF METHODOLOGIES FOR GRADING

In the previous sections examples have been provided to support understanding of the text. In the annexes more examples are provided based on earlier IAEA publications or examples provided by organizations and are based on actual grading mechanisms. Where the examples are related to earlier IAEA publications the references to those publications are included in order to provide additional guidance.

Annexes I–VI provide examples of typical methodologies for grading and annexes VII to XI provide examples on classification and grading. Annexes XII and XIII provide examples of procedures used by organizations to apply grading and controls.

Typical methodologies for grading are presented in:

Annex I. Example of Methodology for Grading the Application of Management System Requirements.

Annex II. Example of Methodology for Grading at a Nuclear Power Plant.

Annex III. Example of Three Grade Level Methodology.

Annex IV. Example of Graded Approach to the Application of Management System Requirements for Smaller Facilities.

Annex V. Example of Grading Methodology Based on Failure Mode And Effect Analysis.

Annex VI. Example of Grading of Quality Assurance and Quality Control Activities of the Supply Chain in Nuclear New Build Projects (Example of a Project Management Company).

Classification and grading examples are presented in:

Annex VII. Example of the Relationship Between Grading and Safety Class of the Systems.

Annex VIII. Example of Classification of Radioactive Waste.

Annex IX. Example of the Application of the Grading of Management System Requirements to the Safe Transport of Radioactive Material.

Annex X. Example of the Application of Management System Requirements to Radiation Protection.

Annex XI. Example of the Grading of Event Reports.

Grading and controls are presented in:

Annex XII. Example of a procedure for assigning quality classes.

Annex XIII. Example of a procedure for assigning quality classes.

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[18] INTERNATIONAL ATOMIC ENERGY AGENCY, The Management System for the Processing, Handling and Storage of Radioactive Waste, IAEA Safety Standards Series, Safety Guide No. GS-G-3.3, IAEA, Vienna (2008).
[19] INTERNATIONAL ATOMIC ENERGY AGENCY, The Management System for the Disposal of Radioactive Waste, IAEA Safety Standards Series, Safety Guide No. GS-G-3.4, IAEA, Vienna (2008).

ANNEX I: EXAMPLE OF METHODOLOGY FOR GRADING THE APPLICATION OF MANAGEMENT SYSTEM REQUIREMENTS

This annex provides an example from a Member State of a methodology for grading the application of management system requirements and some explanation of how this methodology can be used. See also Ref. [7].

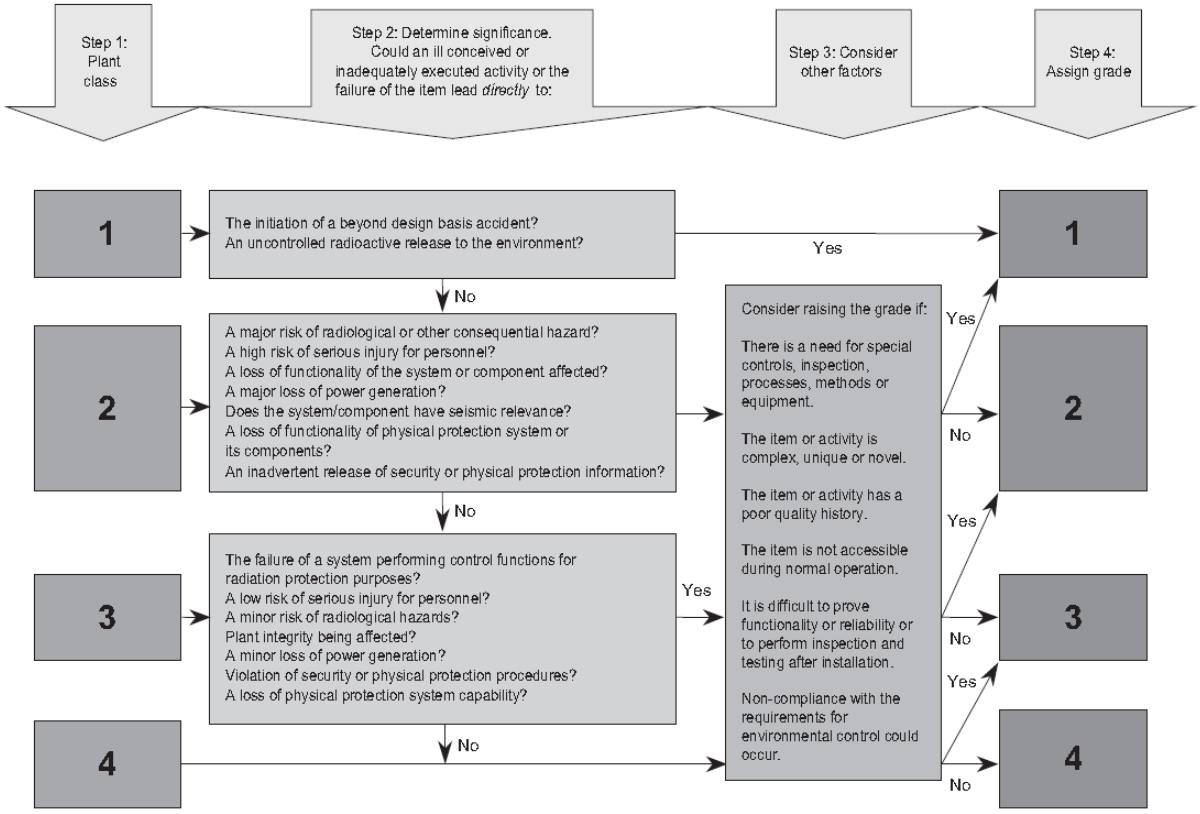


FIG. I–1. Method for grading the application of management system requirements in operation.

Each organization should quantify and define the terms (major, minor, high, low, etc.) used in step 2 of this grading method on the basis of risks and hazards and the magnitude of the risks (potential impacts) associated with the safety, health, environmental, security, quality and economical aspects of each product or activity.

Using the methodology in Fig. I–1, a grade is assigned to the item, service or process. The grade assigned may be either alphabetic or numeric; the example in Fig. I–1 uses a numeric identifier with the number "1" used to identify an item, service or process assigned the highest safety significance. When taking into account the other factors shown in Fig. I–1 (step 3), it is possible to assign a grade lower than 1 to an item, service or process that is in a system classified as class 1, or to assign a higher grade to an item, service or process in a system with a classification that is lower than class 1. The plant classification is normally specified in the original design documents for the installation.

Grade 1 should be selected for items, services and processes of major safety significance and potential major commercial risk, while Grade 4 at the other end of the scale should be selected when the safety significance and the risk of environmental impacts and the commercial risk are only minor. The safety significance of the item, service or process should always be the most important factor in the assignment of a grade.

The next stage is to specify the degree of application of the management system requirements corresponding to each of the four grades. The criteria used in specifying the application of the requirements for activities should be developed so as to achieve varying degrees of control, verification, measurement and record keeping and to maintain confidence that items or services satisfy the relevant requirements. Examples of such controls include written instructions and checklists, quality plans and independent hold point inspections.

ANNEX II: EXAMPLE OF METHODOLOGY FOR GRADING AT A NUCLEAR POWER PLANT

This annex provides an example (Fig. II–1) of classification criteria, classification system and an example (Fig. II–2) of a methodology for grading at Nuclear Power Plant, adapted in a Member State.

Classification criteria:

Class 1	Failure in service could lead directly to any increase in the risk of radiological hazard and is likely to lead to a SERIOUS radiological risk.
Class 2	Failure is likely to lead to a MAJOR but less serious radiological risk or cause serious injury to persons or lead to a breach of the Site Licence or Environmental or Statutory requirements or lead to SIGNIFICANT cost penalty
Class 3	Failure is likely to reduce the integrity of plant items or systems and result in a LESS SIGNIFICANT cost penalty
Class 4	Anything else

Classification applied to plant system and major plant items:

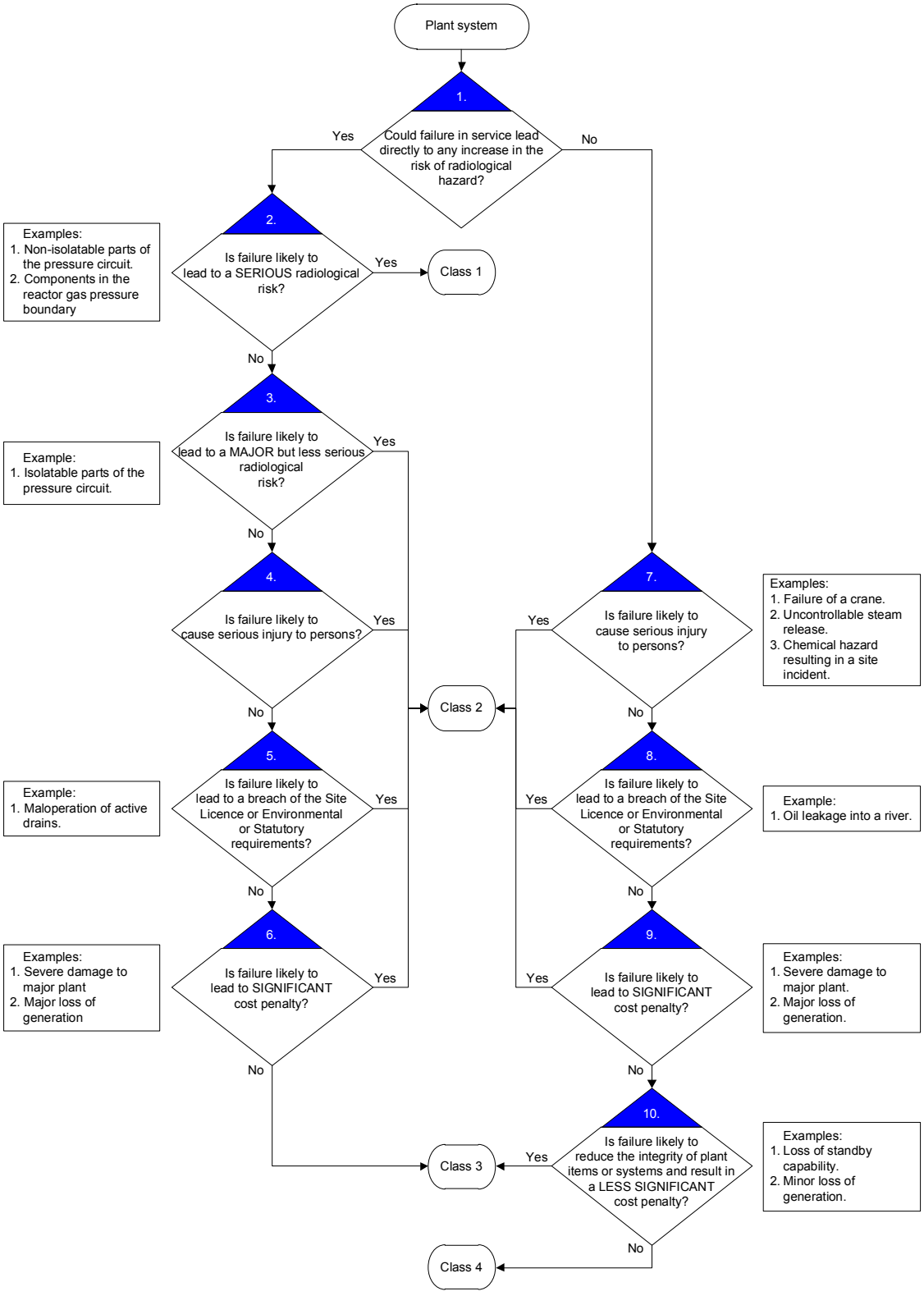
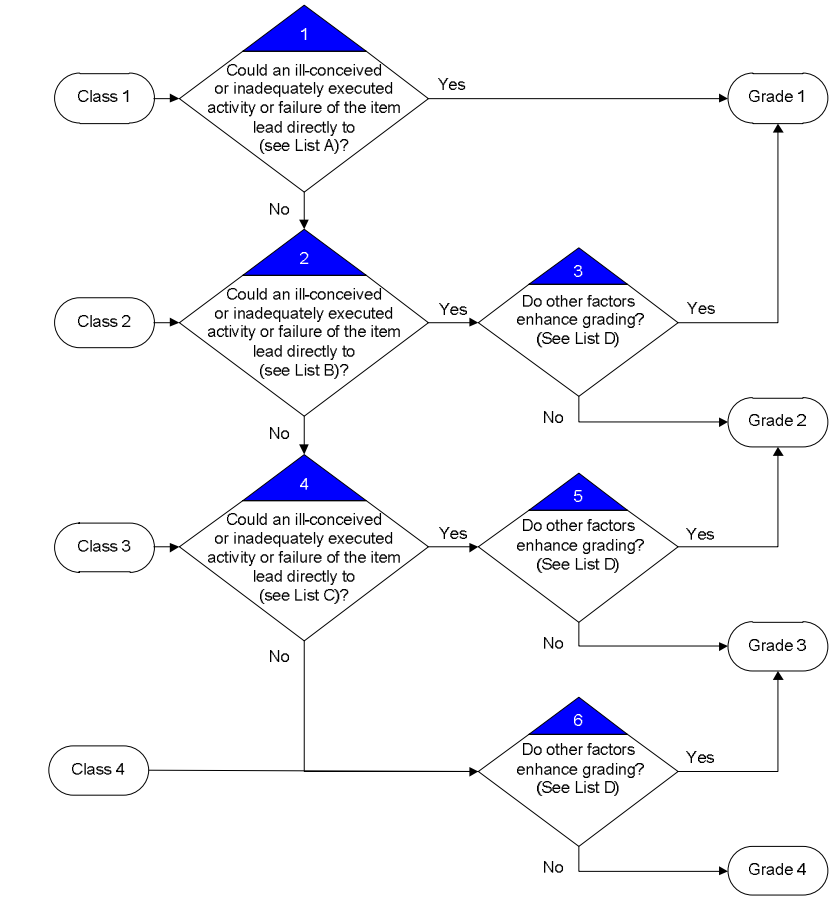


FIG. II–1. Method for classification for plant systems and major plant items at a nuclear power plant.



