IAEA TECDOC SERIES

IAEA-TECDOC-1910

Quality Assurance and Quality Control in Nuclear Facilities and Activities

Good Practices and Lessons Learned

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QUALITY ASSURANCE AND QUALITY CONTROL IN NUCLEAR FACILITIES AND ACTIVITIES

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IAEA-TECDOC-1910

QUALITY ASSURANCE AND QUALITY CONTROL IN NUCLEAR FACILITIES AND ACTIVITIES

GOOD PRACTICES AND LESSONS LEARNED

INTERNATIONAL ATOMIC ENERGY AGENCY
VIENNA, 2020

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Printed by the IAEA in Austria
May 2020

IAEA Library Cataloguing in Publication Data

Names: International Atomic Energy Agency.
Title: Quality assurance and quality control in nuclear facilities and activities / International Atomic Energy Agency.
Description: Vienna : International Atomic Energy Agency, 2020. | Series: IAEA TECDOC series, ISSN 1011–4289 ; no. 1910 | Includes bibliographical references.
Identifiers: IAEAL 20-01314 | ISBN 978–92–0–107020–3 (paperback : alk. paper) | ISBN 978–92–0–107120–0 (pdf)
Subjects: LCSH: Nuclear facilities. | Quality assurance. | Quality control.

FOREWORD

The management of quality has long been recognized as important to achieving safety and other objectives of nuclear facilities and activities. Quality assurance and quality control activities generally take place as part of a nuclear facility's management system or quality assurance programme. However, requirements for quality assurance and quality control have become less explicit in more recent editions of some management system standards. Participants in the Technical Meeting on Quality Control and Quality Assurance and on Their Relationship with Management Systems, held in 2016, highlighted the potential value of a publication on these topics.

The IAEA has developed this publication, describing relevant practices and lessons, to provide information on the implementation of quality assurance and quality control as a part of the management system of nuclear facilities and activities. It is to be used in conjunction with the IAEA Safety Standards Series, IAEA Nuclear Energy Series and other appropriate publications. The expected audience of the publication is broad, ranging from managers to experts dealing with the quality of products and services on a day-to-day basis. Newcomers to the nuclear management and quality management fields will benefit the most from this material.

The IAEA wishes to acknowledge the contribution of D. Brown (United States of America), G. Watson (United Kingdom) and J. Kickhofel (United States of America) for their role in producing the final version. The IAEA officers responsible for this publication were P. Pyy and D. Jeon of the Division of Nuclear Power.

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1. INTRODUCTION

1.1. BACKGROUND

The successful implementation of quality assurance (QA) and quality control (QC) is essential to providing confidence in the nuclear industry. A high degree of reliability and integrity is required of products and services, and the requirements are particularly stringent for assuring nuclear safety. Failure of structures, systems or components to perform their intended function, or their poor performance, could adversely affect the health and safety of workers and the public. Hundreds of years' worth of safe operating performance by nuclear reactors have proven the value of quality assurance and quality control when properly executed.

Some management systems standards associated with the utilization of nuclear energy or generic activities no longer explicitly differentiate quality assurance and quality control activities from other processes necessary to achieve successful outcomes of an organization. Only a few nuclear quality standards are published. Consequently, the important role played by quality assurance and quality control is not always recognised, and particularly newcomer countries in the nuclear field, and persons coming to it from other industrial sectors, may only have experience with generic quality management standards.

The concept of quality as underpinning safety and reliability has a long history. Industrial failures, often causing significant destruction of plant and loss of life, have led to the introduction of national standard bodies such as the American Society of Mechanical Engineers (ASME), the British Standards Institution (BSI) and the Deutsches Institut für Normung (DIN).

Quality assurance developed mainly from the rapid increase of global military production in World War II. This continued into aeronautics, space and civil nuclear sectors and involved contemporary development of reliability engineering. The USA developed standards for its nuclear weapons programme in 1954 and then for naval propulsion reactors in 1964, which resulted in the development of commercial nuclear power standards ANSI N45.2[1] [1] in 1971 and ASME NQA-1 [2] in 1979.

The USA, UK and France also introduced and adopted quality assurance requirements for Nuclear Power Plants (NPPs) during the 1980s. Expansion into general product and service sectors came with BS 5750, Quality Systems [3], which was subsequently developed into the ISO 9000 series of quality management system standards in the 1970s and 1980s.

These developments and new approaches were necessary for the development of high-risk technologies, materials having very unusual properties, requirements for high precision, and guaranteed conformance to strict requirements on the edge of current technology in large production quantities. Products with these attributes were intended to possess a high reliability thorough planning, checking, verification, and oversight. To eliminate human error in product realization, multiple independent confirmations of every aspect were used. The final products had to perform reliably throughout designed lifetimes.

[1] This publication is superseded by ASME NQA-1

In 1978, the IAEA issued the Safety Series 50-C-QA, Quality Assurance for Nuclear Power Plants: A Code of Practice[2] [4]. Separate Guides[3] were published in the 1980s to support 50-C-QA (1978) [4]. They were all revised and incorporated into 50-C/SG-Q (1996)[4] [5], Quality Assurance for Safety in Nuclear Power Plants and Other Nuclear Installations: Code and Safety Guides Q1-Q14. IAEA GS-R-3, The Management System for Facilities and Activities[5] [6], was published in 2006. The safety guides GS-G-3.1 [7], GS-G-3.3 [8], GS-G-3.4 [9], GS-G-3.5 [10] and TS-G-1.4 [11] present more detailed guidance about how to achieve compliance with the overarching management system requirements.

GS-R-3 [6] was then superseded in June 2016 by the publication of GSR Part 2, Leadership and Management for Safety [12]. GSR Part 2 presents the framework for management of nuclear facilities and activities. Figure 1 depicts the evolution of the level on which quality requirements have been presented in the IAEA Safety Standards. They currently represent high level requirements for a nuclear facility or activity.

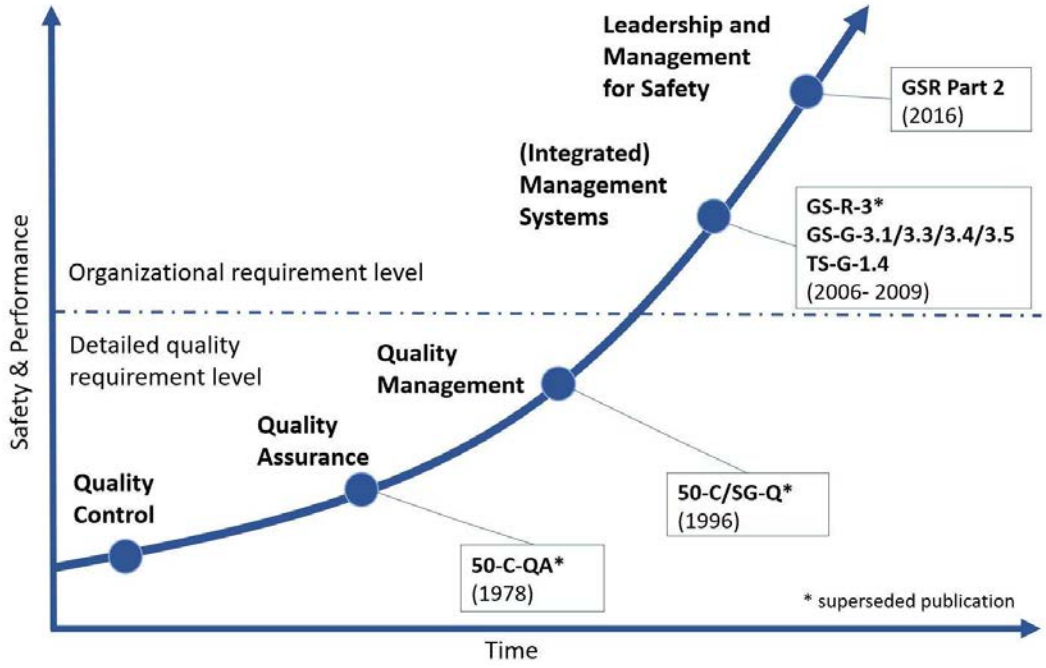

FIG. 1. Evolution of the IAEA approach to quality, leadership and management showing the organizational management system and detailed quality requirements levels.

The IAEA NE Series publication NG-T-1.3 Development and Implementation of a Process Based Management System [13] and TECDOC-1740, Approach in the Application of the Management System Requirements for Facilities and Activities [14] are further examples of guidance publications. These publications do not frequently use the terms quality management, quality assurance and quality control. However, understanding how these quality concepts apply to all processes of the management system is crucial. This becomes very clear in the procurement of products and services where the supply chain normally uses quality

[2] This publication is superseded by IAEA GSR Part 2
[3] These safety guides were numbered 50-SG-QA N, where N was a sequential number.
[4] This publication is superseded by IAEA GS-G-3.1 and GS-G-3.5
[5] This publication is superseded by IAEA GSR Part 2

management or quality assurance related standards. Recent concerns with the reducing number of traditional nuclear suppliers and increases in the number of counterfeit products or certificates have made quality aspects more and more important.

The current IAEA approach to quality as a part of a management system, manifested in the references [7, 10, 12–14], describe all required elements as policy, processes, procedures and instructions that affect people, technology and the organization. An overarching requirement for all processes, as defined in the same references, is to determine and apply the criteria and methods (including monitoring, measurements and related performance indicators) needed to ensure the effective and efficient operation and control of these processes. This can be seen to represent quality assurance and quality control thinking applied to the processes of a management system.

Quality is a key element of a management system as defined in requirement 6 of GSR Part 2 [12]. The importance of quality assurance has also been highlighted in some other recently published IAEA documents e.g. the Safety Guide GSG-13 [15].

1.2. OBJECTIVES

The objectives of this TECDOC are to provide clarification of what is meant by quality assurance and quality control as a part of management system of nuclear facilities and activities, to provide practical examples of these activities, and to offer good practices and lessons learned from quality assurance and quality control in countries building, operating, and maintaining nuclear power plants.

This information is intended to:

- Emphasize that quality assurance and quality control are essential and distinct activities that are particularly important to all activities of a management system;
- Help in ensuring the safe and economic operation of nuclear facilities by ensuring all the activities, deliverables and services are based on well-specified requirements and acceptance criteria;
- Provide a neutral technical basis for dialogue between government bodies, regulators, plant operators and suppliers when dealing with management system, quality assurance and quality control issues.

The focus of this publication is nuclear power plants, but the presented concepts are applicable to all nuclear facilities and activities.

1.3. SCOPE

This publication explains the basic concepts of quality assurance and quality control. It provides examples of good practices of their implementation as processes within nuclear facilities and describes how they are managed through interfaces with suppliers and subcontractors. This publication discusses the elements of a management system relevant for the quality assurance and quality control functions, such as the generation and retention of documented information, sometimes called records. It does not present details of any framework or suggest that one approach would fit all; rather, the idea is to present the spectrum of tools and approaches for a reader for his/her choice.

1.4. USERS

This publication is primarily intended for:

- Senior management, who determine the business objectives and management system policies but also need to understand the role quality assurance and quality control play in delivering those objectives and policies;
- Management and quality specialists who need to interpret the requirements of quality and management systems in nuclear power plants and manage those activities required to assure reliability, sustainability and safety;
- Regulatory bodies;
- Licensee personnel;
- Project management organizations;
- Technical support organizations;
- Manufacturers of products and suppliers of services;
- Newcomer Member States preparing to contract services (and items including the main plant contract); and
- New personnel in operating and expanding Member States with responsibilities for quality in nuclear facilities and activities.

1.5. STRUCTURE

This publication consists of four (4) Sections, eight (8) Appendices and four (4) Annexes.

Section 1 is an introduction to the contents of this publication. Section 2 explains the concept of quality as a part of management systems in the field of nuclear energy. Section 3 deals with quality assurance and quality control activities. Section 4 discusses briefly quality assurance and quality control in different nuclear power plant life cycle phases.

The Appendices provide detail on the various elements and differing aspects of quality assurance and quality control at the different stages in the life of a nuclear facility as described in Sections 1–4.

The Annexes provide examples and lessons learned of actual circumstances where quality assurance and quality control practices play significant roles.

2. MANAGEMENT SYSTEMS AND QUALITY

2.1. QUALITY, QUALITY ASSURANCE, QUALITY CONTROL

Quality in everyday language usually conveys the meaning of reliable, durable, good materials or some degree of excellence. However, a more precise concept is necessary to achieve the level of quality necessary for reliability, sustainability and safety in a nuclear facility or activity.

Definitions of the terms like quality, quality management, quality assurance and quality control have evolved in recent times. There are several definitions in use. This section explores the concepts behind the terms and their definitions and their roles as part of a management system.

2.1.1. What is quality?

ISO 9001:2015 [16] is the most widely used quality management system standard. Quality is defined as the "degree to which a set of inherent characteristics of an object fulfils requirements" in the related vocabulary [17]. This definition is generic and applies to all objects including products and services supplied to or created in the nuclear energy sector.

The customer, or user of the item, needs to be content with the quality delivered. Consequently, to decrease subjectivity, the requirements need to be specified and agreed, and one needs to be able to objectively assess the level of quality. For nuclear facilities and activities, the requirements need to be specified, with tolerances or limits as appropriate, and clearly understood by both the supplier and the customer.

The contents of some central historical management systems, quality assurance and control requirement references are presented in Appendix I to facilitate comparison.