List A

a) uncontrolled release of radioactivity (e.g. a non-isolatable component in the pressure circuit)

List B

a) major risk of a radiological hazard
b) high risk of serious injury (e.g. bulk toxic chemical storage, large pressurised system, cranes)
c) non-compliance with Nuclear Site Licence, environmental and/or Statutory requirements
d) severe damage to major plant
e) major loss of generation

List C

a) minor risk of a radiological hazard
b) lower risk of serious injury
c) reduced integrity of plant
d) minor loss of generation
e) impact on business plan targets

List D

a) Is the item or activity complex, unique or novel?
b) Is there a need for special controls, administrative methods, and inspection processes, methods and equipment?
c) Would it be difficult to prove functional compliance by inspection and test after installation in the plant?
d) Has the item or activity a poor quality history or is it a non-standard item or activity?
e) Is the item inaccessible after installation in the plant for maintenance, in-service inspection and replacement?
f) Is the item or activity relevant to any entry on the NPP register of significant environmental effects?

Note: Class refers to a classification level of the system, structure or component.

FIG. II–2. Method for grading at a nuclear power plant.

ANNEX III: EXAMPLE OF A THREE GRADE LEVEL METHODOLOGY

This annex provides an example (Fig. III-1) from a Member State of an approach for grading the application of management system requirements in a nuclear power plant. The approach involves three grade levels.

Figure III-1 is applied during the initial development of a process to ensure that a graded approach is incorporated into each process or procedure as appropriate. The determination of a safety related system is based on the system classification specified in design documents. For Grade 1 application, the full set of controls is applied as defined in the procedure or work plan applicable to the item or activity. For example, work on a safety related system would require in-hand procedures, higher level authorizations to perform the procedure, specific qualifications for the performer, control of replacement parts and configuration, and detailed recording of task progress and results.

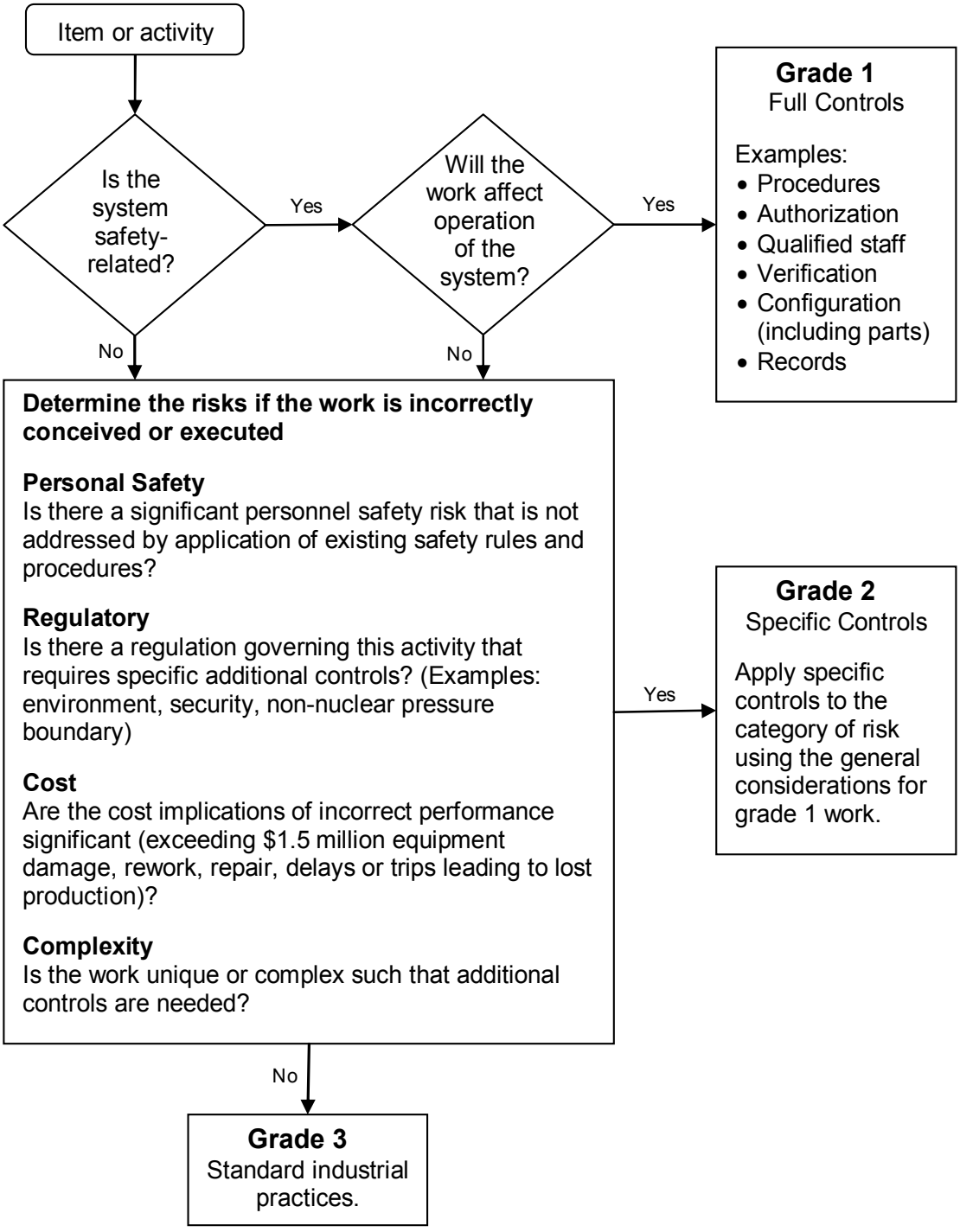


FIG. III-1. A three grade level methodology.

ANNEX IV: EXAMPLE OF GRADED APPROACH TO THE APPLICATION OF MANAGEMENT SYSTEM REQUIREMENTS FOR SMALLER FACILITIES

IV-1. INTRODUCTION

A nuclear installation is divided into Structures, Systems and Components (SSCs), each comprising items, services, and processes. Factors with a significance to nuclear safety, reliability, complexity, design and experience are determined and a 'quality grade' (A, B, C, D) is assigned to each structure, system or component. The quality grade is obtained by applying the results of a 'qualification formula' and the criteria from 'Assignation of Quality Grades' described below. The Management System (MS) defines applicable requirements for each quality grade.

IV-2. QUALIFICATION FORMULA

A 'Total Quality Rating' of the structure, systems and components is obtained by assigning the values for each of the factors considered in the formula. The criteria applied to obtain the different values for each factor are not discussed here.

$$\text{Total Quality Rating (TQR)} = 2a + b + c + d + e$$

The Total Quality Rating may correspond to the TQR of a general system or to its components because the components of a system will not necessarily have the same quality class as the system itself.

A brief description of the factors:

Safety (a): This factor includes nuclear, radiation, physical and what is known as industrial safety. It has a weight of 2 and its value can range from 0 to 5, with 5 having the highest safety relevance.

Reliability (b): This factor includes consideration of possible loss of profit, e.g. through delay, failed repair work, interruption of service i.e. radioisotope production or the irradiation of an experiment, etc. Its values can range from 0 to 5, with 5 representing the greatest threat to reliability

Complexity (c): This factor includes consideration of the complexity of the design, difficulties in replacing parts, accessibility for maintenance and unique structures, systems and components design. Its values can range from 0 to 5, with 5 representing the greatest complexity.

Design State (d): This factor gives consideration to identifying the maturity of the design, from fully tested structures, systems and components design of proven quality able to be used without modifications, to a new design to be developed from basic principles and data. Whenever a prototype is to be built, this action will be valued by assigning a lower factor to it. Its values can range from 0 to 5, with 5 representing the lowest degree of maturity.

Experience (e): This factor takes into account the accumulated and objective experience of the structures, systems and components, obtained by the organization, by suppliers, by other organizations or by recognized consultants and/or contractors. Its values can range from 0 to 5, with 5 representing the lowest level of experience.

IV-3. ASSIGNATION OF QUALITY GRADES

Four quality grades are identified: A, B, C, and D. Quality grade A represents the most stringent level of requirements (Table IV–1).

TABLE IV–1. ASSIGNATION OF QUALITY GRADES

Quality grades		Assignment criteria
A	Items with factor:	a = 4 or 5
	Items with factor:	b = 5
	Items with:	TQR = 25–30
B	Items with factor:	a = 2 or 3
	Items with factor:	b = 3 or 4
	Items with:	TQR = 18–24
C	Items with:	TQR = 5–17
D	Items with:	TQR = 0–4

Tables IV-2 to IV-4 give some examples of the requirements of each of the four quality grades.

TABLE IV-2. GRADED REQUIREMENTS FOR QUALIFICATION AND TRAINING

Qualification and Training	Quality grade			
	A	B	C	D
Qualification				
Regulatory Authority License for reactor commissioning, reactor operation, radiation safety; manufacturing of nuclear fuel element	X	X		
Certification for design and manufacturing	X	X		
Welding Qualification and Welder Qualification / Welding Inspectors	X	X		
Non-Destructive Tests	X	X	X	
Training				
All personnel involved in design control, manufacturing, installation, start-up, commissioning; operation, maintenance, Test and Inspections	X	X		
Internal Auditors	X	X		
Quality Officers	X	X	X	
Company personnel	X	X	X	

TABLE IV-3. GRADED REQUIREMENTS FOR PROCUREMENT

Procurement	Quality grade			
	A	B	C	D
Supplier evaluation and selection (prior to the awarding of the procurement order or contract)	X	X		
Surveillance at the Supplier's facility by the Technical Representative or Quality Officer	X	X	X	
Document evidence from the Supplier on that the procured items meet procurement quality requirements, such as codes, standards, or specifications	X	X	X	X
Periodic verification of the Supplier's certificates of conformance to assure their meaningfulness	X	X		
Evaluation of the performance of the Supplier with the participation of the Technical Representative / Procurement Department / Quality Division	X	X		

TABLE IV-4. GRADED REQUIREMENTS FOR NON-CONFORMANCES AND CORRECTIVE ACTIONS

Non-conformances and Corrective Actions	Quality grades			
	A	B	C	D
Non-Conformances				
Components that do not conform to requirements will be reviewed and approved by the designer and the corresponding management grades	X	X	X	X
There must be indication of the disposition taken: “use as is” / “repair” / “re-work”	X	X	X	
Analyses of reports	X	X		
Corrective Actions				
Promptly identified and corrected (failures, malfunctions, deficiencies, deviations, defective material and equipment)	X	X		
In the case of significant conditions adverse to quality, the cause is determined, and a corrective action is taken to preclude repetition, and further documented and reported to the corresponding management grades	X	X		

ANNEX V: GRADING EXAMPLE IN FAILURE MODE AND EFFECT ANALYSIS

Failure mode effects analysis (FMEA) is an analytical technique utilized by a team as a means to assess the potential modes and their associated causes/mechanisms. This methodology can be applied to both items and processes. The methodology assesses the criticality of failures and determines a risk priority number (RPN) for each failure mode. A control grade can be assigned based on the resultant RPN.

The example in this annex is based on FMAE and can be described as a systemized group of activities intended to:

— Recognize and evaluate the potential failure of a product/process and its effects;
— Identify the likelihood of failure to happen and;
— What are the existing controls that either prevent the failure mode from occurring or detect it should it occur.

The methodology starts by establishing the potential failure modes of the item or process. For each failure mode, the impact or consequence of the failure (i.e. the severity of the failure), the likelihood of this failure and the detectability of the failure mode are assessed. This assessment is typically performed by a team and based on engineering judgment and experience. An RPN is derived from the product of the numerical values of the severity, likelihood and detectability. See also the Three-Grade Level Methodology in table V-1.

TABLE V-1. THREE-GRADE LEVEL METHODOLOGY

Process Step or Variable or Key Input	Potential Failure Mode	Potential Failure Effects	Severity	Likelihood of Failure	Likelihood	Detectability of Failure	Detectability	RPN
What is the process step?	In what ways can the Process Step, Variable, or Key Input go wrong? (chance of not meeting requirements)	What is the impact on the Key Output Variables (customer requirements) or internal requirements?	How Severe is effect to the customer?	What is the likelihood that a particular failure will occur during the intended life of the item?	How frequent is cause likely to occur?	What are the existing controls that either prevent the failure mode from occurring or detect it should it occur?	How probable is Detection of cause?	Risk Priority # to rank order concerns
		High	6 - 10	High	6 - 10	Remote	6 - 10	Severity x Likelihood x Detectability
		Medium	3 - 5	Medium	3 - 5	Moderate	3 - 5	Severity x Likelihood x Detectability
		Low	1 - 2	Low	1 - 2	Almost certain	1 - 2	Severity x Likelihood x Detectability

Table V-2 shows the three control levels with a numerical range assigned to each of the level for severity, likelihood and detectability. Different organizations may assign different numerical values to suit their application.

Table V-2. CONTROL LEVELS

Control Level	Risk Priority Number (RPN) Severity x Likelihood x Detectability	Graded Management Controls
High	215 - 1000	High controls required
Medium	27 - 214	Medium controls required
Low	1 - 26	Low controls required

The resultant RPN from Table V-1 is used to establish the Control Level as shown in Table V-2. The relationship between the control level and the Risk Priority Number (RPN) is selected to suit each organization's application. Appropriate grading of controls is then established by management for each control level.

Table V-3 shows application of the methodology with some practical examples.

TABLE V-3. EXAMPLES OF THE FMEA WITH THE RISK PRIORITY FACTOR

Process Step or Variable or Key Input	Potential Failure Mode	Potential Failure Effects	Severity	Likelihood of Failure	Likelihood	Detectability of Failure	Detectability	RPN
What is the process step?	In what ways can the Process Step, Variable, or Key Input go wrong? (chance of not meeting requirements)	What is the impact on the Key Output Variables (customer requirements) or internal requirements?	How Severe is effect to the customer?	What is the likelihood that a particular failure will occur during the intended life of the item?	How frequent is cause likely to occur?	What are the existing controls that either prevent the failure mode from occurring or detect it should it occur?	How probable is Detection of cause?	Risk Priority # to rank order concerns
Changing oil filter for emergency diesel generator	Install wrong parts	Generator will fail after 2 hours operation	5	Low	1	Moderate	5	25
	Mechanic did not follow the procedure correctly	The generator may fail immediately	5	Medium	4	Almost certain	1	20
A design change from analogue to digital control	Training for operator inadequately updated	Unsafe operation	8	Medium	3	Remote	9	216

ANNEX VI: EXAMPLE OF GRADING OF QUALITY ASSURANCE AND QUALITY CONTROL ACTIVITIES IN THE SUPPLY CHAIN

VI-1. METHODOLOGY

This example provides a generic methodology for grading activities, which starts with the macroscopic view and then further breaks down major activities into detailed activities (tasks). Activities are executed using graded controls, which are applied based on an integrated risk assessment. The methodology links the activities with the equipment (structure, systems, and components) affected and can include consideration on performing parties (resources/effort).

The methodology and the relevant steps are described using an example for supply chain activities in a new nuclear build project that starts with a broad project management view, and then focuses on application of the methodology to identify respective quality assurance (QA) and quality control (QC) activities. In this example, quality assurance means defining the requirements (e.g. technical specifications, fabrication methodologies, required documentation, identification and traceability of materials). Quality control means surveillance activities and inspection activities to confirm requirements have been achieved.

Step 1. Identify the major activities.

a) List the phases of the project or lifecycle of the facility/plant (e.g. pre-contract, design, fabrication/procurement, construction, commissioning, operation).

b) For each phase, identify the major activities/tasks to be completed (e.g. for fabrication, this includes supplier qualification, procurement, supplier engineering, shop fabrication, and packing and transportation). This may be derived from internal processes, as well as contractual, codes, standards and regulatory documents.

c) Identify the activities requiring specific controls (in the example, the activities requiring specific quality assurance and/or quality control aspects for mechanical components are highlighted in green and red respectively).

d)

FIG. VI-1: Example of identification of major project activities with regard to supply chain activities and related QA/QC activities.

Step 2. Grade the major activities.

a) For each activity identified as having specific QA/QC requirements, identify the different controls that can be used to perform this activity (e.g. vendors may be qualified by independent audit, by confirming they have a third party certification, or by reviewing of their QA/Management System documentation). Requirements may be derived from codes and standards, regulatory documents, contracts, and internal programs and standards.

b) Identifying the parties who should be involved in executing each task (e.g. for performing, reviewing and/or approving) will help to further grade the controls.
Although the example concerns broader conventional QA activities, significant resources are also occupied in managing interfaces. Efficiencies may be gained by grading interfaces between various parties (for example, between licensee, inspection agencies, contractor and sub-contractor). Variations may include frequency (e.g. continuous, infrequent, or when there is a problem), level of information provided, and/or nature of the exchange (e.g. for information, for review and comment, for acceptance, or for approval).

c) Create the Activity-Risk Table for each activity and set of graded controls. Using Table 1 as an example (template), identify the graded controls that will be applied to a range of risk levels (the number of risk levels is established as part of the Risk Matrix, in Step 3).

Note: This exercise will help to confirm that the graded controls have been defined in sufficient detail, such that it is possible to properly assign controls to the various risk levels. This may be an iterative process, related to Step 3 (“Create risk matrix”).

TABLE VI-1. EXAMPLE OF AN ACTIVITY-RISK-TABLE WITH REGARD TO SUPPLY CHAIN ACTIVITIES

Activity	**Graded Controls**	**Risk Levels**			
		1	**2**	**3**	**4**
Supplier Qualification The licensee should ensure the contractor has the required QA program implemented.	Supplier audited by licensee audit.	X	(X)		
	Supplier certified by third party registrar (e.g. ISO 9001).		X	X	
	Supplier's QA documentation accepted by licensee.	X	X	X	X
Fabrication Welding supervision procedure (Definition of the licensee' rights for document review/approval)	Licensee must receive certain documents prior to fabrication.	X			
	Licensee may require receipt of certain documents prior to fabrication.		X		
	Licensee will indicate the requirement to access selected document on a sample basis.			X	
	Licensee reserve the right of document review approval where sub-standard execution may induce a major risk.				X
Fabrication Welding supervision (definition of the licensee' rights towards the contractor)	Licensee has the right to attend on listed activities and also the right to additional attendance.	X			
	Licensee has the right and the option to attend on activities and to extend the level of involvement.		X		
	Licensee has the right of sporadic attendance.			X	
	Licensee has the right of attendance where substandard execution may induce a major risk.				X
Fabrication Witness/verify non-destructive evaluation and related processes. (to be defined on code requirements)	Contractor witnesses 100% of the non-destructive evaluation processes and accepts all qualification records of inspectors and inspection procedures prior to use.	X			
	Contractor witnesses' critical non-destructive evaluation processes (e.g. 25-75%) and reviews qualification records and procedures at the witness point.		X	X	
	Licensee reviews and accepts the history file once it is completed by the vendor, which includes the analysis report.	X	X	X	X

Step 3. Create the risk matrix

The risk matrix consists of the equipment classes and influence factor sums. Instructions for defining these parameters are described in Steps 3.1 and 3.2. The risk matrix is then divided into risk levels, as described in Step 3.3.

Step 3.1 Classify the systems, structures and components

a) Based on safety classification methodology from the applicable codes, standards and industry best practices (see other examples in IAEA guide), categorize *all* SSCs into an appropriate number of Equipment Classes (e.g. A, B, C, D, E, F, with decreasing safety significance).

Note: This is typically informed by regulatory requirements or expectations.
Note: For example, this may include major engineered (class A), major electrical (class B), main static (class C), rotating (class D), static (class E) and standard/catalogue commodities (class F).

Step 3.2 Define the Influence Factors

a) Define the factors to be considered in determining the inherent risk of an activity. This should integrate the major objectives and parameters of concern (e.g. industrial safety, design maturity, environmental risk, and commercial risks). See the first column in Table VI-2.
b) For each influencing factor, define the scoring criteria, ideally using a limited scale (e.g. 1 to 3). See the second and third columns in Table VI-2.

Note: This evaluation and subsequent use of the criteria should be performed by a cross-functional group of subject matter experts.

TABLE VI-2. EXAMPLE OF INFLUENCE FACTORS TO REFLECT THE INTEGRATED APPROACH

Influencing factors	Risk / Consequence	Score
Safety to Personnel/ Equipment:	• Low • Moderate • High	1 2 3
Environment Impact:	• No significant impact • Moderate Impact • High Impact	1 2 3
Operational / Process significance:	• Faillure coverd by stand by Unit or without difficulty • Some Loss of production but no loss of integrity • Major Loss of production or jeopardise plant integrity	1 2 3
Design Maturity:	• Proven • Frequently Used • New Design	1 2 3
Fabrication Complexity: (incl.Replacement time and repairability)	• Single known process • One complex process • More than one complex process	1 2 3
Design Data Requirement:	• Not significant in overall design • Partly essential to design • Essential to overall design	1 2 3
Cost, Size:	• Low cost, small item • Moderate cost, moderate item • Large and expensive item	1 2 3
Assembly and schedule impact:	• Not critical • Significant important • Vital important	1 2 3
Supplier Qualif./Capability:	• Main Qualified Supplier Status, • Frequent Supplier Status • Has to be qualified, no relevant experience	1 2 3
	Summary	

Step 3.3. Create the risk matrix

a) Assign the equipment classes to the columns and assign the influence factor sums to the rows, as shown in the Figure VI-2.

b) Define risk levels (e.g. 1, 2, 3, and 4, where 1 is the highest risk), which stands in relation to the assignment of graded controls (see Step 2c). The risk levels should be defined with regard to the magnitude of the potential impact and the possible consequences if a produce fails or an activity is carried out incorrectly.

c) Divide the risk matrix into risk level zones. For example, see Figure VI-2.

Note: It is recognized that division of the risk matrix and assignment of graded controls to the risk levels may be an iterative process. The controls used for each of the risk levels are defined in Step 2 above (“Grade the major activities”).

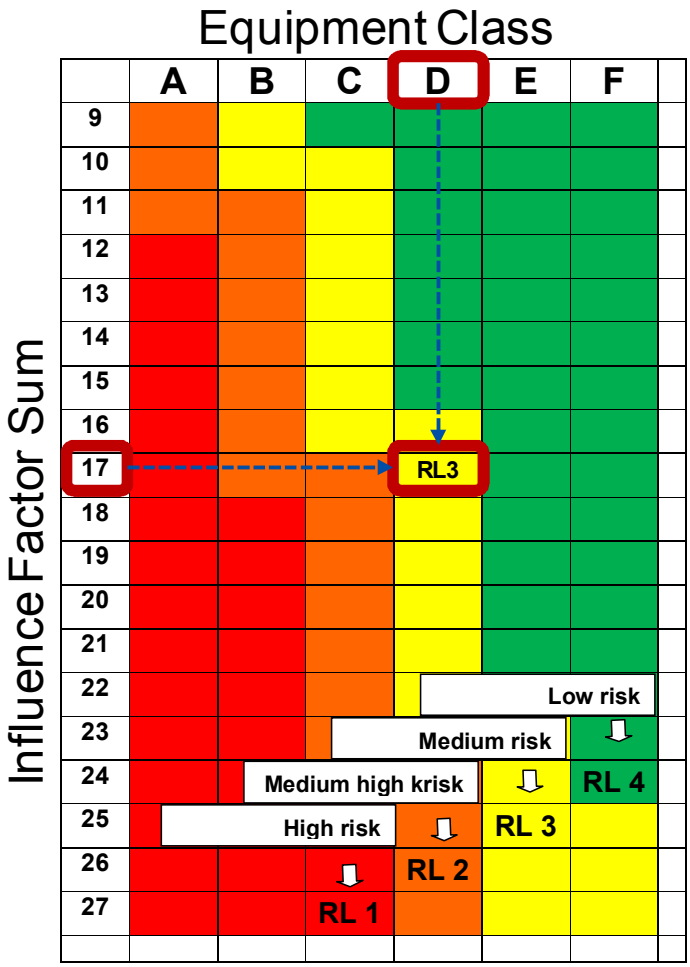


FIG. VI-2: Risk Matrix to determine the Risk Level and subsequently the QA/QC measures (graded controls).