2.1.2. What is quality assurance in the field of nuclear energy?

Here are three relevant definitions of quality assurance.

IAEA Safety Glossary (2018) [18]	The function of a management system that provides confidence that specified requirements will be fulfilled.
ISO 9000:2015 [17]	Part of quality management focused on providing confidence that quality requirements will be fulfilled.
ASME NQA-1-2017 [19]	All those planned and systematic actions necessary to provide adequate confidence that a structure, system, or component will perform satisfactorily in service.

The common feature of these definitions is that they relate to providing confidence that requirements will be achieved. Quality assurance can therefore be considered as identifying, planning and implementing the activities necessary to provide confidence that the products and services will fulfil requirements applicable to them. Such activities will depend on the nature of products and services for which assurance is required. These can include understanding and agreeing on the specification of what is required, the manufacturing processes, procedures, working methods and instructions to be used, the competence of people, identifying and using the right tools and equipment, the working environment and the availability of necessary resources.

Quality assurance needs to be applied to all relevant activities to give confidence in achieving the desired result. In an operating NPP, for example, this would include operations, maintenance, fuel handling, and procurement in addition to managing documents and records. Normally this means that the processes and procedures are planned and clear, that people are trained and competent, that the correct materials and equipment are used, that the working environment is appropriate, and people have access to information to enable them to make the right decisions.

Quality assurance activities need to be identified and planned before any work takes place to provide confidence that the product meets the specification with no defects, or the service meets the specification with no errors. The idea is to make sure that the organization possesses the capabilities of informed customer, i.e. its members have a clear understanding and knowledge

of the product or service being supplied, as discussed in GSR Part 2 [12] and NP-T-3.21 [20]. Necessary competences are discussed in Section 3.6 of this publication.

The contents of some central historical references are presented in Appendix I to depict the areas normally included in quality assurance.

2.1.3. What is quality control in the field of nuclear energy?

Here are two relevant definitions of quality control.

IAEA Safety Glossary (2018) [18]	Part of quality management intended to verify that structures, systems and components correspond to predetermined requirements.
ISO 9000:2015 [17]	Part of quality management focused on fulfilling quality requirements.

The common feature of these definitions is the focus on verifying or demonstrating that the specified requirements have been achieved, including conformity to requirements. Quality control includes verification activities such as measuring, inspecting, testing, recording, witnessing and sampling. Quality control activities provide objective confirmation of achieving defect-free and error-free products and services.

Quality control can be applied to all facilities and activities and their processes to demonstrate that the desired results have been achieved. As a minimum, people would check their own work and keep records that demonstrate that the desired results had been achieved and were free from errors or defects. In certain cases, it is necessary for quality control activities to be undertaken by people who are different from those who produced the product or service in question. This could mean peers, such as people from other parts of the organization or representatives of external organizations.

Quality control activities provide more value when they are well-planned. They are usually incorporated into quality assurance programmes (e.g. as a part of procurement specifications, inspection and testing plans and fabrication drawings) and provide a structured approach to implement verifications (such as records management, training and qualification programmes). Data from quality control activities is a valuable source for determining correction and potential improvement opportunities.

2.1.4. Quality assurance, quality control and continual improvement

The Shewhart-Deming plan-do-check-act (PDCA) cycle is an established model widely used for continual improvement in product, service and process quality as well as overall organizational excellence [21–23]. In the following paragraphs, its application to activities related to quality assurance or quality control is described.

Continual improvement is an organizational philosophy which is driven by improvement opportunities rather than risks. The PDCA cycle is widely implemented within organizations pursuing improvement and one which can be applied to quality assurance or quality control activities to improve their effectiveness and efficiently.

Underpinning the PDCA cycle is communication, which is fostered by a healthy organizational culture. For example, users of management system processes and procedures are empowered to

look for and communicate potential improvements. Those ideas for improvement may, for instance, be taken as the basis for planning an improvement ('Plan'). The plan is then implemented in the 'Do' step, followed by a review ('Check') of how successful the implementation was. If difficulties were noted during the 'Check' action, these are to be addressed during the 'Act' phase. This final phase ('Act'), is an opportunity to make adjustments and can lead directly back to planning ('Plan') the next improvement cycle.

Figure 2 depicts a generic PDCA cycle used in management systems, quality assurance and quality management.

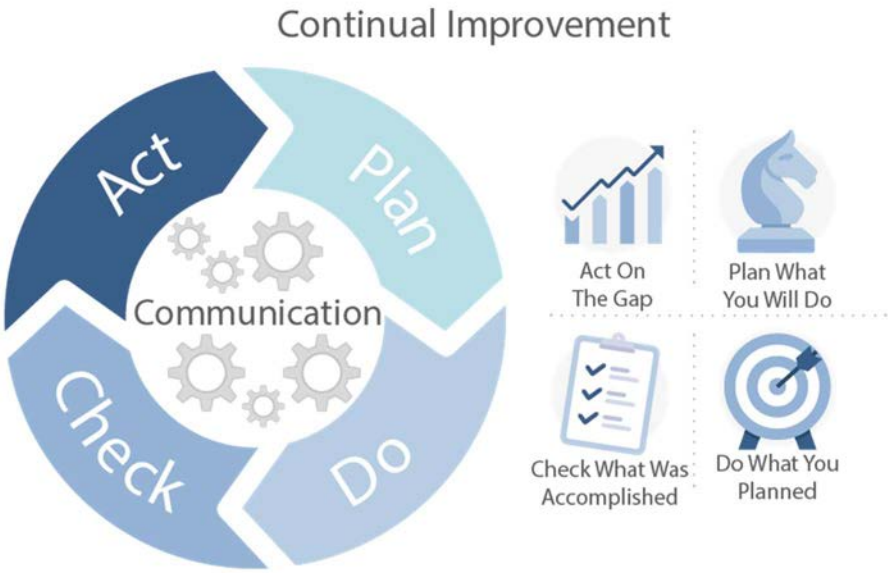

FIG. 2. A general illustration of PDCA cycle.

2.2. IAEA FRAMEWORK OF MANAGEMENT SYSTEMS AND QUALITY

The IAEA Fundamental Safety Principles [24] state that "Safety has to be achieved and maintained by means of an effective management system". Here is a definition of management system.

IAEA Safety Glossary (2018) [18] A set of interrelated or interacting elements (system) for establishing policies and objectives and enabling the objectives to be achieved in an efficient and effective manner.

The key feature of this definition is that a management system is implemented to achieve objectives and it contains a set of interacting elements. The objectives generally include safety, health, environmental, security, quality, safeguards, human-and-organizational-factor, societal and economic objectives [8]. Management system standards, e.g. in ISO 9001 [16], ISO 14001 [25], ISO 45001 [26], have been developed to identify requirements for certain areas such as quality, environment, energy, etc. and to assist the implementing organization in achieving

these objectives. Objectives in all these areas need to be met so that a nuclear facility or activity, including its supply chain, would reach its objectives sustainably.

The IAEA framework of management system includes requirements for leadership, culture for safety, organizational structure, resources and organizational processes, and a requirement to integrate all objectives and processes within its scope. The prime focus of IAEA GSR Part 2 [12] is safety, but it does require other elements to be integrated in one management system. This ensures that safety is not compromised by the other objectives, but also that all the important elements to be managed get the attention in the organizational decision making that is warranted by their significance.

Figure 3 illustrates the elements of a management system, including the relationships between quality assurance, quality control and the management system. Quality assurance and quality control are directed towards providing conforming products and services, and as they deal with supply chain, they extend outside the boundaries of the organization. They are both an essential part of any management system for nuclear facilities and activities that need to comply with GSR Part 2 [12].

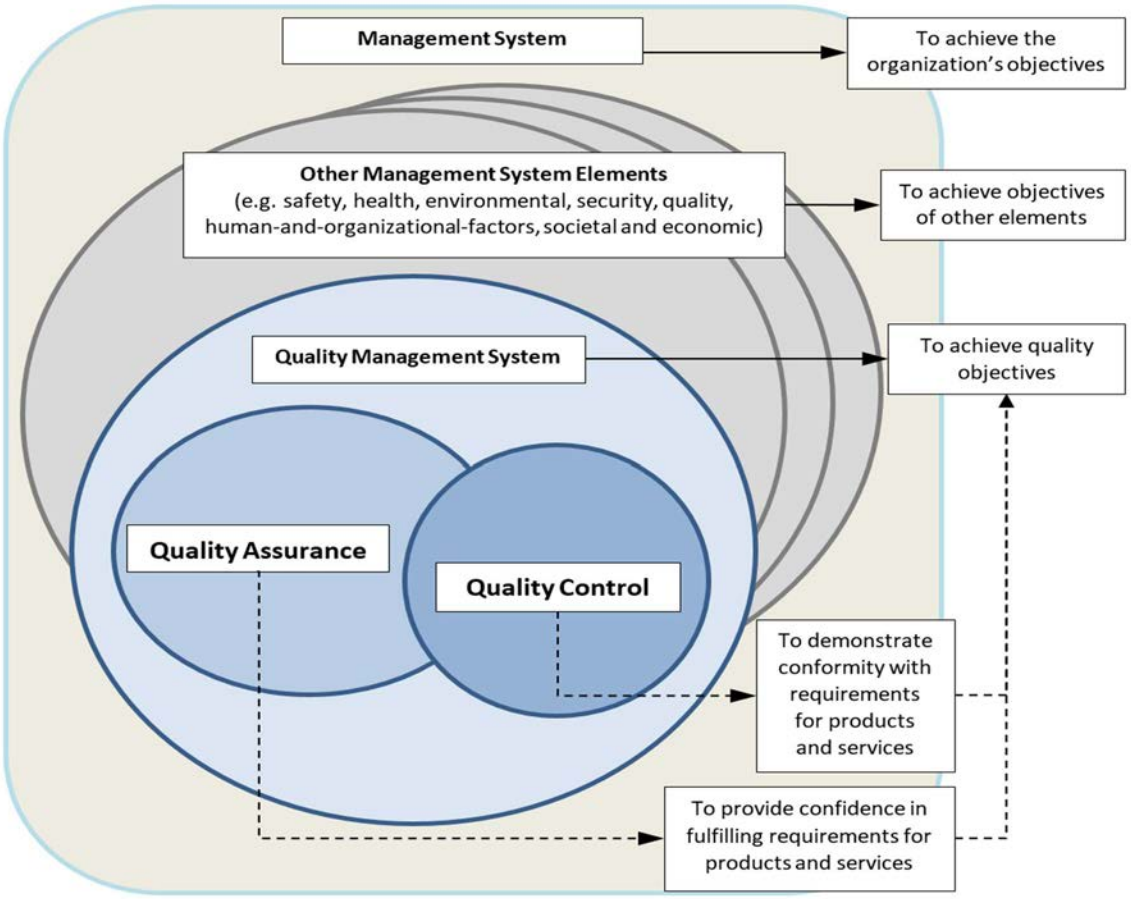

FIG. 3. A high-level illustration of connections between quality assurance, quality control and the management system of nuclear facilities.

A frequently discussed topic in quality and management has been the exact relationship between the management system and quality related activities. Here, the context of the organization, for example the exact type of the facility and activity and the size of the organization play a significant role. Fig. 3 presents a general illustration of that relationship.

2.3. INTERNATIONAL AND NATIONAL STANDARDS ON QUALITY MANAGEMENT SYSTEMS, QUALITY ASSURANCE AND QUALITY CONTROL

Typically, requirements for quality assurance, quality control and quality management in nuclear power plants are defined in applicable international or national standards. Regulatory bodies usually specify their own requirements as part of a nuclear and other national regulation (e.g. building regulation) based on the applicable legislation. The regulatory requirements may reference or supplement international or national standards with national elements.

The standards in question may be IAEA Safety Standards, ISO standards or specific national standards relevant to management system, quality and quality management system. NP-T-3.21 Procurement Engineering and Supply Chain Guidelines in Support of Operation and Maintenance of Nuclear Facilities [20], provides comprehensive lists of applicable regulatory requirements and standards that include the topics of quality assurance and quality control.

Any organization needs to define its quality standards and associated management system to ensure the effective delivery of its products or services. Quality arrangements and management system need to enable the business to deliver its objectives in an efficient and effective manner. It is necessary to consider the legal and regulatory requirements and carry out a gap analysis whenever deviating requirement bases are identified.

In the following section, we give a brief overview of how some standards developing organizations address quality concepts in their standards.

2.3.1. International Organization for Standardization

The International Organization for Standardization (ISO) has developed general quality management related standards in the ISO 9000 series. These standards were primarily intended for manufacturing organizations, but the applicability has been extended to service industries.

ISO 9001:2015 [16] has been developed as a generic quality management system standard that is applicable to all types of products and services and the businesses that produce them. Therefore, the organizations implementing the standard need to apply the requirements appropriately for its own context and circumstances. In ISO 9001:2015 [16], requirements for quality assurance and quality control activities are implicitly included although they may not be explicitly visible.

ISO produces management system standards in more than 35 disciplines. Where product or/and service quality has greater safety implications, the generic requirements have been enhanced for the more exacting sector applications of ISO 9001:2015 [16]. Examples of such sector applications are IATF 16949:2016 [27] for the automotive sector, AS 9100D[6] [28] for the aerospace sector, and ISO 22000 [29] for the food sector. Correspondence between ISO 9001 with the IAEA Safety Standards has been studied in Safety Reports Series No. 69 [30].