VI-2. Application of the Methodology - Use of the tool

a) Identify the task to be completed and the affected SSC.
b) Complete the influencing factors assessment for this task, and calculate the Influencing Factor Sum.
   This assessment should be performed by a cross-functional team of specialists.
c) Identify the risk level, using the calculated Influencing Factor Sum and the Equipment Class corresponding to the affected SSC.
d) Identify the applicable controls for the task, using the Activity-Risk Table.
e) Review the identified controls to evaluate whether there are peripheral considerations that may increase or decrease the controls assigned.
f) Document the results in related tables/database for further use (e.g. development of quality plans and inspections plans, procurement activities).

ANNEX VII: EXAMPLE OF THE RELATIONSHIP BETWEEN GRADING AND SAFETY CLASS OF THE SYSTEMS

VII-1. INTRODUCTION

In chapter 3 of this document it was mentioned how facility operators can classify structures, systems and components (SSCs) based on criteria related to their safety function. This classification is then used to determine the appropriate grade or level of control to be applied to activities. This annex outlines how safety classification methodology applied to pressurized water reactors (PWRs) is used in grading the application of management system requirements.

VII-2. SAFETY CLASSIFICATION

Safety classification is carried out for PWR NPP items making reference to the applicable Safety Code and guide on NPP design. Safety related items are those that fulfil or support the following functions:

— reactivity control;
— residual heat removal;
— radiation material containment;
— other functions preventing event occurrence or reducing event consequence.

Figure VII-1 illustrates how nuclear safety classifications NS1 to NS4 can be determined from the safety function the item performs.

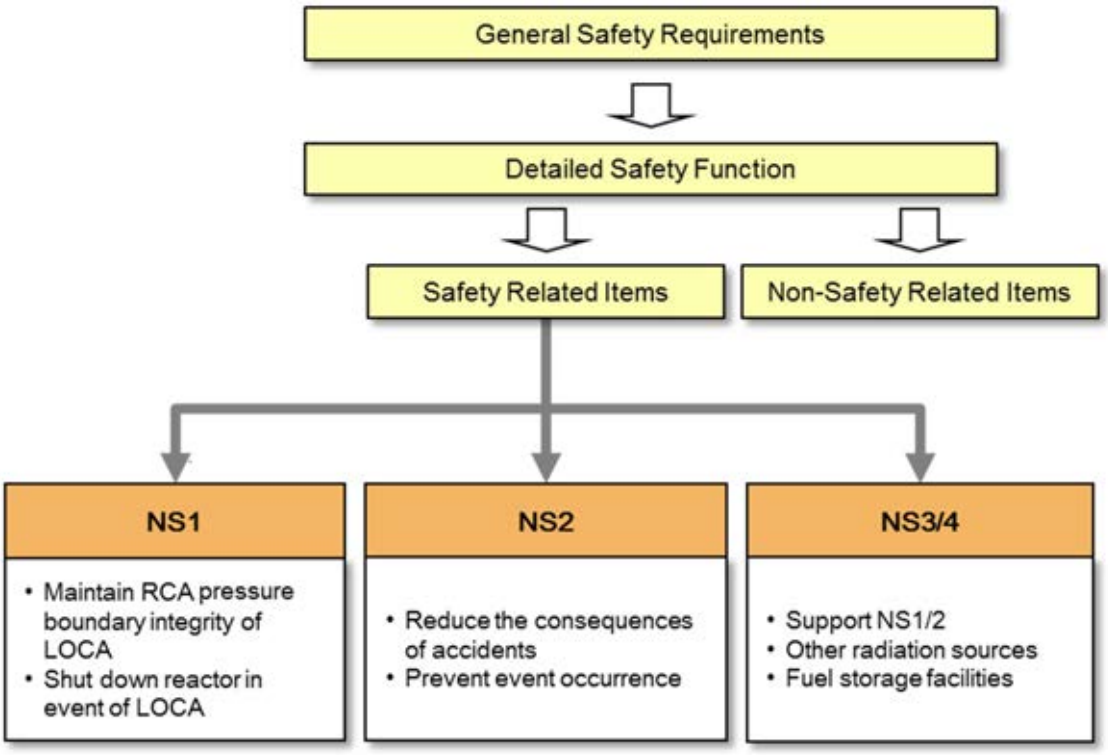


FIG. VII-1: Nuclear safety classification.

VII-3. ELECTRONIC SAFETY CLASSIFICATION

For electric components of NPP systems, an electronic safety classification can be derived from the following system functions.

1E (safety level):

— power supply during/after accidents;
— reactor emergency shutdown;
— System isolation during anticipated operational occurrences, design basis accidents or design extension conditions;
— emergency reactor cooling;
— heat removal from nuclear inventory;
— prevent release of radiation to the environment.

VII-4. ANTI-SEISMIC SAFETY CLASSIFICATION

An anti-seismic safety classification can be derived from the following functional criteria.

TABLE VII-1. SEISMIC SAFETY CLASSIFICATION

Anti-Seismic Safety Classification	Criteria
Anti-seismic I: Meet SSE requirements	• Safety shut down • Maintain reactor core cooling
Anti-seismic II: Meet OBE requirements	• Maintain operating conditions when the historical max earthquake occurs
Non-seismic level: Meet normal standards and codes	

Notes:

SSE	Safe Shutdown Earthquake
OBE	Operating-Basis Earthquake

VII-5. SPECIFICATION CLASSIFICATION

The classification of specifications is mainly based on safety class and reflected in technical codes, standards and specifications. This is illustrated in Figure VII-2.

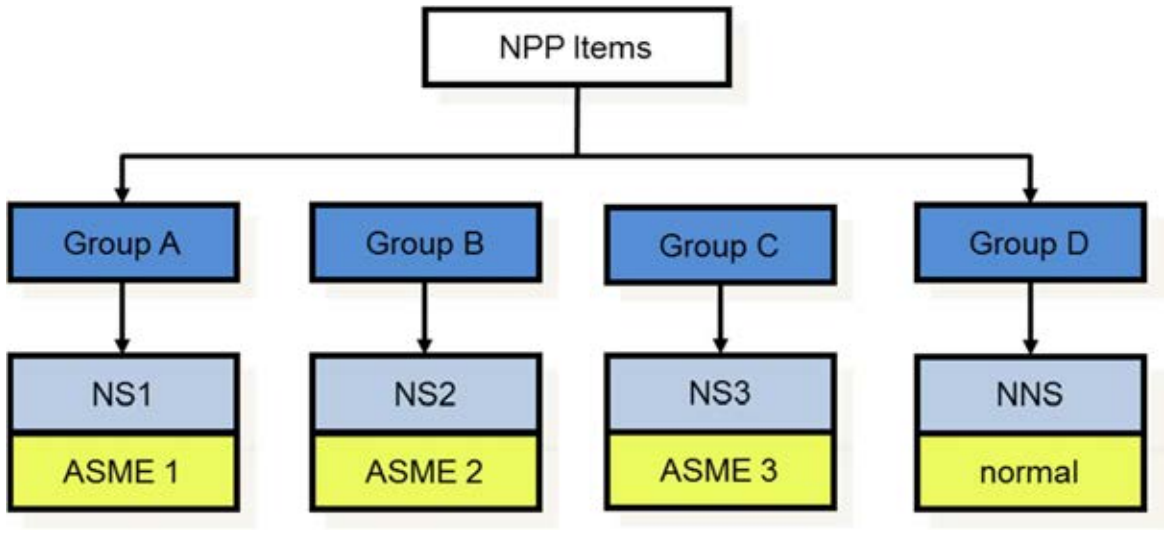


FIG. VII-2: Specification Classification.

Notes:

Group A/B/C/D	Technical code classification group
NS1/2/3	Nuclear safety related classifications
NNS	Non-nuclear safety related
ASME1/2/3	Technical code classification
Normal	common industry standard, outside ASME scope and limits

An example of the classification of nuclear power plant components based on the above safety classification criteria is shown in Table VII-2.

TABLE VII-2. CLASSIFICATION OF NPP COMPONENTS

	Safety Class	Specification Class	Anti-seismic Class
RPV	1	RCC-M-1	1
RPV supports	LS	RCC-M-H	1
RPV internals	LS	RCC-M-G	1
CRDM	LS	RCC-M	1
CRDM penetration	1	RCC-M-1	1
CRDM supports	LS	RCC-M-H	1

Notes:

RPV	reactor pressure vessel
CRDM	control rod drive mechanism
LS	unpressurized, but safety related
RCC-M-xx	identification code of RCC Standard Series issued by France
RCC-M	Series for component design and construction of nuclear island for PWR

VII-5. RELATIONSHIP BETWEEN CLASSIFICATION AND GRADING

The relationship between safety classification and grading is illustrated in Figure VII-3.

This shows that safety classification applies only to physical plant and NPP items. Safety classification is not applied to NPP process. Grading is applied to both items and processes.

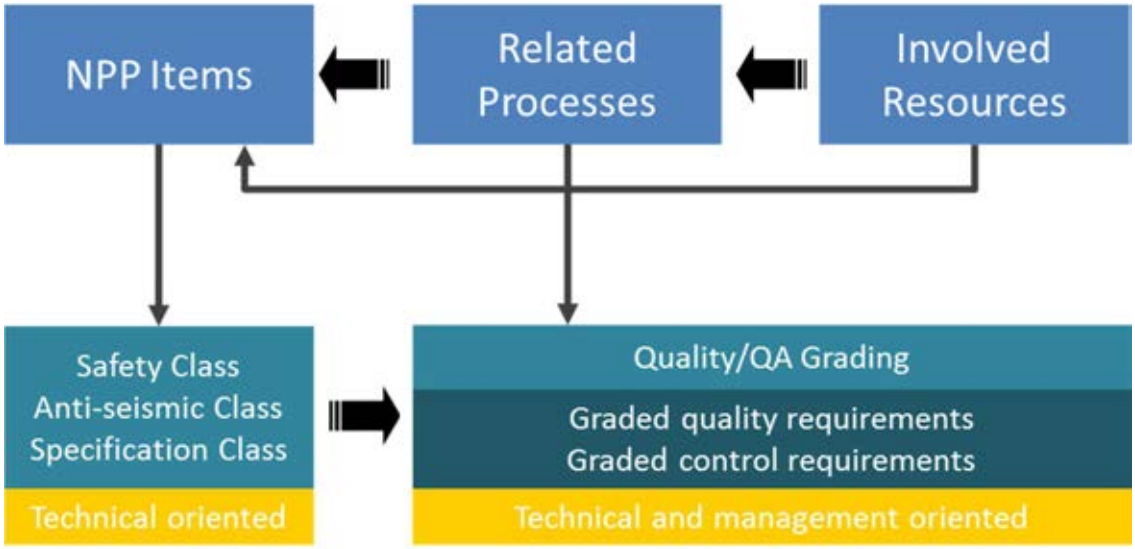


FIG. VII-3: Specification Safety Classification.

There is not a direct correlation between safety classification and grading. If the activity to be carried out on the classified structure, system or component is complex or novel, for example it can be preferable to enhance the grade applied to provide greater assurance that the structure, system or component complies with its required performance specification. Such enhancement of grading is illustrated in Figure VII-4. In this illustration, the grade can be enhanced by up to two levels.

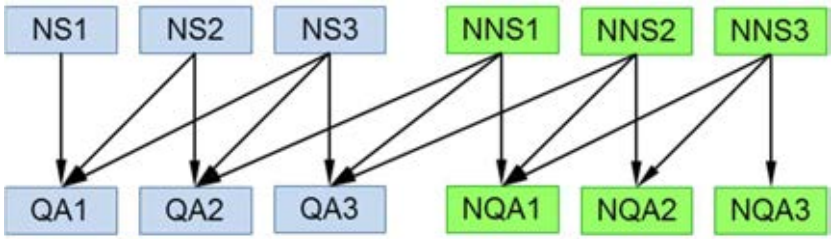


FIG. VII-4: Enhancement of grading.

Notes:

NS1, NS2, NS3	Nuclear safety related classifications
NNS1, NNS2, NNS 3	Non-nuclear safety related classifications
QA1, QA2, QA3	Quality Assurance grades
NQA1, NQA2, NQA3	Nuclear Quality Assurance grades

VII-6. RESPONSIBILITIES FOR CLASSIFICATION AND GRADING

The responsibilities for the classification and grading are determined by the lifecycle and the plant or activity involved. The designer of the NPP is normally responsible for safety classification. The designer of the NPP or those organizations that produce technical codes, standards or specifications are responsible for incorporating graded requirements in these

documents. The owner or operator of the NPP is normally responsible for determining QA or quality grade. All organizations who own or operate a NPP and those who supply items and services or are responsible for carrying out the graded requirements contained in the various documents. These relationships are illustrated in Figure VII-5.

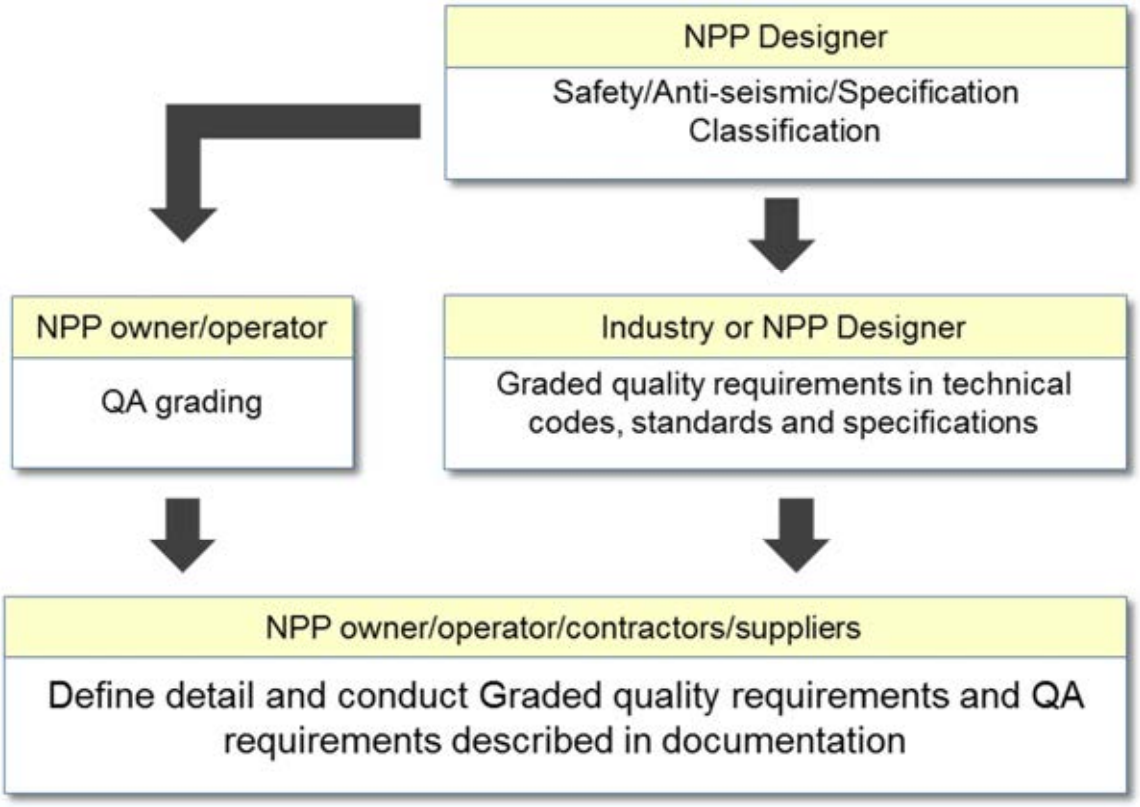


FIG. VII-5: Responsibilities for classification and grading.

VII-7. EXAMPLE: QA GRADING FOR AP1000

To determine the QA grading requirements for the AP1000, the following is taken into consideration. Once the safety classification is determined (see VII-2 to VII-5), factors relating to the reliability of the design and the reliability of the plant are incorporated into the assessment. There is then a systematic consideration of grading for both safety related and non-safety related items in which the operating experiences should be considered.

The application of these factors is shown in Figure VII-6 and summarised in Table VII-3.

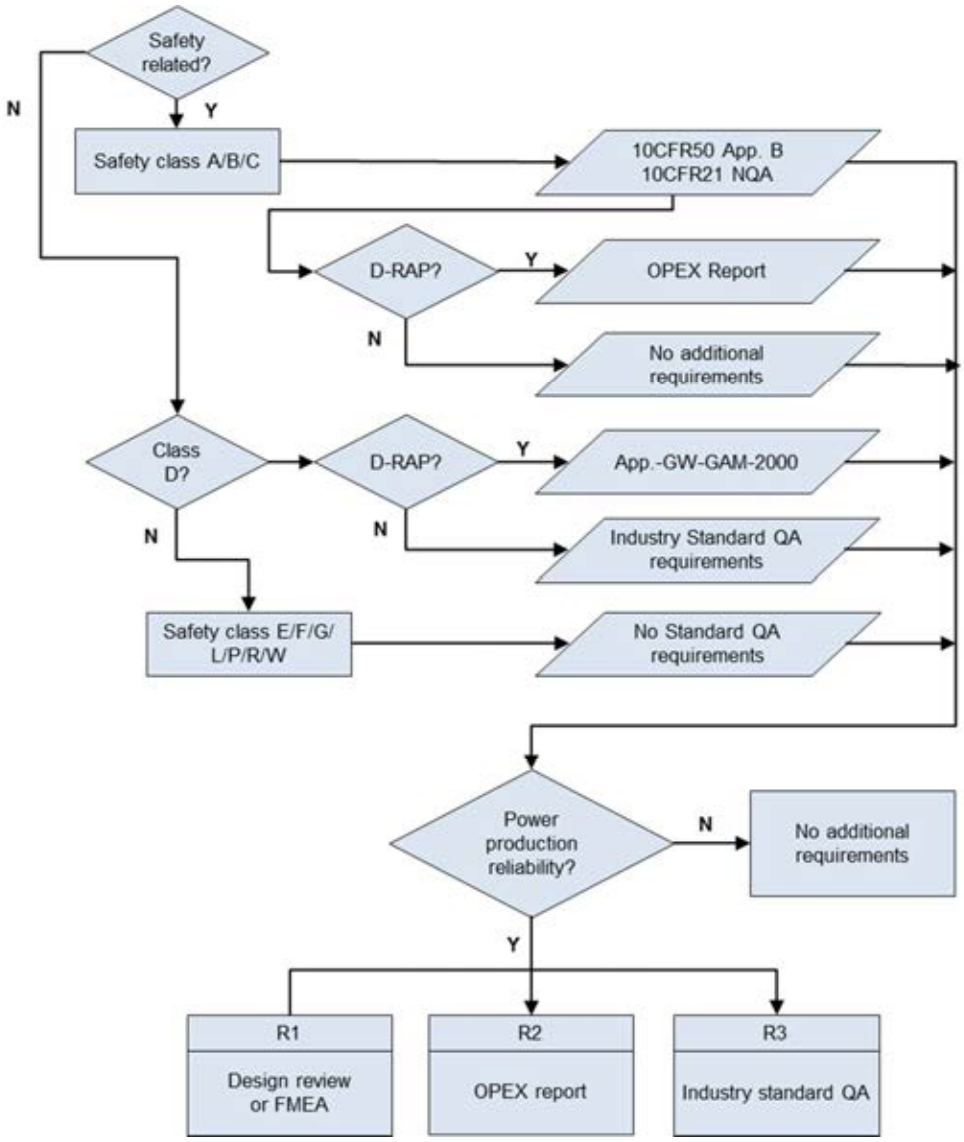


FIG. VII-6: QA for AP1000 Grading.

Notes:

Safety Classes E/F/G/L/P/T/W	Safety classification levels described in related US Codes and Standards
D-RAP	Design Reliability Programme
OPEX	Operation Experience
10 CFR 50 Appendix B	Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants, United States Nuclear Regulatory Commission
10 CFR 21	Reporting of Defects and Noncompliance, United States Nuclear Regulatory Commission
APP-GW-GAM-200	Westinghouse Specification for supplier quality requirements

TABLE VII-3. SUMMARY OF QA GRADING FOR AP1000

Class A/B/C	D-RAP	R1	R2	R3
10CFR50 App. B 10CFR21 NQA-1	OPEX	Design review or FMEA	OPEX report	Industry standard QA
Class D	**D-RAP**	**Design review or FMEA**	**R2**	**R3**
Industry Standard QA	APP.-GW-GAM-2000	Design review or FMEA	OPEX report	Industry standard QA
Class E/F/G/ L/P/R/W	**D-RAP**	**R1**	**R2**	**R3**
No standard QA requirements		Design review or FMEA	OPEX report	Industry standard QA

Notes:

10 CFR 50 Appendix B	Quality Assurance Criteria for Nuclear Power Plants and Fuel REPROCESSING PLANTs, United States Nuclear Regulatory Commission
FMEA	Failure modes and effects analysis

ANNEX VIII: EXAMPLE OF THE CLASSIFICATION OF RADIOACTIVE WASTE

In order to ensure that proper and adequate provision is made for the safety implications associated with the management and disposal of radioactive waste, the waste is characterized and classified. The general scheme for classifying radioactive waste as presented here is based primarily on considerations of long term safety, and thus, by implication, disposal of the waste. This classification provides a starting point for the grading of activities associated with the packaging and disposal of radioactive waste so that appropriate controls can be applied to protect workers, the public and the environment.

The classification of radioactive waste can be used to guide activities associated with planning a disposal facility and at any stage between the generation of raw waste and its disposal. Such grading can apply:

— at the conceptual level:
  - in devising waste management strategies;
  - in planning and designing waste management facilities;
  - in assigning radioactive waste to a particular conditioning technique or disposal facility.
— at the legal and regulatory level:
  - in the development of legislation;
  - in the establishment of regulatory requirements and criteria.
— at the operational level:
  - by defining operational activities and in organizing the work to be undertaken with the waste;
  - by providing a broad indication of the potential hazards associated with the various types of radioactive waste;
  - by facilitating record keeping.
— for communication:
  - by providing terms or acronyms that are widely understood in order to improve communication among all parties with an interest in radioactive waste management, including generators and managers of radioactive waste, regulators and the public.

The classification process is described fully in [9].

The classes of radioactive waste identified in [9] are summarized in the following table.

TABLE VIII-1. CLASSES OF RADIOACTIVE WASTE

Radioactive Waste Class	Description
Exempt waste (EW)	Waste that meets the criteria for clearance, exemption or exclusion from regulatory control for radiation protection purposes.
Very short lived waste (VSLW)	Waste that can be stored for decay over a limited period of up to a few years and subsequently cleared from regulatory control according to arrangements approved by the regulatory body, for uncontrolled disposal, use or discharge.
Very low level waste (VLLW)	Waste that does not necessarily meet the criteria of EW, but that does not need a high level of containment and isolation and, therefore, is suitable for disposal in near surface landfill type facilities with limited regulatory control.
Low level waste (LLW)	Waste that is above clearance levels, but with limited amounts of long lived radionuclides. Such waste requires robust isolation and containment for periods of up to a few hundred years and is suitable for disposal in engineered near surface facilities.
Intermediate level waste (ILW)	Waste that, because of its content, particularly of long lived radionuclides, requires a greater degree of containment and isolation than that provided by near surface disposal. However, ILW needs no provision, or only limited provision, for heat dissipation during its storage and disposal.
High level waste (HLW)	Waste with levels of activity concentration high enough to generate significant quantities of heat by the radioactive decay process or waste with large amounts of long lived radionuclides that need to be considered in the design of a disposal facility for such waste.

The determination of the appropriate class for radioactive waste requires consideration of both the amount of activity and the half-lives of the radionuclides contained in the waste. This is illustrated conceptually in Fig. VIII-1, see also Ref. [9].