In the nuclear sector, ISO 19443 [31] was recently issued for organizations supplying products or services that are important to nuclear safety. It expands the generic ISO 9001:2015 [16] requirements to include some IAEA GSR Part 2 [12] requirements and sector-specific

[6] AS 9100D, based on ISO 9001:2015 is an internationally recognized quality management standard for the aerospace industry, operated by the International Aerospace Quality Group (IAQG).

requirements for nuclear safety. Guidance on the implementation of ISO 19443 [31] will assist users of the standard in implementing the requirements.

2.3.2. American Society of Mechanical Engineers

The American Society of Mechanical Engineers (ASME) has developed the nuclear quality assurance standard NQA-1 [32]. The purpose was originally to provide for practical implementation of the requirements in the United States Federal Regulation 10 CFR 50 Appendix B — Quality Assurance Criteria for Nuclear Power Plants and Reprocessing Plants [33]. NQA-1 was developed originally as a national standard, however, it is also widely used internationally.

ASME NQA-1 [32] and its 18 requirements (see Appendix I) have been developed to address the full scope of nuclear facilities and activities. Non-mandatory appendices include guidance on the requirements and include engineering insights. NQA-1 retains a focus on assuring item conformance to technical requirements rather than providing requirements for a total management system.

ASME NQA-1 [32] requires a documented quality assurance programme rather than a management system. The quality assurance programme includes many IAEA requirements (see Safety Reports Series No. 70 [34]) with the notable exceptions of integrated management system, leadership and culture for safety.

2.3.3. Other national regulations and standards

Legal, or statutory, and regulatory requirements among Member States vary in their acknowledgement of quality management or quality assurance as a unique management system element. Some Member States comprehensively describe quality assurance requirements, publish supporting guidance, and endorse quality assurance standards. Others focus on the integrated management system level without recognizing quality management systems or quality assurance in detail.

Member States' practices regarding management system or quality assurance fall into three distinct categories (see Figure 4):

- Legal requirements only;
- Legal and regulatory requirements;
- Legal and regulatory requirements with reference to:

  - Mandatory standards;
  - Non-mandatory (endorsed) standards;
  - Standard neutrality (licensee to propose).

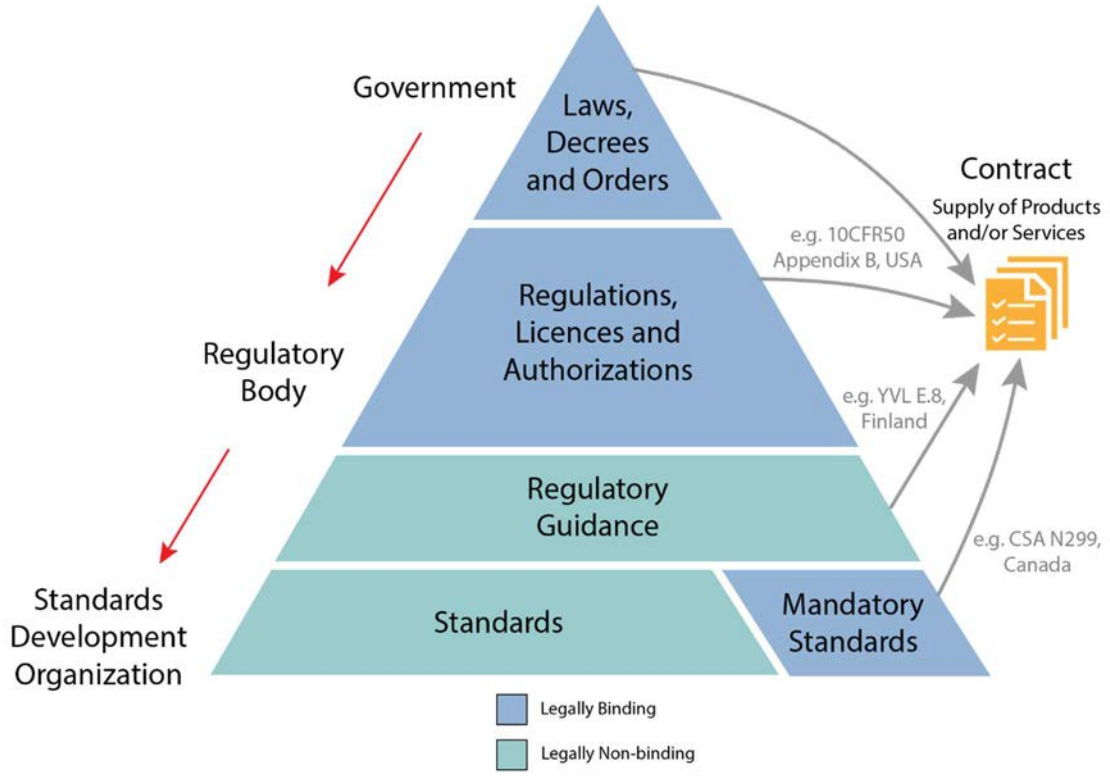

FIG. 4. Hierarchy of legal requirements, regulations and standards and the bodies issuing them.

Governments issue legislation. Regulatory bodies issue both legally binding regulations and non-legally binding guides. Standards are most often developed by standards development organizations, and they may be mandatory or non-mandatory, depending on local regulation and law. Other mechanism that may make standards mandatory are contractual stipulations. The contracts need to include all the relevant stipulations for a successful delivery.

In Member States which do not require or endorse compliance with an international, national or regional quality standard, NPPs often utilize a quality management system in accordance with ISO 9001:2015 [16] which is then augmented with country specific requirements for licensing.

3. MANAGING QUALITY ASSURANCE AND QUALITY CONTROL ACTIVITIES

3.1. QUALITY AND ORGANIZATION

The senior management of an organization has the ultimate responsibility for the quality of its products and services. A senior manager or executive typically assigns responsibility to distinct parts of the organization[7] and staff to: 1) provide confidence that requirements for quality will be achieved (e.g. quality assurance function); 2) deliver products and services in accordance

[7] Later in this publication, these are referred to as the quality assurance function and the quality control function. They can sometimes be combined as a quality function.

with all requirements (e.g. manufacturing, operating, maintenance or delivery functions); and 3) verify or demonstrate that the specified requirements have been achieved (e.g. quality control function). To be effective, the position of quality in the organizational structure, authority, scope and responsibilities need to be clearly defined in the quality assurance programme or management system.

The actual position of these functions within the organizational structure varies between organizations. This is due to several considerations, such as: level of nuclear risk; nature of the product or service and its significance to nuclear safety; complexity and maturity of the work processes; size of the organization; and, scope of quality assurance and quality control work activities.

External drivers also influence or specify where a quality assurance and quality control function may be positioned in the organizational structure and what activities need to be included within their scope. Regulatory requirements as specified by the relevant regulatory body, contract requirements and applicable national or international standards are the most common source of external drivers.

Some examples of structures and responsibilities in the organization are:

- An organizational unit, reporting directly to senior management, that combines all assurance functions including quality assurance and quality control. Such a group has full independence from the organization responsible for delivering the product or service and may be referred to as a ‘quality’, ‘quality assurance’, ‘performance assurance’, ‘quality audit/assessment’, ‘independent assessment/oversight’, or ‘quality assurance and control’ department/office. Such a group normally has the responsibility for developing and maintaining the organization’s quality assurance programme or management system, and for quality control activities (tests and inspections);

- Two organizational units reporting directly to senior management that split the quality assurance and quality control functions and yet retain full independence from the organization responsible for delivering the product or service (e.g. for an operating NPP they would be independent from the operations). These two groups are typically referred to as a ‘quality (or performance) assurance’ and ‘quality control’ department/office. In this example, the quality assurance or performance assurance organization is independent from the quality control organization to increase the objectivity of assessments of quality control functions;

- An organizational unit reporting directly to senior management that includes the quality assurance function with full independence from the organization responsible for delivering the product or service. In this example, quality control activities are carried out by functions within the organization responsible for delivering the product or service; and

- In smaller organizations, it may not be possible to establish separate groups for the quality assurance and quality control functions. In these cases, functions are split amongst the management team. The organization needs to rely on peer reviews; trained and competent personnel to carry out inspections and tests; and, customer or third parties to perform independent audits/assessments.

Quality control activities (e.g. inspection, testing and witnessing) and quality assurance activities (e.g. auditing, surveillance) need to be impartial and demonstrably objective. For

products and services important to safety, this is achieved by ensuring that the reporting line of the quality control function is independent from the parts of the organization responsible for delivery of the products and services. For products and services less important to safety, independence can be achieved by ensuring that people do not assess or verify their own work. For smaller organizations, it can be necessary to employ external agencies to ensure independence.

Regardless of the position, scope or configuration of the quality assurance and quality control functions, it is important that arrangements for ensuring independence are clearly communicated within the organization to ensure that the integrity of those performing quality control activities and the validity of their results are not challenged or compromised. It is also important that those carrying out quality control activities can report directly to senior management about the findings to enable changes on the level of organization where this is considered necessary.

3.2. DOCUMENTS FOR QUALITY MANAGEMENT SYSTEM

Where quality assurance and quality control activities are established within an organization, several management system documents are required to provide strategic direction for the function.

Typically, with many possible variants, these may include all or some of the following:

- Quality policy, as one of the integrated management system policies, which sets out the organization's intentions and direction with regard to quality as formally expressed by its senior management;
- Quality strategy, if defined, which defines the short, medium and long-term strategy for the function to arrive in the objectives of the quality policy;
- Quality improvement plan, which defines those activities which will be implemented in order to improve the delivery of a quality capability across an organization (not to be confused with quality plans, see Section 3.5. for quality plans);
- Resource strategy (as a part of workforce planning strategy), which sets out how people are available in sufficient numbers, taking into account demand on the function, demographic profiles, recruitment strategies and succession plans;
- Competency matrix, which sets out the training and competency requirements for each role within the function; and
- Quality manual[8], which specifies and describes identified processes, methods, criteria and responsibilities belonging to the quality management system as well as its organizational structure.

The quality manual usually includes the above documents (quality policy, quality strategy, quality improvement plan, resource strategy, competence matrix), their summary or references to them. The role of the quality manual is to make it easier for personnel to understand how quality activities are implemented in their organization. A description of the documents and an example of how they have been applied by one organization is given in Appendix II.

[8] Quality manual may have different names and it can be referred to as, for example, a quality assurance manual, quality assurance programme or quality management system manual.

The quality manual is different from the management system manual [13]. The management system manual describes how the whole organization works, and includes its mission, vision, policies, processes, procedures and instructions or references to where to find them.

3.3. MANAGEMENT OF DOCUMENTS AND RECORDS

A large amount of documentation is generated throughout the lifetime of a nuclear facility, some of which undergoes numerous revisions and is retained during all phases of the lifecycle. Managing this abundance of documentation is crucial for guaranteeing not only safety but also the effectiveness of quality assurance and quality control activities.

Some key quality management system documents have been described in Section 3.2. Quality control activities typically generate documentation which evidences test or inspection results or may act as a record of conformance or acceptance. Quality assurance activities are governed by documented management system processes and their subprocesses.

The managing documentation is in many cases required explicitly by national regulation or applicable quality assurance standard. Document management requirements can also be found in GSR Part 2 requirement 8 and its guides [7, 10]. Specific requirements related to document control vary from nation to nation and standard to standard. Typical topics for which requirements presented under document control theme are:

- Preparation;
- Review;
- Approval;
- Clarity;
- Correctness;
- Issuance;
- Distribution;
- Changes;
- Revisions;
- Accessibility;
- Identification; and
- Retention.

Quality documentation, e.g. completed document of quality or inspection and testing plans, forms quality assurance records and is sometimes also referenced as evidence.

While requirements exist, not all documentation is treated equally. The manner in which documentation is controlled depends on its type, use or significance, e.g. to safety. A graded approach needs to be applied when controlling documentation. As an example of this, the retention period for each document needs be based on the organization's needs, risks and related regulations. Also, the media onto which documentation is recorded may be based on these graded needs. Revisions to documents are subject to control, review and retention commensurate with the requirement level of their predecessors.

Types of documentation are often depicted in tiers. A hierarchy of document types exists including, e.g. high level (high tier) quality management system documents, such as a quality policy, and the processes, procedures, instructions and records generated during daily business. [13]

3.4. MANAGEMENT OF DESIGN ACTIVITIES

The management of design activities is a cornerstone of overall reliability and safety at nuclear power plants. Quality assurance activities, in helping to ensure that specified requirements are fulfilled, play an important role in making certain that design is defined, adhered to, and maintained during all lifecycle phases. Additionally, the design organization responsible for design basis, sometimes denoted as design authority, needs to adhere to integrated management system expectations, which includes the activities required, e.g. by IAEA SSR-2/1 (Rev. 1) [35], INSAG-19 [36].

The quality assurance requirements specified by national laws, the regulatory body or a standard are likely to include some, or all of the following design-related requirements:

- Design input;
- Design process;
- Interface control;
- Configuration management;
- Analysis;
- Verification;
- Validation; and
- Software design control.

The management of design-related documents is important for the control of the design itself. It ensures that design documents are appropriately reviewed, issued, distributed and retained. Typical tools of verification are design reviews. For verification and validation, also technical tools such as 3-D models and calculations are used.

Document management plays a central role in many aspects of design management, depicted in Fig. 5. The management of design makes sure that design requirements are wholly and accurately reflected in the documentation such as specifications, drawings, procedures and instructions. Also, the physical systems, structures and components need to be consistent with the documented design requirements, as shown e.g. in the IAEA GS-G-3.5 [10].

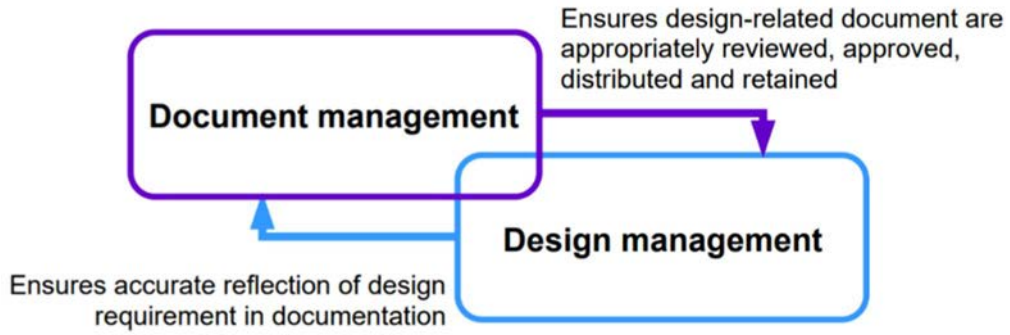

FIG. 5. Relationship between document management and design management.

During the operational lifetime of a nuclear facility, the design of some systems, structures and components will, for a variety of reasons, be modified. Quality assurance procedures help to ensure these modifications are performed in a manner which will continue to ensure that the design requirements will be fulfilled. Design changes may be the result of operational experience or findings derived from quality control activities. The impacts of the changes and

the related risks need to be analysed. Changes to design are subject to the same controls as the original design. The same principle is applied in good document management practices as discussed in Section 3.3.

In large projects, such as a new NPP, the concept of requirements management is often used to denote the quality assurance and quality control work to make sure the design complies with the huge amount of different requirements (Requirements management: a practice guide, PMI (2016) [37]).

3.5. PLANNING QUALITY ASSURANCE AND QUALITY CONTROL ACTIVITIES

Several factors need to be considered in planning the scope and extent of quality assurance and quality control activities. A plan needs to be developed outlining the work to be performed and the work procedures or instructions required to comply with the requirements of the defined scope. It is useful to document the main principles of this planning in a quality manual with the documents mentioned under Section 3.2.

Planning for activities such as fabrication, installation, construction, commissioning, operation, modification, repair, maintenance, decommissioning, inspection, testing, and software verification and validation can include a review of:

- Structure, system or component design and procurement specifications;
- Material properties lists;
- Drawings;
- Construction work plans, and schedules to ensure that appropriate activities have been incorporated;
- That the work can be accomplished as specified; and
- That time and resources, plus training, are sufficient to accomplish the work in accordance with the specified requirements.

Planning identifies the operations to be performed, the systematic sequential progression of operations, and the overall measures to be used to ensure the quality of the work.

An example of how one operator identifies quality assurance and quality control activities is given in Appendix III.

Examples of quality control along with acceptance criteria and competence of quality control personnel are given in Appendix IV.

A quality plan (QP) describes how an organization, typically a vendor or supplier, will provide an intended output, whether that output is a process, product, or service. Typical use is when the safety or economic significance is high, the activities to be carried out are complex, novel or infrequently carried out and when more than one organization or group of people is involved. Sometimes, a quality plan can cover a range of activities with varying complexity from high-level planning, such as the installation of new plant or system, to the detailed manufacture, verification and testing of an individual component.

A quality plan can be useful in identifying the requirements, processes or procedures that control the activities, their sequence and interaction and who is responsible for carrying them out. A quality plan is also useful in identifying the quality control activities, such as witnessing, the type and extent of inspecting, monitoring and measuring, and may include hold points

beyond which work could not progress until conformity of the preceding activity has been verified. A completed quality plan can also provide a record of product or service conformity to requirements.

A quality plan used as the basis for monitoring conformity with specified requirements is sometimes referred to as an inspection and testing plan (ITP). This often has to do with detailed manufacturing process oversight. TABLE 1 illustrates some practical differences of depth between a quality plan and an inspection and testing plan from two different regulations. It is worth noting that in some circumstances the names "quality plan" and "inspection and testing plan" are used interchangeably.

TABLE 1. A SAMPLE COMPARISON BETWEEN THE CONTENTS OF A QUALITY PLAN AND AN INSPECTION AND TESTING PLAN IN TWO DIFFERENT REGULATIONS

Quality plan content requirements found in Finland (YVL A.3 15.3.2019 [38])	Inspection and Testing Plan content requirements found in Switzerland (ENSI-G11/d Rev. 2 [39])[9]
• Responsibilities and obligations of the supplier as well as interfaces with other suppliers or organizations contributing to the delivery in question. • Standards and guidelines to be complied with in the delivery. • Supply organization and assurance of sufficient resources and competence. • Potential division or phasing of delivery. • Initial data of the delivery and the resulting documents and records. • Reviews relating to delivery and its division or phasing, including the content of the reviews, performing party, acceptance criteria, and the responsibilities and decision-making procedures to be followed. • Procedures for subcontractor supervision. • Procedures for the management of the technical configuration and modifications. • Delivery-specific processes of the supplier's management system and their potential delivery-specific additions. • Consideration of safety significance in accordance with subsection 3.5 of Guide YVL A.3. • Ensuring a good safety culture in the delivery. • Management of human and organizational factors in the delivery. • Updating procedures for the quality plan.	General Data: • Manufacturer, facility, name of the component or assembly, if known, component number according to the plant system • Number of the assembly drawing • Safety and seismic classification • Design specification and construction provision • Designation of the related list of materials For each manufacturing step: • Incoming inspection • Numbering of the manufacturing steps e.g. welding • Name and description of the manufacturing step • Applied specifications, norms, drawings • Execution by the manufacturer or a sub-supplier • Acceptance by the manufacturer, an expert or the customer • Review of the documentation by the manufacturer, an expert or the customer • Welding: reference to the welding plan with data for checking the process, qualification of the welder and examination of the lot • Hold Points for the customer, manufacturer, expert

The excerpt from STUK YVL A.3 [38] demonstrates the focus of quality plans is not so much on product quality but rather with quality assurance activities applied to the delivery as a whole. The contents of a quality plan in this example are procedures, processes and other information concerning a given procurement. The content requirements ensure that the necessary quality

[9] Please note that this excerpt is a translation for comparison purposes.

assurance is in place to mitigate risks and ensure conformity of the delivery with regulatory demands.

The example of inspection and testing plan content requirements from ENSI-G11 [39] for safety relevant vessels and pipes is typical of the information expected in such a document. The inspection and testing plan (ITP) is a working document which tracks a component or assembly lot through its fabrication, assembly inspection and testing. In some cases, the ITP physically moves through a facility together with the component or assembly to which it belongs. Each manufacturing step is expected to be recognized in the ITP along with space for approval by the manufacturer, customer and/or technical specialist.

When viewed side by side in TABLE 1, the difference between quality plans and inspection and testing plans becomes apparent. For example, while the quality plan contains procedures for subcontractor supervision, the inspection and testing plan indicates if a subcontractor was responsible for a given manufacturing step. The quality plan includes delivery-specific processes such as those for welding while the inspection and testing plan evidences compliance with welding procedures including verification of welder qualification.

Guidelines on the various types of quality plan can be found in literature, for example, in ISO 10005 [40]. An example of one operator's application of quality plans is given in Appendix III.

3.6. QUALIFICATION AND MANAGEMENT OF SUPPLIERS

Today, organizations often have less in-house capability or capacity, and managing supply chain has become increasingly important beyond just managing procurement. Nuclear supply chains have become increasingly complex and frequently transcend national boundaries. Also, several new actors have come to the marketplace since the original equipment suppliers are not available anymore. Hence, the evaluation of suppliers has gained increasing attention by both the power companies and the regulatory bodies.

GSR Part 2 [12] requires the operating organization (customer) to retain responsibility and to include in its management system arrangements with its suppliers for specifying, monitoring and managing the supply to it of items, products and services that may influence safety. It specifically requires these arrangements to include qualification, selection, evaluation, procurement, and oversight of the supply chain. The organization, furthermore, needs to make arrangements for ensuring that suppliers of items, products and services important to safety adhere to safety requirements and meet the organization's expectations of safe conduct in their delivery. This principle also includes the idea that the applicable requirements need to be cascaded to the sub-contractors in the supply chain.

An example of the interaction with the supply chain and cascading various levels of requirements is shown in Fig. 6. The requirements recognize the responsibilities placed on operators of nuclear facilities and activities not to install or put into service products, items and services that can have an adverse effect on nuclear safety and reliability.

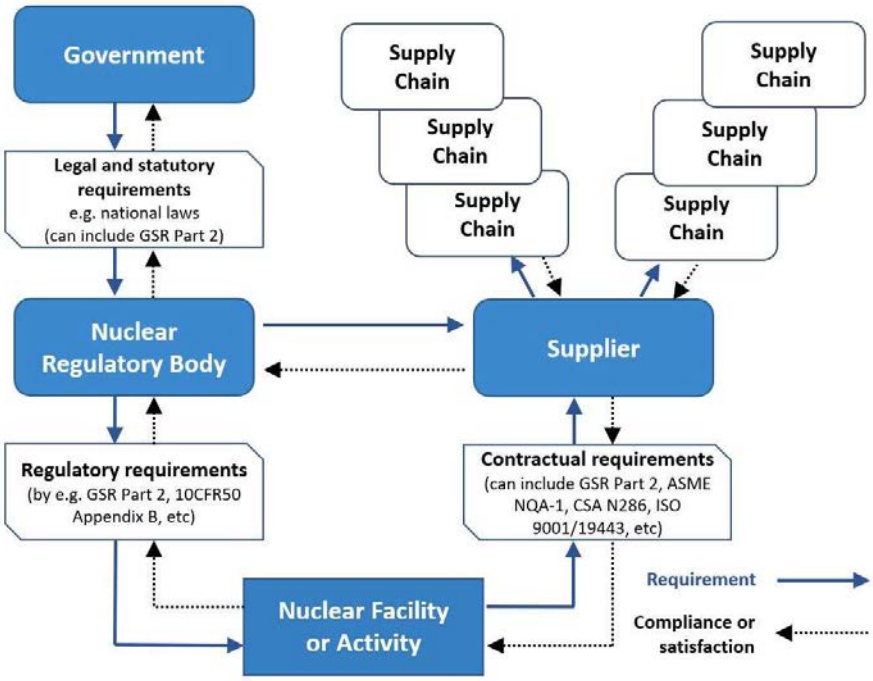

FIG. 6. Example of the cascading quality requirements in the nuclear supply chain.

To cascade the requirements, the customer needs to include all the relevant ones in the contract. Such requirements may be commercial, technical or quality related. For instance, there may be a requirement to work according to a certain quality management system standard or a quality assurance standard. Some of the requirements are legal, some regulatory and some defined by the customer.

Figure 7 manifests general process activities in different phases of the procurement planning and supply/delivery management (need identification, supplier selection, purchasing, manufacturing/delivery and receipt/use). It is important that the quality control verifications are performed according to the plan, and that the plan may need to be changed if new risks are identified.

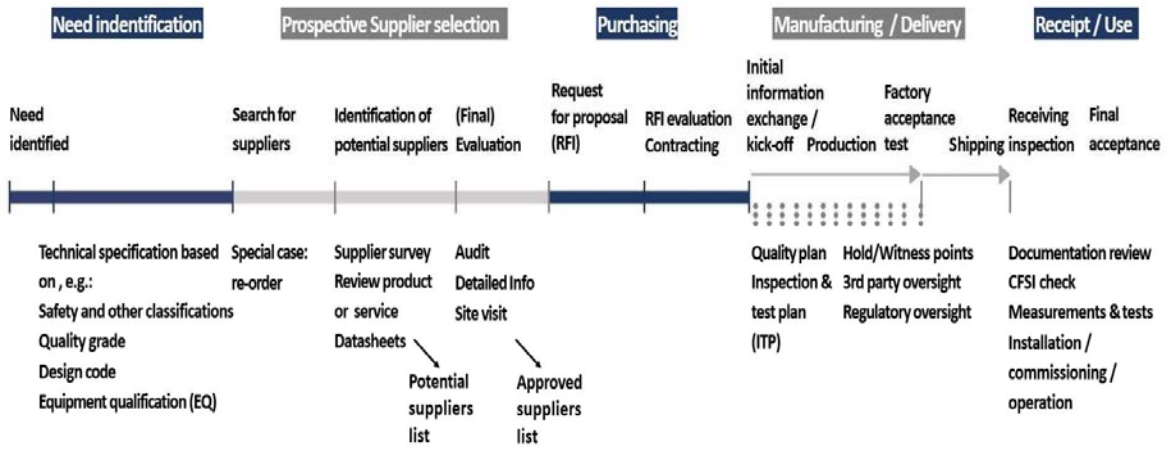

FIG. 7. Example of the process of procurement and supply.

The supplier selection process typically includes a review of the supplier's quality or management system documentation, key quality assurance processes as well as the qualifications of those personnel tasked with carrying out quality related activities such as inspection and testing before purchasing/procurement takes place.