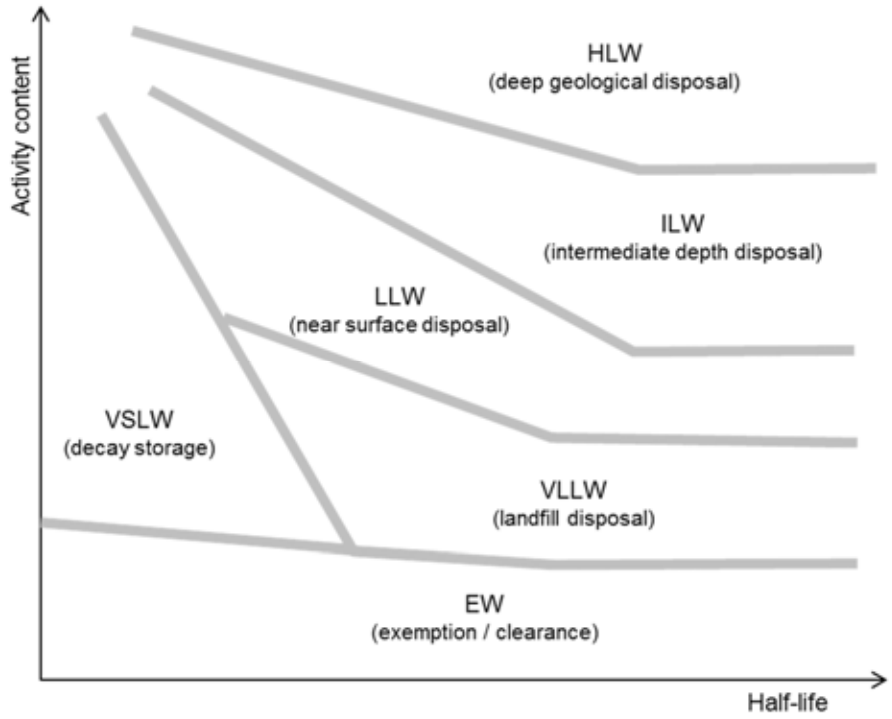


FIG. VIII-1: Conceptual illustration of radioactive waste classification.

VIII-1. GRADING OF REQUIREMENTS FOR RADIOACTIVE WASTE ACTIVITIES

The selection of the best disposal option for each class of waste can be considered as a graded application of controls to ensure long term safety.

For lower classifications, the extent of control required is minimal, with adequate safety being provided through administrative control measures.

For higher classifications, a greater degree of control will need to be applied to an increasing number of factors such as site selection, inventory control, cooling, containment and secure storage.

A reasonable degree of assurance can be given that institutional control measures to contribute to the safety of near surface disposal facilities for waste containing mainly short lived radionuclides can be kept in place over such time frames. Limitations placed on the activity (total activity, specific activity or activity concentration) of waste that can be disposed of in a given disposal facility will depend on the radiological, chemical, physical and biological properties of the waste and on the particular radionuclides it contains.

The degree of containment and isolation provided in the long term varies according to the waste class and the disposal option selected. The following options for management of radioactive waste are considered, with an increasing degree of containment and isolation in the long term:

— exemption or clearance;

— storage for decay;

— disposal in engineered surface landfill type facilities;

— disposal in engineered facilities such as trenches, vaults or shallow boreholes, at the surface or at depths down to a few tens of metres;

— disposal in engineered facilities at intermediate depths between a few tens of metres and several hundred metres (including existing caverns) and disposal in boreholes of small diameter;

— disposal in engineered facilities located in deep stable geological formations at depths of a few hundred metres or more.

ANNEX IX: EXAMPLE OF GRADING OF THE MANAGEMENT SYSTEM REQUIREMENTS TO THE SAFE TRANSPORT OF RADIOACTIVE MATERIAL

IX-1. INTRODUCTION

Organizations involved in the design and manufacture of transport packages typically use a component based graded approach and qualitative expressions of risk based on the safety consequences of failure of the packaging component.

IX-2. A GRADING APPROACH

Steps in the grading approach are:

1) identify the package type according to applicable transport regulations;
2) classify the package by developing a list of the packaging components and software used in the design, fabrication, use, inspection or testing and assign a quality grade to each (Table IX-1);
3) specify the management controls required and assign a quality grade to each (Table IX-2).

Many quality requirements are specified by applicable codes or standards for design, fabrication, inspection and testing that are determined as a result of grading during the initial stages of the package design. These codes, for example, can impose controls on the procurement, receipt, storage and use of the package materials.

Quality codes and standards can vary between different components of a single package type and between similar components of packages of different types. The package materials can, for example, include bulk material such as metal plate, sheet, castings, weld metal and forgings. Items fabricated by sub-tier suppliers (e.g. seals, bolts, pressure relief valves, rupture discs and closure assemblies) can also be included. Typically, traceability of material, control of chemical and physical properties of materials and segregation of non-conforming materials are used to ensure proper fabrication. Where applicable, sub-tier suppliers can be required to control the quality of component materials used.

Fabrication requirements can vary between different components of a single type of container and between similar components of containers of different categories, according to the materials used in the construction. For example, welds that attach or join components should be assigned the same quality grade as the higher level component unless a lower grade can be justified. Welds that join a component (e.g. a longitudinal seam weld for a cylinder) should be assigned the same quality grade as the component of which they are part. Many requirements for fabrication processes (e.g. welding and hear treatment) are specified in applicable codes. However, for some “special” processes (e.g. the pouring of gamma shielding material) no specific code exists and approved procedures are needed to control the task. Such procedures should be qualified to ensure their conformity to requirements.

Where manufacturers do not have an approved management system for Grade 1 component materials such as foam, honeycomb or wood (used in impact limiters), concrete or lead (used in shielding) and polymers (used in seals), the suppliers of packaging can use the manufacturer’s management system to control the procurement of Grade 1 components. This

places responsibility on designers to specify the properties and characteristics of materials, and on the manufacturers to comply with these specifications.

TABLE IX-1. EXAMPLES OF QUALITY GRADE BASED ON CONSEQUENCES OF FAILURE

Quality grade	Safety classification	Consequences of failure
Grade 1	Safety class – critical to safe operation	Grade 1 items are those directly affecting package leak tightness or shielding, or, for packages of fissile material, those directly affecting geometry and thus control of criticality. Examples include the primary and secondary containment vessels, outer and inner O-rings on the vessels and lead shield, as well as software used in their design, fabrication, use, inspection or testing.
Grade 2	Safety significant – major impact on safety	Grade 2 items are systems, structures or components whose failure could indirectly affect safety in combination with a secondary event or failure. Examples include impact absorbers that provide impact protection between the primary and secondary containment systems during an accident, and software used in their design, fabrication, use, inspection or testing.
Grade 3	Production support – minor impact on safety	Grade 3 items are those systems, structures or components whose malfunction would not affect the effectiveness of the packaging and so would be unlikely to affect safety. Examples include devices that provide evidence of tampering, such as secure locks and seals and package identification plates.

Note: Items whose failure does not impact on the safety or quality of the packaging does not need to be included in the grading system. An example of such a non-graded item is software that facilitates routine operation, handling or use of the package or packaging.

TABLE IX-2. GRADED MANAGEMENT CONTROLS

Graded management controls	Quality Grades		
	Grade 1	Grade 2	Grade 3
The design is based on the most stringent industry codes or standards, and the design verification is accomplished by prototype testing or formal design review	X		
The suppliers and sub-tier suppliers have a management system based on applicable criteria established in an acceptable national or international standard.	X		
The manufacturing planning specifies complete traceability of raw materials and the used of certified welders and processes.	X		
The procurement documentation for materials for services specifies that only suppliers from qualified vendor lists are used.	X	X	
A comprehensive programme for specifying commercial grade items and controlling counterfeit parts is required.	X	X	
Verification planning (inspection and testing) requires the use of qualified inspectors (i.e. individuals performing non-destructive examinations such as radiography and ultrasonic testing are qualified in accordance with recommended practices described in appropriate national or international standards).	X	X	
Only qualified auditors and lead auditors perform audits	X	X	
Comprehensive design, fabrication and assembly records, results reviews, inspections, tests and audits, results of the monitoring of work performance and materials analyses, and results of maintenance, modifications and repair activities are maintained.	X	X	
The design is based on the most stringent industry codes and standards, but design verification can be achieved by the use of calculations or computer codes.		X	
The manufacturing planning need not require traceability of materials, and only specified welds are done by qualified welders.		X	

TABLE IX-2. GRADED MANAGEMENT CONTROLS (cont.)

Graded management controls	**Quality Grades**		
	Grade 1	**Grade 2**	**Grade 3**
Only the lead auditor need meet certain qualification requirements.		X	
Verification activities still require the use of independent inspectors qualified to appropriate codes, standards or other industry specifications.		X	X
The procurement of materials need not be from a qualified vendor list.			X
Items are purchased from a catalogue of 'off the shelf' items			X
When the item is received, he material is identified and checked for damage.			X
Self-assessments rather than independent assessment are the primary method of assessing and verifying performance.			X
Records are maintained in temporary files for a specific retention period (e.g. six months) after shipment.			X

IX-3. RELATIONSHIP OF GRADING TO PACKAGE TYPE

The level of management control applied to a package is required to be commensurate with the hazard posed by the radioactive contents. The following guidance is applicable to each category of package listed, but is not intended to cover all situations. However, it gives a general indication of the degree to which the management system requirements are to be applied. A higher quality grade than that suggested can be used.

TABLE IX-3. QUALITY GRADES APPLIED TO WASTE PACKAGES

Activity	Quality grades		
	Grade 1	**Grade 2**	**Grade 3**
Excepted packages and industrial packaged Type 1 (IP-1)			
Instrumentation and processes used in the determination of the radioactive contents and package radiation levels.	X		
All other aspects, such as design, manufacture, etc.			X
Non-fissile Type A packages and industrial packages Type 2 (IP-2) and Type 3 (IP-3)			
Matters affecting shielding integrity and containment.	X		
All other matters except where there is minimal effect on safety.		X	
Other matters where there is minimal effect on safety.			X
Special form radioactive material			
All matters affecting compliance with the requirements for special form radioactive material.	X		
Fissile packages (other than Type B packages)			
Criticality assessment and other factors affecting the assumptions in criticality assessment.	X		
Other aspects except where there is minimal effect on safety.		X	
Other aspects where there is minimal effect on safety.			X
Type B packages (non-fissile and fissile)			
All aspects contributing to the integrity of shielding, containment and criticality safety.	X		
Other aspects except where there is minimal effect on safety.		X	
Other aspects where there is minimal effect on safety.			X
Shipments and special arrangements			
Management system requirements are applied according to individual features	X	X	X

ANNEX X: EXAMPLE OF GRADING IN THE APPLICATION OF MANAGEMENT SYSTEM REQUIREMENTS TO RADIATION PROTECTION

Requirement 6 in [15] requires a graded approach to the application of the international basic safety standards for radiation protection in planned exposure situations which is commensurate with the characteristics of the practice or the source within a practice, and with the magnitude and likelihood of the exposures. Ref. [15] gives the definition of graded approach as:

Graded approach

For a system of *control*, such as a regulatory system or a *safety system*, a *process* or method in which the stringency of the *control* measures and conditions to be applied is commensurate, to the extent practicable, with the likelihood and possible consequences of, and the level of *risk* associated with, a loss of *control*.

This annex gives examples of a graded approach to the application of management system requirements to radiation protection. The information in this annex is derived from Ref [10]. Examples of the factors to be considered as part of grading are identified. The management system requirements are primarily related to control of working environment, planning, human resources and monitoring and measuring.

The following tables provide examples of a graded approach in the application of the requirements to radiation protection.

TABLE X-1. CLASSIFICATION OF WORKING AREAS AND ACCESS CONTROL

Requirement	Example of graded approach
Designate controlled areas	Controlled areas should be designated according to the safety significance of tasks to be performed. An example of area classification is given in Table VI-1.
Delineate controlled areas	Demarcation of controlled areas should use structural barriers for areas of high safety significance. For areas of low safety significance, warning signs may be sufficient.
Control access	Access to a controlled area should be restricted by way of a limited number of checkpoints in order to limit the spread of any contamination and to facilitate control at any time of exposure and occupancy. Procedures should be established for control of access to a controlled area or to a particular zone. These should include an authorization to enter, together with instructions on the use of monitoring devices, the wearing of specified protective clothing and equipment, and time limits for remaining on the premises.
Authorize personnel	Persons who enter controlled areas should be authorized in accordance with administrative procedures having received training appropriate to the nature of the radiation hazard. The validity of the authorization can be limited by time or according to the nature of the area. Unauthorized persons can be granted permission to enter controlled areas provided that they comply with a written system of work procedures and are accompanied at all times by an authorized escort.

TABLE X-2. CLASSIFICATION OF ZONES IN A CONTROLLED AREA FOR NUCLEAR POWER PLANTS

Zone	Description
Radiation zones	
R1	Access is normally prohibited because of high levels of radiation or contamination, but may be permitted under certain conditions (such as reactor shutdown) as specified in the operating procedures.
R2	Compliance with the applicable dose limit for external exposure can be ensured only by restricting working time.
R3	All other areas within the controlled area.
Contamination zone	Special protective measures are necessary, owing to actual or potential air contamination or loose surface contamination in excess of a specified level. Subdivisions may be considered on the basis of the levels of precautions necessary in different areas of this zone.