The responsibilities of licensees with regards to supplier selection and supplier management are largely influenced by national legislation, regulation and applicable standards, as discussed before. Important factors can include historical performance and references, technical and quality capabilities, review of current quality documentation and the results of an on-site audit in supplier's premises. An evaluation process results in a qualified supplier when the licensee, based on the output of the evaluation, has a high degree of confidence in the supplier's ability to fulfil the necessary requirements.

In cases when the supplied equipment or service is of safety significance, supplier qualification before final selection may require the approval of the national regulator. Some regulatory bodies publish detailed rules for qualifying suppliers. Regulatory approval of suppliers can be one-time in nature or have a period of validity subject to requalification.

The supplier selection process is in some cases only the beginning of supplier oversight. In addition, there may be ongoing activities applied to suppliers throughout the life of a contract such as surveillance, audits, inspections and witnessing tests in manufacturing/delivery phase. The extent of these activities varies between different regulatory regimes, as does the extent to which the sub-contractors are subject to inspections. Reference [20] includes information about these topics.

An example from one licensee on the evaluation of the capability of suppliers to provide products and services that comply with quality requirements is given in Appendix V.

Evaluation methods including first party, second party and third party and their audits are presented in Appendix VI. First party evaluation or assessment is carried out by the organization itself; second party evaluation or assessment is carried out by the customer; and third party evaluation or assessment is carried out by an independent organization.

3.7. QUALITY GRADING AND RISK

IAEA TECDOC-1740 [14] provides guidance on, and examples of, a graded approach to the application of the management system requirements for facilities and activities. Also, the extent and application of quality assurance and quality control activities need to be proportionate to the level of risks involved. This is because applying the most stringent controls to all activities is not viable resource-wise.

Defining a reasonable quality oversight level can be determined through a grading process — a structured method by which the stringency of application of requirements is varied in accordance with the circumstances, the regulatory systems, the management systems established, etc.

When determining the appropriate level of quality assurance and quality control, one needs to consider [18]:

- The significance and complexity of a product or service;
- The potential impacts of the product or service on health, safety, security, the environment, and the achieving of quality and the organization's objectives; and
- The consequences if a product fails or if a service is carried out incorrectly.

Generally, analysing the related risks is vital. Other factors that need to be taken into account include, novelty of a product, uniqueness of the supplier and experience. A graded approach is fundamental in establishing that a process, product and service are fit for purpose, recognising different levels of necessary controls and also considering the limited resources of an organization.

For example, the extent and depth of controls applied may include:

- 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.

Any consideration of risks needs to be carried out using a defined risk management process. The risk management process needs to prescribe the methodology used to assess the level of the risk, assign a priority to risks and to record and register any mitigating actions.

INSAG-25 [41] presents a framework for an integrated risk informed decision making process that utilizes both deterministic and probabilistic safety analysis, organizational, security and other considerations to arrive in well-balanced decisions on matters related to safety. Many risk-informed applications are to be found at nuclear power plants, such as testing and in-service inspection [42].

ISO 9001:2015 [16] introduces the concept of risk-based thinking where an organization needs to plan and implement actions to address risks and opportunities. This principle of addressing risks and opportunities provides a basis for increasing the effectiveness of the quality management system.

Typically, a risk-based approach covers the full range of risks faced by the organization. These include commercial, financial, environmental elements and quality and safety. Consideration of risk needs to be as broad as possible to ensure that the needs and expectations of all interested parties are not compromised by a risk that not been subject to adequate mitigation. All types of risk need to be considered for example, nuclear/radiological safety; industrial safety; environmental impact or business risk of a nuclear facility or activity.

Examples of factors influencing the level of nuclear risk associated with a system, structure, component, product or service, or any activity carried out on it are given below:

- Is it nuclear safety critical, such as an electrical sub-station supplying power a plant safety system?
- Is it safety critical such as a high-pressure steam line?
- Is it accessible for future inspection or maintenance?
- Is it needed to operate reliably over a long period of time?
- Is it easy to replace?
- Is it possible to obtain spare parts?

3.8. COMPETENCIES OF QUALITY PERSONNEL

The competencies required of personnel engaged in quality assurance and quality control activities need to be clearly defined and be relevant to their role and the process, service or product to which those competencies will be applied, based on the resource strategy and competency matrix (see Section 3.2). For example, in many organizations quality assurance personnel are expected to be proficient in investigations, risk assessments and root cause analysis. Systemic and systematic thinking and understanding the roles of technology, human and organizational aspects in achieving quality is important.

Competency can be achieved through a combination of training, qualification and experience often completed with a suitable educational background. Educational and training qualification can be in a specific discipline, i.e. mechanical, electrical or civil, appropriate to the role. To support technical and educational qualifications, it is usual to define or recommend the level of experience expected of an individual discharging the duties of a particular role. For some roles, competency can be required to be demonstrated through examination and periodic repetition tests.

Technical skills are usually defined within a competency matrix which describes the specific skills and experience required for a particular role. Examples of some technical skills required for quality control are included in Appendix IV.

The role of the quality professional in defining and upholding standards in an organization means it is imperative that the quality personnel maintain a high standard of integrity, consistency and demonstrable ability to discharge their role. Conduct or behavioural competencies which set down the expectations of senior management in an organization for its quality personnel are more usually specified in a job profile or job description for each role within the quality organization.

IAEA Guide NG-G-2.1 Managing Human Resources In the Field of Nuclear Energy [43] provides comprehensive guidance on Human Resources issues including skills and competency of individuals within a nuclear organization. IAEA Guide NG-T-3.10 [44] provides guidance to assist Member States in developing an effective workforce plan. IAEA Safety Guide NS-G-2.8 Recruitment, Qualification and Training of Personnel for Nuclear Power Plants [45] provides further guidance and needs to be considered along with other IAEA guidance on fitness for duty.

3.9. NON-CONFORMANCES AND CORRECTIVE ACTIONS

Managing non-conformances and corrective actions are a vital part of any management system. Documented processes need to be in place to control non-conforming product, processes and services. The implementation of corrective actions stemming from a non- conformance may represent a continual improvement opportunity for which the PDCA model discussed in 2.1.4 is suitable.

GSR Part 2 [12] calls for the management of non-conformances and corrective actions, and GS-G-3.1 [7] provides guidance on processes for non-conformances and corrective actions. These processes need to define a range of actions, dependent on the type of non-conformance, required to return a product, process or service back to conformity. The corrective actions may include repair, rework, process changes, concession, additional sampling, etc.

Where corrective action is not appropriate or acceptable then a process needs to be defined to reject and scrap an item and preclude its future use. Any such process needs to clearly define the control, identification and segregation of non-conforming product. Non-conforming products and services are usually addressed using the example methods in TABLE 2.

TABLE 2. MOST COMMONLY ENCOUNTERED TYPES OF CORRECTIVE ACTIONS ESPECIALLY WITH PRODUCTS

Action	Explanation	Example/additional information
Reject	The non-conforming product, service or process is not fit for the intended use. Such non-conformances need to be marked and segregated as soon as the action is agreed and approved. Also sometimes referred to as 'Scrap'.	For example: when a product is found to be outside of specification with no possibility of rework or repair, and in the case of a critical use component would not be considered for concession.
Repair	The non-conforming item, when repaired (or in the case of documents revised) is capable of functioning in accordance with the design requirements, although it does not fully conform to the original design specification. Temporary repairs normally have a prescribed period of validity.	For example: when a product is found to be outside of specification, but the product could be returned to a conforming state following repair by an approved repair procedure. A component repaired by welding would fall into this category.
Rework	The item is capable of being fully restored to the original specification requirements, i.e. some additional rework carried out under suitable conditions will correct the non-conformance.	For example: when a product is found to be outside of specification, but the product could be returned to a conforming state following additional work being carried out. A component that may have had a machining operation omitted would be reworked by completing the omitted operation, this would fall into this category.
Accept with Conditions	In this instance it is likely that the non-conforming item, service or process will be fit for use under special, specified conditions.	For example: when a product is found to be outside of specification, but the product could be accepted the by the design authority[10] on concessions with restrictions for example placed on its usage in specific applications or its duration of service. This could apply to any non-conforming product or process which is submitted on concession to a design authority for acceptance.
Accept without Modification	In this instance it is likely that the non-conforming item, service or process deviates marginally from specified requirements but is still declared fit for use. Also sometimes referred to as Use-as-is.	For example: when a product is found to be outside of specification, but the product could be accepted the by the design authority on concessions without restrictions. This could apply to any non-conforming product or process which is submitted on concession to a design authority for acceptance.

[10] Design authority is the name commonly given to the part of the organization responsible for ensuring the integrity and configuration of the NPP against design codes, standards and the operating safety case.

Guidance on tools for analysis of non-conformances, corrective and preventive actions is given in Appendix VII.

3.10. EVALUATION, ASSESSMENT AND AUDIT OF QUALITY ASSURANCE AND QUALITY CONTROL ACTIVITIES

Requirement 13 of GSR Part 2 [12] calls for self-assessments, independent assessments as well as management reviews of the management system. The Safety Guide GS-G-3.1 [7] gives guidance in all these forms of evaluation.

Similarly, quality being a part of the management system, these different evaluations extend to quality assurance and quality control processes to judge how they are performing. Evaluations span from self-assessments, peer reviews, management reviews, customer reviews and feedback and finally to independent assessments.

A systematic independent evaluation of quality assurance and quality control activities against a regulation or standard is most often called an audit. In the following text, audits are discussed because of their role in conformity assessment and supplier selection. Appendix VI includes more discussion on all forms of evaluation.

Where exactly audits are required, either in national laws, regulatory requirements, in a standard or a related contractual requirement, varies by Member State and by case. Audits are used to assess internal processes and areas (such as a specific department or project), as well as the nuclear facilities' supply chain on a regular basis. Just as quality control activities can verify the conformance of an item to specifications, audits act to assess the conformance of the quality assurance and control activities with respect to the documented quality (assurance or management) process and, in some cases, to laws, regulations standards and contractual requirements.

Audits are carried out by various parties for differing purposes. These include:

- By customer (nuclear facilities, second party) itself to measure, assess and improve the quality management system, to qualify a supplier or evaluate its performance;
- By a regulatory body to assess compliance of nuclear facilities quality management system, to assess the compliance of nuclear facilities vendor or supplier to regulatory requirements (these are often called inspections), or by joining licensee audits; or
- By an independent third party (often called certification bodies) to certify the quality management (or assurance) system, or its part, of nuclear facilities or a supplier against a regulation or standard.

The supplier selection and evaluation process described in Section 3.6 may utilize audits to asses conformity of the suppliers with certain requirements. Suppliers are often required by legal, regulatory of contractual requirements to qualify their sub-contractors, so the audits may take place in the whole supply chain.

Depending on the products or services, the scope of a supplier audit can include nuclear-specific requirements and can take the form of a second-party audit or third-party audit, depending on the applicable regulation and local practices. The independence of the audit team from the audited process or activity is an important aspect of credibility. GS-G-3.1 [7] states that individuals within the organization that is conducting independent assessments should not have

the responsibility for the work performance being assessed. Consequently, auditors should not participate or have stakes in the work being assessed.

Appendix VI describes the assessment and review of quality in more detail, including independence, management review as well as internal and external quality audits.

4. QUALITY ASSURANCE AND QUALITY CONTROL IN DIFFERENT NPP LIFE CYCLE STAGES

The nature and extent of quality assurance and quality control activities will be determined by the requirements associated with the process applicable to the particular stage of the life cycle, including the development of the infrastructure for a nuclear power programme. In the IAEA milestone approach [46], site evaluation and all the other pre-contract activities belong to phases I-II, whereas construction belongs to phase III that ends with the commissioning.

Typically, the following stages of the life cycle (see, for example GS-G-3.5 [10]) require quality assurance and quality control arrangements:

- Site evaluation (pre-contract phase);
- Design (and long lead manufacturing);
- Construction (and manufacturing);
- Commissioning;
- Operation; and
- Decommissioning.

Quality assurance and quality control of services are necessary for site evaluation and design before any NPP delivery contract has been signed. Therefore, the necessary arrangements and organization need to be in place.

Most quality assurance arrangements need to be ready in the design phase to be included for their main part in the NPP contract. They may be part of project implementation plan and include the agreed way to manage quality plans or inspection and testing plans. Alternatively, the exact plans may be based on agreed standards. Also, some long lead item material (e.g. for pressure vessel) manufacturing begins very early during the project.

Construction, manufacturing and commissioning involve many quality control activities. In many cases, plans also need to be modified. During operation, quality assurance and quality control processes take place in a repetitive manner in plant daily life. When preparing for decommissioning, the activities again change from stable operations to project work. The objective is in this case to have a brown or green field instead of an operating NPP.

Quality assurance and quality control requirements applicable to the life cycle stages are described in Appendix VIII.

APPENDIX I.
REQUIREMENTS FOR QUALITY ASSURANCE AND QUALITY CONTROL IN RELEVANT STANDARDS

I.1. IAEA QUALITY ASSURANCE AND QUALITY CONTROL REQUIREMENTS

Quality assurance and quality control requirements in previous IAEA standards are presented in TABLE 3.