TABLE X-3. LOCAL RULES AND SUPERVISION OF WORK

Requirement	Example of graded approach
Local rules	The local rules should include: (a) a specification and location for each controlled area; (b) procedures for access to and exit from controlled areas; (c) procedures for ensuring adequate levels of protection and safety for radiation workers and other persons (including visitors and workers who are not radiation workers); (d) the values of any relevant investigation level or authorization level and the procedures to be followed if the level is exceeded; (e) designation of persons who are responsible for supervising work within controlled areas; (f) emergency procedures for each controlled area.
Supervision	Persons supervising work should be trained in applicable requirements for radiation protection and be able to apply the local rules to the work they supervise.

TABLE X-4. MONITORING THE WORKPLACE AND INDIVIDUALS

Requirement	Example of graded approach
Types of monitoring	Three types of monitoring of the workplace should be conducted. (a) routine monitoring - to demonstrate that the working environment is satisfactory for continued operations; (b) task related monitoring - to provide information about a particular task or operation and to provide, if necessary, a basis for immediate decisions on the execution of the task; (c) special monitoring - normally undertaken at the commissioning stage for new facilities, following major modifications to either facilities or procedures, or when operations are being carried out under abnormal circumstances such as those following an incident or an accident.
Investigation levels for individual doses	Investigation levels for workplace monitoring should be set on the basis of the expected levels of dose rate and contamination and operational experience. The purpose of, and the actions associated with, each investigation level should be clearly defined in advance.
Monitoring instruments and calibration	The instruments used should cover measuring ranges that extend from below any applicable reference level up to radiation levels anticipated to prevail under accident conditions. All radiation monitors and contamination monitors, both permanently installed and hand held, as well as personal dosimetry systems, should be periodically calibrated, tested and maintained.

TABLE X-4. MONITORING THE WORKPLACE AND INDIVIDUALS (cont.)

Requirement	Example of graded approach
Monitoring the workplace	Monitoring should be performed by means of an appropriate combination of fixed monitors for radiation and air contamination and through periodic monitoring and sampling by trained personnel. The selection of location for the monitors and the frequency of sampling should reflect the nature of the prevailing radiation conditions.
Monitoring individuals	Individual monitoring should be undertaken where appropriate, adequate and feasible for any worker who is normally employed in a controlled area, or who occasionally works in a controlled area and may receive significant occupational exposure. The nature, frequency and precision of individual monitoring should be determined following consideration of the magnitude and possible fluctuations of exposure levels and the likelihood and magnitude of potential exposure. Persons who work under conditions in which internal exposures may occur should be appropriately monitored. When it is known or suspected that an external exposure of an individual will be significantly non-uniform, additional dosimeters should be worn on the parts of the body concerned, if appropriate, particularly the hands. Consideration should be given to making accurate estimates of dose when individuals are not provided with individual dosimeters.

TABLE X-5. WORK PLANNING AND WORK PERMITS

Requirement	Example of graded approach
Planning	Work to be undertaken in controlled areas should be planned to keep doses as low as reasonably achievable. The following should be considered. (a) information on similar work completed previously; (b) the intended starting time, the expected duration and the personnel resources necessary; (c) the plant's operational state; (d) other activities in the same area or in a remote area of the plant that may interfere with the work or may require the work to be conducted in a particular manner; (e) the need for preparation for and assistance in operations (such as isolation of the process, construction of scaffolding or insulation work); (f) the need for protective clothing and a listing of tools to be used; (g) communication procedures for ensuring supervisory control and co-ordination; (h) the handling of waste arising; (i) requirements and recommendations for industrial safety in general.
	The planning should ensure that personnel, tools, equipment, instructions and materials are available when needed. A check for completeness should be carried out before the work is started.
Work permits	A radiation work permit (RWP) should be prepared for tasks necessitating radiological precautions. Information and instructions to be considered as part of the grading and to be provided in the RWP could include for instance: (a) details of average dose rates and possible areas of elevated activity in the working area on the basis of a survey made prior to the work or otherwise estimated; (b) estimates of contamination levels and how they might change in the course of the work; (c) additional dosimeters to be used by the workers; (d) protective equipment to be used in different phases of the work; (e) possible restrictions on working time and doses; (f) instructions on when to contact members of the radiation protection group.

TABLE X-6. PROTECTIVE CLOTHING AND PROTECTIVE EQUIPMENT

Requirement	Example of graded approach
Protective clothing	The type and nature of protective clothing should be selected after consideration of the prevailing radiation conditions and working environment. Gloves should be selected to provide appropriate protection whilst not adversely affecting manual operations. For certain tasks additional coveralls can be required over normal coveralls. Waterproof boots should be used when there is the possibility of a wet floor. For physically demanding work or as protection from tritium hazards, stronger plastic suits, ventilated if necessary, can be required. The suit may be pressurized by means of a supply of breathing quality air from a compressor or from pressurized air bottles. The type of protective equipment selected should not prolong the working time and thus increase the external dose received during the work.
Respirators	In areas where airborne contamination or loose surface contamination is present or may be produced during work, use of respiratory protective equipment should be considered. Respiratory protective equipment should protect against the specific radionuclides of concern.
Changing areas	As changing areas are intended to prevent the spread of contamination by means of partition into a clean side and a potentially contaminated side, their design should accommodate the type of protective clothing and protective equipment being used.
Other equipment	Other types of special equipment can be required for reducing doses. Examples include portable shields, portable ventilation equipment with filters for local exhaust, remote handling tools, special monitoring and communication equipment, special temporary containers for solid radioactive waste, and containers for radioactive liquids.
Training	All persons working in, or supervising work in, controlled areas should be trained and qualified in the use of protective clothing and special protective equipment, as appropriate. Those persons handling, issuing or decontaminating protective clothing and respiratory protective equipment should also be appropriately instructed. The nature and extent of the training will be dependent on the prevailing radiation conditions and the clothing and equipment being used.

ANNEX XI: EXAMPLE OF GRADING OF EVENT REPORTS

XI-1. INTRODUCTION

The facility prepares Event Investigation Reports [16] to allow taking adequate corrective actions based on the event analysis results and learning lessons and provides them to other plants. The events and activities related to their investigation and report development are characterized and classified.

XI–2. CLASSIFICATION AND GRADING OF EVENT INVESTIGATION REPORTS

This classification provides a starting point for the grading of activities associated with:

- Identification of event causes;
- Identification and evaluation of quantitative characteristics of events and conditions which may lead to accidents;
- Analysis of event consequences;
- Identification of adverse trends or conditions related to safety;
- Evaluation of adequacy of corrective actions aimed at resolution of safety challenges;
- Prevention from event recurrence;
- Identification of problems associated with human factor, etc.

XI-3. CLASSES OF EVENT REPORTS

The classes of event reports are summarized as follows:

- **First quality grade**
  Reports for events associated with improper work performance that resulted in severe radioactive releases and accidents that requires reporting to the regulatory body.

- **Second quality grade**
  Reports for events associated with improper work performance that resulted in non-compliance with the requirements set, serious radiological risk, serious injuries of people and economic damage that requires reporting to the regulatory body.

- **Third quality grade**
  Reports for events associated with improper work performance that resulted in minor economic damage and risk of radiological hazard.

- **Fourth quality grade**
  Reports for events associated with improper work performance not included in the first three quality grades and not influencing the reliability and safety of the plant, personnel, population and environment.

XI-4. GRADING OF REQUIREMENTS FOR REPORTS ASSOCIATED WITH EVENTS

The Report for significant event is developed for the first and second quality grade. The Low Level Event Reports are made for the third and fourth quality grade. According to their content and format the Event Reports are divided into:

— **Preliminary Report** (sometimes it is called Early Notification Report). As a rule this type of a report is developed by the plant immediately after an event and then submitted to the concerned organizations (operating organization and regulatory authority). The Report should include brief description of the event and its consequences.
— **Safety Significant Event Report**. This type of report should be as comprehensive as possible and should be set in an orderly and consistent manner. The Report should include the following:

  - Basic information. This should include such items as the type of event, the date of occurrence, identification of the plant (name, site), and the plant type.
  - Narrative description. The narrative description should explain exactly what happened and what was discovered in the event.
  - The safety assessment. It should be focused on the safety consequences and implications of the event.
  - Causes. The direct causes, root causes and causal factors of the event should be clearly described.
  - Corrective actions. Corrective actions taken or planned owing to equipment failures or human errors should be reported.
  - Lessons learned. The report should clearly identify learning points.
  - Graphic information for a better understanding of the event. The report should provide supporting information, such as: diagrams, data printouts, plots of the changes in the equipment parameters, etc.

— **Low Level Event Report**. This type of a report as a rule includes name of the event, overview of the performed analysis, causes and consequences, suggested corrective actions.

Reports of different quality grades require different levels of control and record keeping.

The reports of the first and second quality grades are drawn up in a specified format, the preparation dates and responsible people are clearly defined. People responsible both for control of preparation and for reports dissemination, accounting and keeping are assigned and defined by a procedure. As a rule, these reports are kept in a special place till the end of the plant service life.

Reports of the third and fourth quality grades are prepared in a specified format within established dates. People responsible for control of report preparation are assigned at the plant level. These reports are kept in the plant subdivisions. The plant itself establishes the dates of keeping these reports. Practically this period is from 3 to 5 years.

There are no special requirements for keeping and dissemination of these reports based on their lower significance.

ANNEX XII: EXAMPLE OF A PROCEDURE FOR ASSIGNING QUALITY CLASSES

XI1-1. INTRODUCTION

This Annex provides an example of a procedure used by an organization to assign quality classes.

The quality classes apply to SSC necessary for the project operation or for supporting its operation, whether safety related or non-safety related.

The quality classes provide a basis upon which a grade approach is used to implement the quality programme requirements.

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Contents

Terms and Definitions

Term	Definition	Acronym
Contract	The Contract can be: • the supply or service Contract as result of a procurement, or • the Grant Agreement	---
IO or ITER	The ITER International Fusion Energy Organisation.	IO
NDE	Non Destructive Examination	NDE
NSR	Non-Safety Related	NSR
QA	Quality Assurance	QA
QAO	Quality Assurance Officer	QAO
SIC	Safety Important Class (as defined in the Quality Order – 10 August 1984)	SIC
Supplier	The Supplier is either: - the contractor as defined in the supply or service contract, or - the beneficiary as defined in the grant agreement. The supply-chain follows the scheme below Supplier -> Organization (F4E) -> Customer (e.g. IO)	---
SSC	Structures, Systems and Components	SSC
SR	Safety related	SR
Safety Related Activity	The importance for safety of an activity is appreciated on the basis of direct or potential consequences for safety in case on inappropriate exercise of the activity	SRA

Reference Documents

[1] F4E-QA-115 – Supplier Quality Requirements (F4E_D_22F8BJ)

[2] F4E-QA-100 – Quality Graded Application (F4E_D_22EPT2)

[3] F4E-QA-013 – Safety Arrangements Follow-Up (F4E_D_23CA9U)

[4] ITER Quality Classification Determination (ITER_D_24VQES)

1. Purpose

A Quality classification is introduced to provide a basis upon which a grade approach is used to implement the Quality Program requirements.
This document defines the quality classes and specifies the procedure for assigning quality classes.

2. Scope

Classification applies to Structures, Systems and Components (SSC) necessary for the Project operation or for supporting its operation, safety related or non-safety related.

3. Definition of Classes

3.1 Defining Quality Classes is a function of the Project Structures, Systems and Components end use as items classified by the project as Nuclear Safety Important (SIC), Safety Related (SR) or Non-Safety Related (NSR) but affecting the performance, cost or reliability of the Project facility.

3.2 They are defined on the basis of:

- Safety Importance Class assigned to the item,
- Anticipated impact of item failure or malfunction on Machine availability,
- Maturity and complexity related to a risk of failure or malfunction.

3.3 Safety Important Class (SIC) is classified in two categories:

SIC-1	Those SIC components required to bring to and to maintain the Project in a safe state.
SIC-2	Those SIC components used to prevent, detect or mitigate incidents or accidents, but not required for the project to reach a safe state.