TABLE 3. QUALITY ASSURANCE AND QUALITY CONTROL REQUIREMENTS IN PREVIOUS IAEA STANDARDS

50-C-QA[11] (1978)	50-C/SG-Q[12] (1996)
1. Quality Assurance Programmes 2. Organization 3. Document Control 4. Design Control 5. Procurement Control 6. Material Control 7. Process Control 8. Inspection and Test Control 9. Non-conformance Control 10. Corrective Actions 11. Records 12. Audits	Management • Quality Assurance Programme • Training and Qualification • Non-conformance Control and • Corrective Actions • Document control and Records Performance • Work • Design • Procurement • Inspection and Testing for acceptance Assessment • Management self-assessment • Independent assessment

[11] This publication was revised to 50-C/SG-Q and is superseded by IAEA GSR Part 2
[12] This publication is superseded by IAEA GS-G-3.1 and GS-G-3.5

I.2. MANAGEMENT SYSTEM REQUIREMENTS

IAEA management system requirements are presented in TABLE 4.

TABLE 4. MANAGEMENT SYSTEM[13] REQUIREMENTS

GS-R-3[14] (2006), GS-G-3.1(2006), GS-G-3.5 (2009)	GSR Part 2 (2016)
Management System (MS) • General requirements • Safety culture • Grading the application of management system requirements • Documentation of the management system Management Responsibility • Management commitment • Satisfaction of interested parties • Organizational policies • Planning • Responsibility and authority for the MS Resource Management • Provision of resources • Human resources • Infrastructure and the working environment Process Implementation • Developing processes • Process management • Generic MS processes Measurement, Assessment and Improvement • Monitoring and measurement • Self-assessment • Independent assessment • MS review • Non-conformances and corrective and preventive actions • Improvement	Responsibility for Safety • Achieving the fundamental safety objective Leadership for Safety • Demonstration of leadership for safety by managers Management for Safety • Responsibility for integration of safety into the management • Responsibility of senior management for the MS • Goals, strategies, plans and objectives • Interaction with interested parties • The management system • Integration of the MS • Application of the graded approach to the MS • Documentation of the MS Management of resources • Provision of resources Management of processes and activities • Management of processes and activities • Management of the supply chain

[13] The terms quality management and management system were adopted in the revised standards in place of the terms quality assurance and quality assurance programme in IAEA Safety Glossary [18]
[14] This publication is superseded by IAEA GSR Part 2

I.3. ASME QUALITY ASSURANCE REQUIREMENTS

ASME quality assurance requirements of NQA-1 (2017) are:

1. Organization;
2. Quality Assurance Program;
3. Design Control;
4. Procurement Document Control;
5. Instructions, Procedures, and Drawings;
6. Document Control;
7. Control of Purchased Material, Equipment, and Services;
8. Identification and Control of Materials, Parts, and Components;
9. Control of Special Processes;
10. Inspection;
11. Test Control;
12. Control of Measuring and Test Equipment;
13. Handling, Storage and Shipping;
14. Inspection, Test, and Operating Status;
15. Nonconforming Materials, Parts, or Components;
16. Corrective Action;
17. Quality Assurance Records;
18. Audits.

I.4. ISO QUALITY MANAGEMENT SYSTEMS — REQUIREMENTS

Quality management systems requirements of ISO standards ISO 9001 (2015) / ISO 19443 (2018) are:

- Leadership:

  - Leadership and commitment;
  - Policy;
  - Organizational roles, responsibilities and authorities;

- Planning:

  - Actions to address risk and opportunities;
  - Quality objectives and planning to achieve them;
  - Planning of change;

- Support:

  - Resources;
  - Competence;
  - Awareness;
  - Communication;
  - Documentation information;

- Operation:

  - Operational planning and control;

- Requirements for products and services;
- Design and development of products and services;
- Control of externally provided processes, products and services;
- Release of products and services;
- Control of nonconforming outputs;

- Performance evaluation:

- Monitoring, measurement, analysis and evaluation;
- Internal audit;
- Management review;

- Improvement:

- Nonconformity and corrective action;
- Continual improvement.

APPENDIX II.
MANAGEMENT SYSTEM DOCUMENTS USED TO PROVIDE STRATEGIC DIRECTION FOR QUALITY ACTIVITIES

This appendix provides an example of how one UK organization has applied certain management system documents to provide strategic direction for the quality activities. These documents are identified in the Fig. 8.

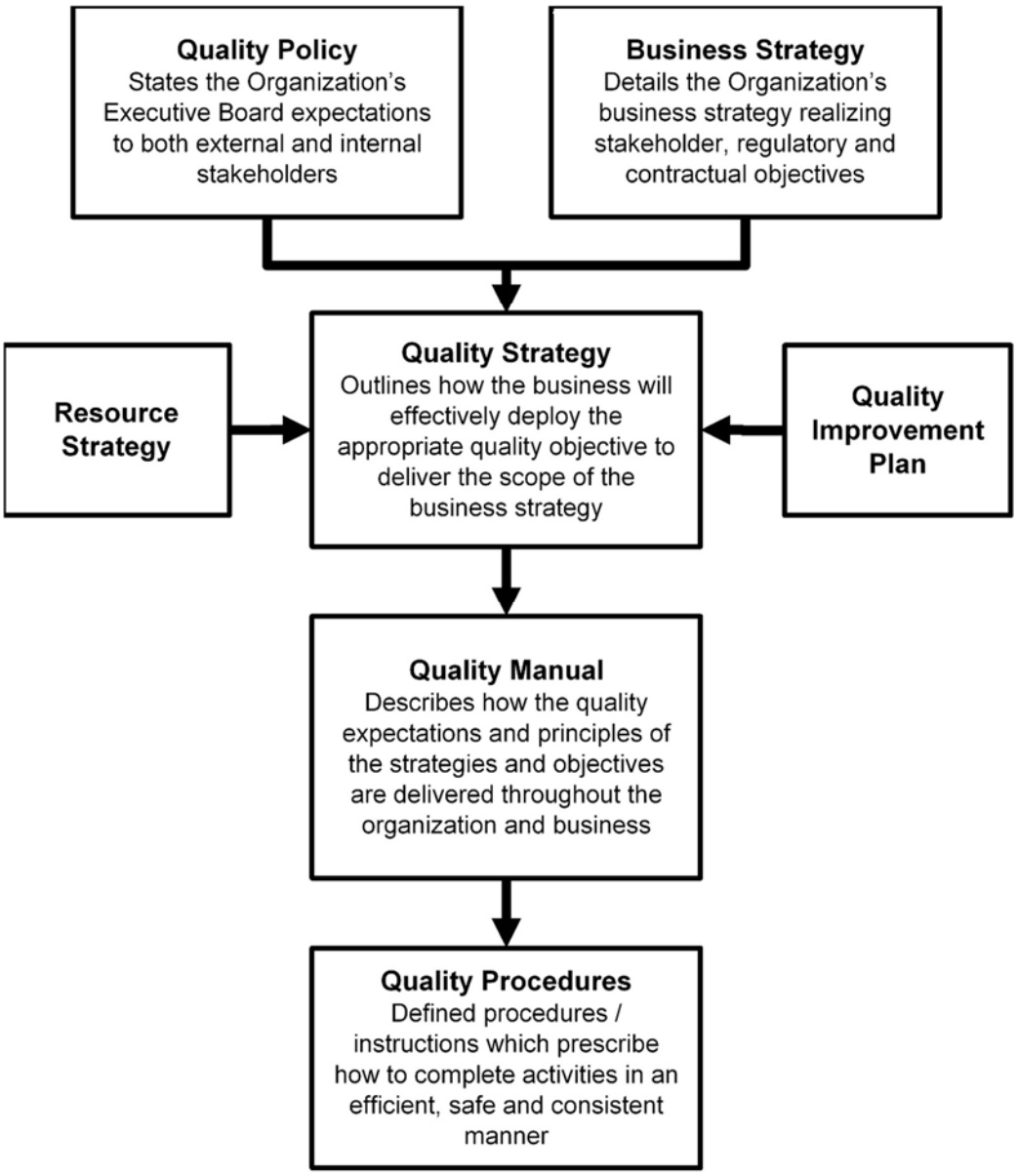

FIG. 8. Example of management system documents used to provide strategic direction for quality activities.

The content and application of some of these documents is explained below.

II.1. QUALITY POLICY

Policies which define how quality arrangements are established, documented, implemented and reviewed are an integrated part of the overall management system. The quality policy is usually the top-level document in the quality management system. The quality manual, quality objectives and quality strategy provide the framework to enable the organization to meet the commitments within the quality policy.

Those policies may be in a specific quality policy or detailed as sections within other management system policies.

Where a management system standard has defined requirements for a quality policy then that requirements need to be complied with.

Typically, a quality policy includes a series of commitments that detail how the company will deliver the quality objectives. Examples of commitments may include:

- Meet customer requirements (as a minimum) and applicable national legal and regulatory requirements;
- Enhance internal and external customer satisfaction by continually improving the delivery of our quality, fit for purpose products and services;
- Use appropriate national and international standards, certification and awards schemes and excellence and improvement tools to help satisfy customers and achieve business objectives;
- Control, assess and monitor changes to ensure the desired effect is achieved in all aspects of business activities and performance;
- Encourage innovation and improvement by providing clear and uncompromising leadership that actively promotes a positive quality culture;
- Encourage our people to work in partnership, questioning and challenging each other in pursuit of quality goals;
- Learn from bad and good experiences and rapidly put in place measures to ensure that mistakes will not be repeated, and good practices will be promoted;
- Encourage consultation at all levels in the organization to ensure that quality controls are effective and adequate;
- Ensure sufficient suitably qualified and experienced persons (SQEPs) and actively develop their quality competence; and
- Employ simple and effective management systems, which govern all aspects of our business and ensure that there is a quality aware workforce.

II.2. QUALITY STRATEGY

A quality strategy defines the short, medium- and long-term strategy for the function. It usually covers as a minimum the scope for a quality strategy defined in Section 3.2.

The depth and complexity of the strategy is typically based on the size, scope and context of the organization and its position within or with regard to the supply chain. It uses the forward-looking business strategy as one of its important components.

Typical headings for a quality strategy may include:

- Introduction;

- Purpose;
- Forward looking business review;
- Assumptions;
- Quality policy;
- Quality objectives;
- Quality organization;
- Risks;
- Key performance indicators; and
- Summary.

II.3. QUALITY IMPROVEMENT PLAN

The quality improvement plan defines those activities which will be implemented in order to improve the delivery of a quality capability across an organization. The quality improvement plan needs to be periodically reviewed and amended to ensure it reflects the up to date needs of a business.

Typical headings for a quality improvement plan may include:

- Introduction;
- Purpose;
- Forward looking business review;
- Assumptions;
- Areas for improvement;
- Implementation programme;
- Risks;
- Key performance indicators;
- Reporting; and
- Summary.

II.4. RESOURCE STRATEGY

Where appropriate a resource strategy for the function needs to be in place. This usually considers demand on the function, demographic profiles, recruitment strategies and succession plans.

Typical headings for a Resource Strategy may include:

- Introduction;
- Purpose;
- Forward looking business review;
- Assumptions;
- Resource demand;
- Short term strategy;
- Medium term strategy;
- Long term strategy;
- Implementation programme;
- Risks;

- Key performance indicators;
- Reporting; and
- Summary.

II.5. COMPETENCY MATRIX

A competency matrix covering the function is normally compiled which clearly defines the training and competence requirements for each role within the function.

The matrix usually defines the areas of competence required by quality practitioners at all levels of the organization. This list only represents typical examples and is far from exhaustive.

The scope and breadth of knowledge required for each element of competence will vary dependent on the seniority of the role and the experience requirements.

Typically, areas of competence to be defined and assessed may include:

- Management systems;
- Organization and leadership;
- Customer focus;
- Continual improvement
- Management review;
- Planning for quality;
- Quality assurance;
- Quality control;
- Validation, verification and certification;
- Management of non-conforming items;
- Supply chain oversight and assessment;
- Records management; and
- Audit and surveillance.

II.6. QUALITY MANUAL

A quality manual provides a specification for or a description of the organization's quality management system or quality assurance programme. The content, detail and format of the quality manual can vary to suit the size and complexity of the quality management system. The content is sometimes prescribed in an applicable quality management standard or by a regulator or customer. A quality manual provides a convenient medium for communicating the quality management system to interested parties.

A typical content of a quality manual includes, but is not limited to:

- The quality policy statement:

  − The quality strategy;

- The mission and objective of the organization;
- The organizational structure and outline of the management procedures;

- The arrangements for the development of detailed working documents for the performance and assessment of work;
- The arrangements for establishing a graded approach to nuclear safety;
- The level of authority and the responsibilities and accountabilities of persons and organizational units;
- The lines of internal and external communications and interface arrangements;
- The responsibilities of each organization involved in the work;
- The arrangements for training, facilities and working environment:

  − The resource strategy;
  − The competence matrix;

- The arrangements for measuring effectiveness and management self-assessment of the quality assurance programme;
- The quality improvement plan.

APPENDIX III.
EXAMPLE OF THE APPLICATION OF QUALITY ASSURANCE AND QUALITY CONTROL BY A NUCLEAR OPERATOR

This appendix describes the approach taken by a UK operator of NPPs to the application of quality assurance and quality control as a part of their management system together with the suppliers' management systems.

For activities with no direct impact on safety, or with low indirect impact on safety, quality assurance and quality control have become so enshrined in processes and procedures that specific quality assurance and quality control activities are not explicitly identified — they are accepted as the normal industrial way of working. The situation is different for higher risk activities with greater safety significance.