3.4 Items may belong to one of four (4) quality classes, defined as follows:

Class	Criteria
1	Any SIC-1 Item OR any item (SIC-2, SR, NSR) whose failure/malfunction could result in LARGE impact
2	Any safety important class 2 Item (SIC-2), safety related Item (SR) or non-safety related item (NSR) whose failure could result in ADVERSE impact.
3	Any safety related Item (SR) or non-safety related item (NSR) whose failure could result in MODERATE impact
4	Commercial Grade or Proprietary Items that are purchased using a manufacturer's catalogues or other commercially available documentation without the need to provide an engineering specification (even if initially assessed as QC 1, 2 or 3). Modified commercial or proprietary items shall conform to QA-115 – Supplier Quality Requirements. No specific Quality Plan required. A minimum of a Certificate of Conformity (CoC) is required on delivery.

3.5 Factors to be considered when assessing potential downtime duration would include:

- ease of replacement/repair,
- ease of fault/malfunction detection,
- ease of identification of defective part,
- availability of spare part,
- availability of qualified personnel.

3.6 Factors to be considered when assessing the risk of failure or malfunction would include:

- degree of design innovation,
- complexity or uniqueness of the item,
- design, performance and manufacturing margins,
- involvement of innovative processes,
- need for special controls and surveillance over processes and equipment,
- involvement of processes which cannot be fully verified by inspection or test,
- degree to which functional compliance can be demonstrated by inspection or test,
- quality history and degree of standardization of the item.

4. Responsibilities

4.1. (Technical) Project Officers are required to indicate the classes relevant to the items placed under their technical responsibility.

4.2. The selection of quality classes and the grading of the QA requirements shall be in accordance with tables 1 and 2.

4.3. Rationale and adequacy of the assigned class shall be reviewed as part of the item design review and recorded properly by Technical Project Officers.

5. Determining Quality Class and Requirement

5.1. Preparation:

i. Define plan/develop activity scope of work to a sufficient level of detail so that quality requirements can be identified.

ii. Identify any specified regulatory requirements.

iii. Decide whether the activity will be used in or to support Project structures, systems, or components (SSC).

iv. Request assistance from a QAO if you have any questions on preparations.

5.2. Determine Quality Class:

If the activity will be used in or to support Project Structures, Systems, Components, determine Quality Class in accordance with tables 1 and 2.

i. Technical Project Officers responsible for the SSC are responsible for making the Class determination

ii. QAO assist in the determination as appropriate so that quality class is assigned to individual parts and the item/activity does not receive a “blanket assignment” of one quality class.

iii. For ITER tasks, in case of conflict between this classification and the ITER classification (ITER Quality Classification Determination ITER_D_24VQES), the ITER Quality Classification will prevail. Define plan/develop activity scope of work to a sufficient level of detail so that quality requirements can be identified.

5.3. Determine Quality Requirements:

i. The application of the Quality Requirements shall follow the indications of table 2 and the graded application described in FE-QA-100. Define plan/develop activity scope of work to a sufficient level of detail so that quality requirements can be identified.

Table 1. Determination of quality class

	QA Graded Quality Levels		
Risk Type	**Class 1** SIC-1 / SIC-2 / SR / NSR **Large Impact**	**Class 2** SIC-2 / SR / NSR **Adverse Impact**	**Class 3** SR / NSR **Moderate**
Functional	Failure has Potential for a loss of Plasma operations for more than 3 weeks.	Failure has Potential for loss of plasma operations for less than 3 weeks OR a loss of data essential for machine operation	Failure has No potential for loss of plasma operation OR loss of data essential for machine operation
Environment, safety, and health	Failure has potential for: (1) a death or total disability or severe adverse impact on the health or safety of a worker or the public, OR (2) environmental damage that could exceed regulatory limits or involve significant clean-up costs.	Failure has potential for: (1) injury or illness requiring hospitalization, temporary or partial disability, OR (2) moderately adverse impact on the environment or health or safety of a worker or the public.	Failure has potential for: (1) minimal impact on the health and safety of the public or a worker, such as injury or illness requiring minor supportive treatment but not requiring hospitalization, OR (2) a negligible impact on the environment.
Compliance	Failure has potential for non-compliance with state, federal or international laws, regulations or requirements	Failure has potential for non-compliance with established management practices and procedures (F4E or Customers).	Failure has potential for minor non-compliance with established management practices.
Cost/ Schedule Impacts	---	Failure has potential for: (1) a financial loss of 500K Euro or more OR (2) major Impact of Project construction schedule	Failure has potential for a financial loss less than 500K Euros.

Class 4: for items whose failure has no safety, operational, cost or schedule impact
No QA Program applicability or specific quality requirements.

Note: Permanent lifting attachments shall be designated as Class 1 items

Table 2. Actions appropriate to quality class

Quality Classification[(a)]	Class 1	Class 2		Class 3	
Safety Class	SIC-1 / SIC-2 / SR / NSR	SIC-2	SR / NSR	SR	NSR
Design	Design controls including design reviews and *independent* [b] verifications		Design controls including design reviews and verifications		No design review required, unless otherwise agreed between the parties
Software	Acceptance of Software used for Design and Operation, including life cycle management		Identify and validate software usage		No requirement, unless otherwise agreed
Minimum Documents and Records to be delivered	Quality Plans, Control Plans (MIP), Procedures, calculation note (where design is involved), working instructions, Special Process Qualifications (if applicable), Operator Qualifications, 'As Built drawings', Release Note, Certificate of Conformity. Material certification and inspection documents according to EN 10204 Type 3.1 (or equivalent) traceable to the component part and equipment.		Quality Plans, Control Plans (MIP), Release Note, 'As Built drawings', material certification and inspection documents acc. to EN 10204 Type 3.1 (or equivalent) traceable to the component part/equipment.		Quality Plans, Control Plans, Certificate of Conformity according to EN 10204 Type 2.1 (or equivalent)
Monitoring of performers	Audit of performers including qualification and surveillance		Limited on-site reviews		No Monitoring, unless otherwise agreed between the parties
Measurements and test equipment	Controlled measuring and test equipment (M&TE)				Controlled M&TE for validation processes
Minimum NDE (on welding) [(c-d)]	100% visual, surface and volumetric inspection and testing as *appropriate* [c]	100%visual, surface and 20% volumetric inspection and testing as *appropriate* [c]		100%visual, surface and 10% volumetric inspection and testing as *appropriate* [c]	
Special processes Personnel Qualifications and Training (i.e. welding, brazing, N.D.E.)	Documented personnel qualifications and training				
QA requirements	QA representative approvals of documents related to special processes and inspections are required		QA representative consultations on special processes and inspections are required		QA consultations on as-needed basis
Safety Related Activities (SRA) [3]	For SIC (1 and 2): Assessment, Surveillance and Follow-up of the SRA		Limited Monitoring		No Monitoring, unless otherwise agreed between the parties

[a] To determine the grade and subsequent actions for an item or activity, first locate the appropriate risks on the matrix in Table 1. Example: Selection of any one of the four risk types in class 1 makes all the actions come from class 1.

[b] Independent means individual, groups, divisions, departments who were not involved in the original design. '*Independent'* can also mean a Third Party organization.
"The verification will take place in the course of examinations carried out by persons who did not participate directly in the performance of the study in question"
"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"

[c] On welding where the required volumetric inspection is not practicable, reference shall be made to the specific inspection and testing requirements of the applicable Technical Specifications

[d:] Permanent lifting attachments if welded must be 100% inspected using NDE before and after lifts

ANNEX XIII: EXAMPLE OF A PROCEDURE FOR ASSIGNING QUALITY CLASSES

XIII-1. INTRODUCTION

This Annex provides an example of a procedure used by an organization to provide guidelines for assigning the quality assurance category of systems, sub-systems, assemblies and parts.

These quality assurance categories are used to identify the most critical items to ensure that a correct level of Quality Assurance is assigned to every item.

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Quality Assurance Definition

QUALITY ASSURANCE CATEGORIES

Abstract

This document provides guidelines for assigning the Quality Assurance Category of the LHC systems, sub-systems, assemblies and parts. Quality Assurance Categories are used to identify the most critical items of the LHC and to ensure that a correct level of Quality Assurance is assigned to every item.

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History of Changes

Rev. No.	Date	Pages	Description of Changes
0.1	1998-03-11		1st draft
0.2	1998-03-18		Update following QAPWG meeting
0.2	1998-06-18		Reviewed by QAPWG- Approved by PLO Deputy for QA.
1.0	1998-06-25		Released

Table of Contents

1. PURPOSE

To provide guidelines for assigning the Quality Assurance Category of the LHC systems, sub-systems, assemblies and parts.

- To ensure a correct level of Quality Assurance and Quality Control for each item.
- To identify the most critical items of the LHC.

2. SCOPE

This procedure is applicable to:

- All LHC systems, sub-systems, assemblies and parts.
- The complete life cycle of the Project, from design up to commissioning and operation.
- All Institutes, Contractors and Suppliers involved in the LHC Project.

3. POLICY

A graded approach to Quality Assurance is used to place the most emphasis and allocate adequate resources to those items of the LHC that would have the most detrimental effect on safety, performance, cost and schedule in case of failure.

This is achieved by assigning, at the design stage, a QA category to all the LHC hardware items. This category is then used to assign the correct level of Quality Assurance at each stage of the life-cycle of the items.

4. RESPONSIBILITIES

At the basic design stage of all LHC systems, sub-systems, assemblies and parts the Project Engineer (PE) in charge of the item shall determine the appropriate QAC for the item.

The Division or Group Leader responsible for the system, sub-system, or assembly to which the item belongs has the ultimate responsibility to approve the proposed QAC.

The LHC Project Management has the overall responsibility to review and approve the QAC designations.

5. GUIDELINES

The QAC of an item is determined by evaluating the consequences of the item's failure in terms of:

- The financial loss incurred by the redesign and/or replacement of the failed item
- The LHC unscheduled downtime brought about by the failed item.

In the case of a failure occurring before the item is in operation and causing a delay in the LHC construction schedule, this delay shall be considered as LHC downtime.

Quality Assurance Categories based on the preceding criteria are indicated in table 1.

Category	Impact of failure	Financial loss	LHC unscheduled downtime
A	Catastrophic	Over 2 MCHF	1 week or more
B	Significant	Over 200 kCHF and less than 2 MCHF	Less than 1 week
- (none)	Minor	Less than 200 kCHF	No immediate incidence on operation

Table 1: Quality Assurance Categories

When assigning the QAC of an item, the following guidelines shall be followed:

- The selection of the QAC is based either on the cost of replacement of an item or on the consequences of its unavailability or malfunction for the operation of the LHC.
- When using table 1, only one of the criteria has to be met to assign the QAC.
- QAC need not be assigned to items such as tooling, transport and measuring equipment etc., which are not essential to the LHC operation.
- The impact of failure shall be assessed independently for each item of a system, sub-system, or assembly. This means that the QAC of a lower level item can be less significant than the QAC of the upper level item it belongs to. For example, a part or a sub-assembly can be in category B even though the assembly it belongs to is in category A.
- QAC should be specified as early as possible in the design process [1], and in any case before drawing production starts.
- The QAC is written in the item's drawing title block [2], and it determines the review and approval process of the drawing.
- QAC are used to determine the Quality Assurance activities applicable to the item during manufacturing, assembly, installation and commissioning.

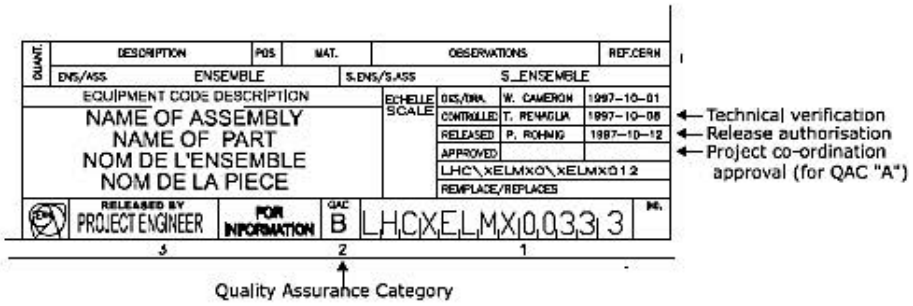

Figure 1: Location of QAC in drawing's title block

6. RELATED DOCUMENTATION

[1] LHC-PM-QA-307.00	Design Process and Control
[2] LHC-PM-QA-402.00	Design Standards - Mechanical Engineering and Installations

LIST OF ABBREVIATIONS

EW	exempt waste
FMEA	failure mode effects analysis
HLW	high level waste
ILW	intermediate level waste
IP	industrial packaged
LLW	low level waste
MMIC	man machine interface control
MS	management system
OLC	operational limits and conditions
OPEX	operating experience
PWR	pressurized water reactor
QA	quality assurance
QC	quality control
RPN	risk priority number
RWP	radiation work permit
SSCs	structures systems and component
TQR	total quality rating
VLLW	very low level waste
VSLW	very short lived waste

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