The type and extent of quality assurance and quality control methods applied are not identical for all but are related to the nature of the operation or activity involved and its quality assurance grade (QA Grade). QA Grade is determined using a systematic, risk-based method, discussed briefly in Section 3.7. It is based on the safety significance of the plant item or system or item on which the activity is being carried out and the potential impact on safety and other factors if the activity is inadequately carried out. QA grade 1 applies the greatest degree of assurance and quality control; QA grade 4 the least.

Responsibilities for quality assurance and quality control are allocated to persons who are competent. The processes for ensuring the competence of quality assurance and quality control personnel are not included in this appendix. Figure 9 illustrates how responsibilities for typical quality assurance activities are allocated to functions within the organization. It is necessary to note that responsibilities are not allocated to one function only but reside within areas of responsibility for processes.

FIG. 9. Responsibilities for typical quality assurance activities.

Figure 10 illustrates organizational functions or groups with responsibilities for typical quality control activities.

FIG. 10. Responsibilities for typical quality control activities.

As an example of a typical NPP process, Fig. 11 illustrates the distinction between quality assurance and quality control applied to the supply, receipt and installation of items and equipment to the NPP. This figure indicates the activities involved, but not the functions or groups that would carry them out. The functions and groups and their required competence will be determined by the nature of the item or equipment and the role that it is required to perform.

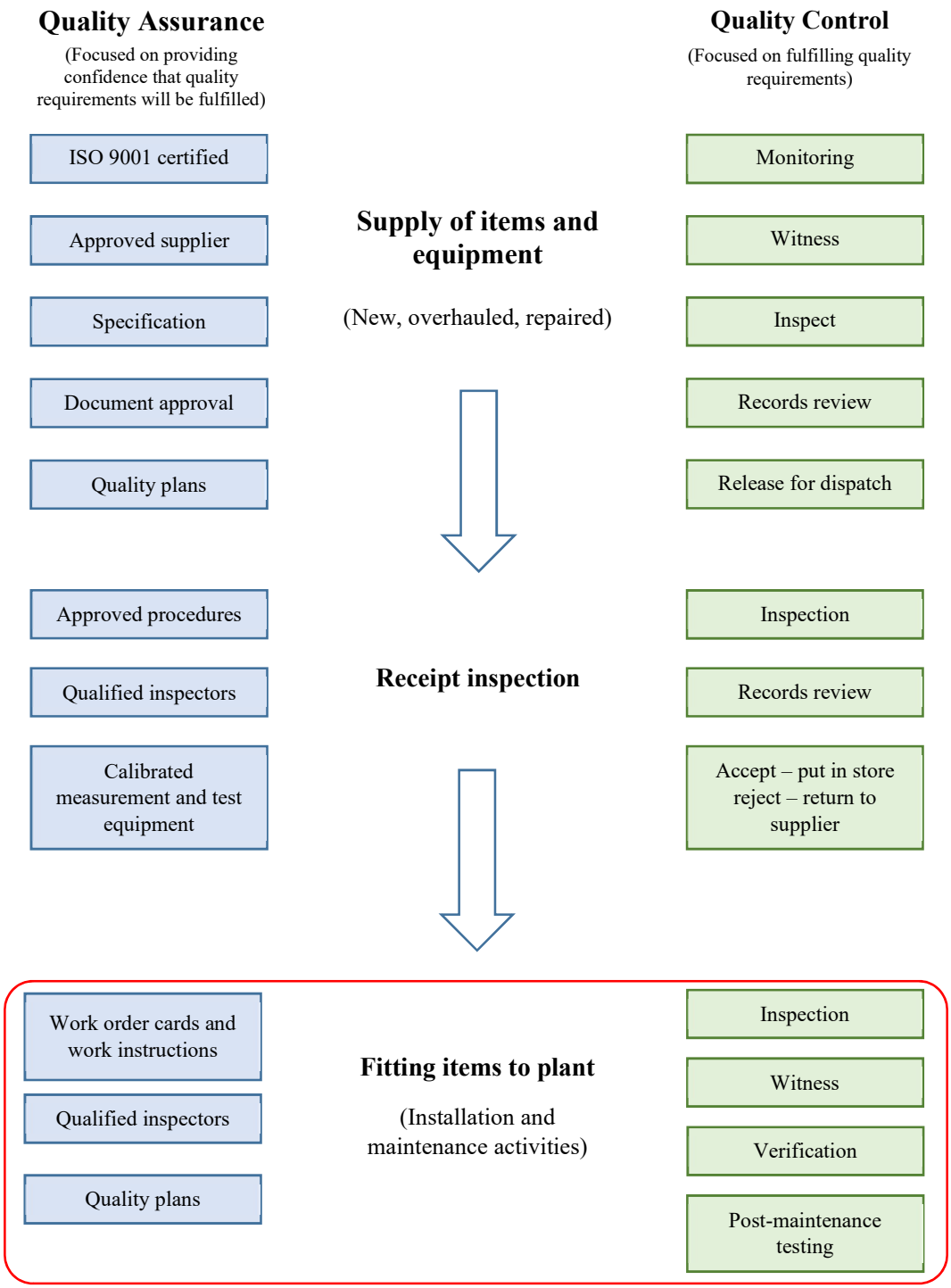

FIG. 11. Quality assurance and quality control activities associated with the supply and installation of items and equipment.

III.1. SPECIFICATION OF QUALITY ASSURANCE AND QUALITY CONTROL REQUIREMENTS

Requirements for quality assurance and quality control applied to any particular case are determined by the QA Grade. As explained previously, the QA Grade is derived from a risk assessment based upon risk to nuclear safety, people's health and safety, breach of nuclear regulatory, environment or statutory requirements, cost penalty or loss of generation. The QA Grade is the basis of the type of quality assurance and quality control activities and the rigour with which they are applied.

Two examples are provided below. Note that in these examples, some information has been withheld to protect proprietary information.

The first example relates to work control, which includes maintenance. TABLE 5 illustrates how quality assurance and quality control activities are specified to work control. Note that these requirements need to be customized and for each application. The requirements are generic, but their application is not.

TABLE 5. EXAMPLE OF SPECIFICATION OF QUALITY ASSURANCE AND QUALITY CONTROL REQUIREMENTS TO PLANT (MAINTENANCE) WORK CONTROL

No.	ACTIVITY	QA GRADE 1	QA GRADE 2	QA GRADE 3	QA GRADE 4
1	Preparation of work order cards and minor work.	Refer to (name of procedure withheld).			Work instructions to be included in the work order card or minor work as free text.
2	Review and approval of work order cards and minor work.	Self-check Review and approval completed by a minimum of 2 additional persons	Self-check Review completed by a minimum of 1 additional person:	Self-check only	
3	Preparation of work instructions and procedures	Produced to a level of detail that allows a suitably qualified and experienced person to complete the work. Specify practicable pre-installation inspection of spares.	Produced to an engineering standard that allows a suitably qualified and experienced person to complete the work		Written procedure not required. Verbal instruction to be corroborated, e.g. via drawing or action plan.
4	Approval of work instructions and procedures and their quality assurance requirements	Assigned approver			Person with document approval rights
5	Procedure use and adherence	Refer to (name of procedure withheld).			

TABLE 5. EXAMPLE OF SPECIFICATION OF QUALITY ASSURANCE AND QUALITY CONTROL REQUIREMENTS TO PLANT (MAINTENANCE) WORK CONTROL

No.	ACTIVITY	QA GRADE 1	QA GRADE 2	QA GRADE 3	QA GRADE 4
6	Competence	Work to be completed by a suitably qualified and experienced person who has successfully attained the necessary plant or plant item training.		Work to be completed by a suitably qualified and experienced person deemed sufficiently knowledgeable of the plant or plant item.	Work to be completed by a suitably qualified and experienced person.
7	Special processes	Completed to a qualified or validated procedure, using qualified and calibrated equipment. Completion of special process, e.g. welding and non-destructive testing, requires attainment of any certificates listed by the controlling code or standard.			
8	Non-conformance	Non-conformances are treated as condition reports within the corrective action programme (CAP) and are differentiated according to the criteria defined within CAP.			
9	Verification of technical support work	Independent critical examination - all significant aspects	Independent critical examination - certain specified aspects	Independent examination and judgement of fitness for purpose - (e.g. at least one calculation must be fully checked)	Self-check
	Technical review	Where technical support work is carried out by external agencies under contract and the work is to be used in a nuclear safety significant application, the requirements for a technical review shall be in accordance with (name of procedure withheld).			
10	Verification of work – observation of physical activities	Physical checks at identified points throughout the work to gain confirmation of expected results or alarm initiation /elimination. Checks defined as: 1) Self-check, completed by the person doing the work; 2) Independent check, completed at identified or key stages of the work by a suitable qualified and experienced person other than the person doing the work; 3) Hold Point, completed at significant stages by an identified nominated approver.		Self-check at identified points throughout the work to gain conformation of expected results or alarm initiation/ elimination. - Independent checks when identified.	Self-check - Independent checks when identified.

TABLE 5. EXAMPLE OF SPECIFICATION OF QUALITY ASSURANCE AND QUALITY CONTROL REQUIREMENTS TO PLANT (MAINTENANCE) WORK CONTROL

No.	ACTIVITY	QA GRADE 1	QA GRADE 2	QA GRADE 3	QA GRADE 4
11	Post maintenance testing and commissioning	Complete to documented test procedure with listed acceptance standards. Authorization to perform the test and acceptance of results verified. Results must be agreed with the Responsible Engineer / suitably qualified and experienced person.		Documented test procedure available, test observed for adequacy of performance to agreed acceptance criteria.	Observed for adequacy of performance.
12	Restoration of operational plant (authority to return to service)	Authorized by control room supervisor, documented and recorded pre-start and alignment check (where applicable). Record of post maintenance testing.		Authorized by control room supervisor.	Supervised action to daily /shift plan.
13	Records	Contents defined by work instruction and retained to demonstrate compliance, work actually carried out and spare parts used.		As specified to demonstrate compliance and spares used.	As specified to demonstrate work completion.

The second example relates to the procurement of products and services. TABLE 6 illustrates how quality assurance and quality control activities are specified for procurement activities. Note that these requirements need to be customized as they are applied to different types of items.

TABLE 6. EXAMPLE SPECIFICATION OF QUALITY ASSURANCE AND QUALITY CONTROL REQUIREMENTS TO PROCUREMENT OF PRODUCTS AND SERVICES

No	ACTIVITY	QA GRADE 1	QA GRADE 2	QA GRADE 3	QA GRADE 4
1	Materials and spares control	Identification, suitable storage environment (prescribed in the specification or by the manufacturer), inspection status identified, stock history. Physical segregation and, where applicable, material traceability appl.	Identification, suitable storage environment (prescribed in the specification or by the manufacturer), inspection status identified, stock history.	Identification, suitable storage (prescribed in the specification or by the manufacturer) environment, stock history	Identification, suitable storage environment (prescribed in the specification or by the manufacturer)
2	Selection of suppliers	Management system certified to ISO 9001 and, where applicable, ISO 14001 or suitably assessed by (name of operator withheld). For suppliers of services for nuclear safety related work see (name of procedure withheld).		Evidence of previous good performance available	

TABLE 6. EXAMPLE SPECIFICATION OF QUALITY ASSURANCE AND QUALITY CONTROL REQUIREMENTS TO PROCUREMENT OF PRODUCTS AND SERVICES

No	ACTIVITY	QA GRADE 1	QA GRADE 2	QA GRADE 3	QA GRADE 4
3	Specifications	A specification is required for all goods and services to be purchased as per requirement of (name of procedure withheld). The specifier is responsible for producing the specification. The specification shall be reviewed and approved before issue. The detail contained in the specification will vary depending upon the complexity, cost and risk associated with the item or service to be procured as per (name of procedure withheld).			
		The specification shall detail key attributes of the procured items, such as materials, dimensions, testing and operational performance requirements, that can be clearly understood by the supplier and also used to carry out receipt inspection.		A simple specification can be used which may consist of a product brand and part number for the procured item.	
4	Supplier quality plans	Quality plan is required. Marked-up with the necessary interventions (hold points, inspections, witnessing, review) by the specifier in consultation with the QA engineer as required. Quality plan to be approved by the specifier or SQEP* Procurement Engineer. Where the specifier considers that a quality plan would serve no useful purpose, e.g. simple components which are readily available and where evidence of meeting quality requirements can be assured by other records, a documented justification to proceed without a quality plan must be agreed with the station procurement engineer.		Not normally required. The requirement for quality plans is to be considered if the item is new, infrequently manufactured or complex by design or process	Not normally required.
5	In-process inspections	100 % Inspection / test of elements 'critical to quality' to be conducted by the supplier. Verification activities to be conducted as applicable by a SQEP Engineer or an Inspection Agency. Verification activities, that may include Inspections / witnessing tests / surveillance / document review, shall be as required by the Specifier and included in quality plan mark-up or, where applicable. Elements 'critical to quality' requiring inspection / test by the	Inspection / test of elements 'critical to quality' to be conducted by the supplier. Verification activities to be conducted as applicable by a SQEP engineer or an inspection agency on behalf of (name of operator withheld). Verification activities, that may include Inspections / witnessing tests / surveillance / document review, shall be as required by the specifier and included in quality plan mark-up Elements 'critical to quality' requiring	Inspection by supplier. By exception, in-process inspection by a SQEP engineer or an inspection agency on behalf of (name of operator withheld) may be requested by the specifier in the quality plan.	Inspection by supplier only.

TABLE 6. EXAMPLE SPECIFICATION OF QUALITY ASSURANCE AND QUALITY CONTROL REQUIREMENTS TO PROCUREMENT OF PRODUCTS AND SERVICES

No	ACTIVITY	QA GRADE 1	QA GRADE 2	QA GRADE 3	QA GRADE 4
		SQEP Engineer or the inspection agency to be defined by the specifier. Unless otherwise stated in the quality plan, the following applies: 100% Inspection / test of elements 'critical to quality' to be witnessed / conducted by the SQEP engineer or inspection agency. Note: If it is deemed by the specifier that in-process inspections at the supplier's works by SQEP engineer / inspection agency would not add any value to the process, the receipt Inspection of such items and verification of the supporting documentation will need to ensure that quality has not been compromised and that elements 'critical to quality' are as per requirements.	inspection / test by the SQEP engineer or the inspection agency to be defined by the specifier. Note: If it is deemed by the specifier that in-process inspections at the supplier's works by a SQEP engineer / inspection agency would not add any value to the process, the Receipt Inspection of such items and verification of the supporting documentation will need to ensure that quality has not been compromised and that elements 'critical to quality' are as per requirements.		
6	Receipt inspections	For catalogued plant spares, covered by materials management (name of procedure withheld), receipt inspection shall be in accordance with (name of procedure withheld). For non-stock goods and services, the specifier ensures receipt inspection of QAG (quality assurance grade) 1 and QAG 2 goods and services. For projects, receipt inspection shall be conducted by a nominated project engineer. Quality release certification to be defined to include release note. The specifier shall ensure that adequate verification resources are available for inspections and tests conducted at site.			
7	Document submission prior to manufacture	Supplier must provide for station approval all quality plans, nominated drawings, procedures for test and documentation required for special processes, e.g. welding, Non-destructive testing (NDT).		As required for information only.	

TABLE 6. EXAMPLE SPECIFICATION OF QUALITY ASSURANCE AND QUALITY CONTROL REQUIREMENTS TO PROCUREMENT OF PRODUCTS AND SERVICES

No	ACTIVITY	QA GRADE 1	QA GRADE 2	QA GRADE 3	QA GRADE 4
		Where a quality plan has not been requested, documents to be as specified in purchase order.			
8	Records and other documents to be provided by the supplier	Lifetime records as identified in quality plan/specification to demonstrate conformance, provide quality history including any applicable test certificates and certificates of conformance. Operating and maintenance instructions. Where a quality plan has not been requested, records and documents to be as specified in purchase order. A certificate of conformity shall be provided as a minimum.		Operating and maintenance instructions and release notes / certificate of conformity and any other certification as required by the specification.	Operating and maintenance instructions as necessary. Delivery note required.
9	Quality assurance audit	All new suppliers must be evaluated. Existing suppliers to be evaluated as determined by supply chain, specifier and/or quality assurance engineer.		Not normally required.	
10	Stores issue of components	Only against approved work order cards.		Work order number required	
11	Approval of the documentation for procurement and its quality assurance requirements.	Assigned approver		Person with document approval rights	

*Note: In this table the abbreviation SQEP stands for suitably qualified and experienced person. It is a requirement of the UK nuclear site license that only suitably qualified and experienced persons perform any duties which may affect the safety of operations. SQEP conveys the same meaning as competent person.

III.2. THE USE OF QUALITY PLANS

Quality plans play an important part in ensuring quality requirements are fulfilled. The use of quality plans is included in several parts of this appendix. There are over 35 templates for quality plans, each for a particular application.

Two examples of quality plans are included below. The first is a general use quality plan. Note that printed names and signatures of those completing the steps are required so that their competence can be checked through examination of records of training, qualification and experience.

This general quality plan template (see Table 7) is used where verification of conformity by several parties is required and several different sampling and inspection regimes are required. In some organizations, a quality plan of this type can be called an inspection and testing plan, but this name is not used by this operator.

TABLE 7. EXAMPLE OF A GENERAL QUALITY PLAN

Quality Plan

For work requiring sign-off by more than one body (for internal and supplier use)

Title:			
Description:			
Plant Class:		QA Grade	
Originated By:	Name Post	Date:	
Reviewed By:	Reviewer(s)	Date:	
Endorsed By:	Name Post	Date:	
Approved By:	Name Post	Date:	

REVISION	AMENDMENT	DATE

1 PURPOSE

Provide information as appropriate

2 SCOPE

Provide information as appropriate

3 RESPONSIBILITIES

Provide information as appropriate

4 REFERENCES

Provide information as appropriate

5 RECORDS

Provide information as appropriate

TABLE 7. EXAMPLE OF A GENERAL QUALITY PLAN

6 SIGNATORY LIST

Role	Name (print)	Signature

7 VERIFICATION CODES

KEY	CONTROL
H	Hold point[15]. No further activity may proceed until the indicated activity has been completed
A1	100% actual inspection or test
A2	Random sample inspection or test
N% A1/A2	100% initial actual inspection for N% of items, followed by sample actual inspection of the remainder
W1	100% witness inspection[16] or test
W2	Random witness inspection or test
N% W1/W2	100% initial actual inspection for W% of items, followed by sample actual inspection of the remainder
S	Surveillance of specific operation
R1	100% review of verifying documents
R2	Sample review of verifying documents
AP	Control documents/ procedures which are to be approved
X	Verifying documents which are to be retained for records
V	Verification point

[15] Hold point is a pre-determined witnessing or inspecting point in QP/ITP, beyond which work shall not proceed without the attendance of and written authorization of the purchaser's designated representative, whichever is applicable.

[16] Witness inspection (or witness point) is a pre-determined witnessing or inspecting point in QP/ITP, beyond which work may proceed, provided that the purchaser's designated representative has been formally notified in accordance with the agreed notification of readiness period.

8 SCHEDULE OF ACTIVITIES

Activity No.	Activity Description	Reference/ Specification Document	Records/ Verifying Documents	Verification Code	1st Party* Verification		2nd / 3rd Party* Verification	
					Responsible Person	Acceptance Signature and Date	Responsible Person	Acceptance Signature and Date

Completion.

All activities in this quality plan have been completed satisfactorily and the records have been stored.

Name of Responsible Person:	Signature:	Date:

Note: The default method for completion of activities detailed above is in SEQUENTIAL ORDER UNLESS OTHERWISE STATED. Out of sequence steps may be permitted under certain circumstances - refer to (name of procedure withheld) for full details.

* 1st Party — Organization conducting the work or service. i.e. (name of operator withheld) function / department, supplier or contractor.

2nd Party — Client or client's representative. i.e. (name of operator withheld) or inspection agency contracted by (name of operator withheld).

3rd Party — Independent third-party inspector / regulatory body

The second example of a quality plan (see Table 8) is one used to verify the content and adequacy of suppliers' quality plans in compliance with this operator's requirements for quality plans.

TABLE 8. EXAMPLE OF CHECKLIST FOR SUPPLIER'S QUALITY PLAN

No	Detail	Applicable?			
Quality Plan (QP) Requirements				Comments	Resolution of Comments
1	Supplier Name/Address:				
2	Has this work been completed before and has a previous quality plan been submitted? Were there any lessons learned which would be expected to be in the latest revision?	☐ Yes	☐ No		
3	Quality Plan number/identification:	☐ Yes	☐ No		
4	(Name of operator withheld) identification and order number	☐ Yes	☐ No		
5	Ensure that there is a minimum number of columns or the equivalent for: (i.e. step, activity, controlling document, mark-up columns, signature/name/date, record)	☐ Yes	☐ No		
6	All signatures on the document must be traceable to the role of the signatory. The (name of operator withheld) prefers a signature table; otherwise minimum requirement is that all names must be printed alongside each signature.	☐ Yes	☐ No		
7	Provision for wet approval signature (with printed name and date) (or equivalent electronic signature with supporting evidence e.g. email)	☐ Yes	☐ No		
8	Ensure there are enough columns for mark-up codes and sign offs Minimum is supplier and the (name of operator withheld)/3rd Party, but a third column may be required (e.g. for 3rd Party / ANI[17])	☐ Yes	☐ No		
9	Ensure that the document has a unique document number and that the revision status is shown.	☐ Yes	☐ No		
10	Ensure that where multiple quality plans are used for separate components under the same order each quality plan can be explicitly linked to the component e.g. by recording the component serial number somewhere on the plan.	☐ Yes	☐ No		

[17] Authorized nuclear inspector

TABLE 8. EXAMPLE OF CHECKLIST FOR SUPPLIER'S QUALITY PLAN

No	Detail	Applicable?			
Quality Plan (QP) Requirements				Comments	Resolution of Comments
11	Sufficient legends must be available for all mark-up codes required by the (name of operator withheld).	☐ Yes	☐ No		
12	Can the logic of the work be understood from reading the plan? Are there sufficient document references? Is it clear where subcontractors are doing the work (either to their own plan or as part of this one)?	☐ Yes	☐ No		
13	QP mark-ups should be done in conjunction with engineering and/or any other relevant departments. Basic requirements for QC (normally via the 3rd party call off contract) could be for up to four visits, depending on (for example) QA grade: 1. pre-manufacturing visit to ensure documentation, including QPs, weld procedures etc. have been approved and that any subcontractors have been identified and approved. 2. During manufacturing to check traceability, identification, procurement, certification. 3. Testing including FAT, hydro etc. Any testing that confirms the design should be considered for witnessing. 4. Final inspections, quality release, life-time record package. Refer to (name of procedure withheld).	☐ Yes	☐ No		
14	For ASME Repair / replacement activities and other activities involving a competent person (e.g. pressure regulations related, lifting etc.) discuss the plan with the local 3rd Party team regarding any mark ups they require for inspection at works. The appropriate programme coordinator should also be asked.	☐ Yes	☐ No		

TABLE 8. EXAMPLE OF CHECKLIST FOR SUPPLIER'S QUALITY PLAN

No	Detail	Applicable?			
Quality Plan (QP) Requirements				Comments	Resolution of Comments
15	For ASME work in general include steps that assure correct (i.e. to the spec) certification and traceability of materials including any reconciliations required if different version of the ASME code have been used. For the USA in particular (where Lloyds has no jurisdiction) the plan should include hold/review points for the ASME inspector (usually marked up beforehand). These include material certification, inspection against drawings, special processes, testing, review of records/quality release plus review of any design changes where applicable.	☐ Yes	☐ No		
	Other				
	Insert if relevant	☐ Yes	☐ No		
	Insert if relevant	☐ Yes	☐ No		
	Insert if relevant	☐ Yes	☐ No		
	Insert if relevant	☐ Yes	☐ No		

Date of initial QA comment submission:	

Date of final comment resolution:		
Approval		
Where applicable other affected stations are notified	☐ Yes	☐ No
Approved By: (Name) Signature: Date:	Title:	

APPENDIX IV.
QUALITY CONTROL

IV.1. DIRECT AND INDIRECT QUALITY CONTROL

As in all observations and verifications, quality control tools consist of direct and indirect actions.

IV.1.1. Direct Quality Control

Direct quality control is just as it sounds, direct observation and recording of witnessing an activity or process as it occurs. Watching a workman tighten a fastener, watching a solder joint being performed, observing a millwright measure a part are all examples of direct quality control. The recording of such direct observation may need to include factors such as the date and time of the observation, the adequacy and level of illumination, the serial number of measuring tools being utilized, the identity and number of items or activities observed, applicable controlling documents such as drawings or process control sheets, and the identity of the person performing the activity observed. These supporting details may also need to be verified and validated later, after-the-fact to make the observation complete, conforming to requirements and *free from defect*; but quality control can still be considered direct.

IV.1.2. Indirect Quality Control

Indirect quality control is usually more complicated. A quality control verifier, after the activity is complete and possibly in a separate location from where the activity occurred, needs to verify that the item or the activity was and is *free from defect and conforms to requirements.*

The following typically can all be used to conduct a reasonable non-intrusive, non-destructive examination (NDE) of the item or service to verify that the item is *free from defect and conforms to requirements*:

- Visual observation of surface conditions and manual manipulation may be involved;
- Calibrated measuring devices will most likely be used to verify dimensional acceptability;
- Visual aids such as inspection mirrors and magnifiers may be used to extend normal vision and field of view;
- Adequate or alternative lighting may be utilized;
- Visual confirmation of required markings and labelling;
- Verification of the absence of deleterious coatings or surface contamination; and
- Use of various gages and go/no-go jigs or fixture determine if parts are dimensionally correct.

In some instances, NDE and non-destructive testing (NDT) may be involved. The following can all used to determine the items are *free from defect and conform to requirements*:

- Weighing of items and parts;
- Surface examinations using magnetic particle and liquid penetrant testing to determine surface nonconformities and conditions not visible to the naked unaided eye;
- ‘Spark’ testing may be used for a rough approximation of carbon content of ferrous materials;

- Use of a magnet to determine if carbon steel versus stainless or other alloys are present; and
- Radiography and ultrasonic testing may be necessary if volumetric examination and material soundness is a required attribute.

IV.2. IDENTIFICATION OF DEFECTS

The overall quality management system will specify what actions need to be taken upon discovery of defects. These may include but not be limited to:

- Marking or tagging;
- Separating items with defects into identified batches or lots;
- Scrapping or destroying items with defects;
- Generating detailed reports of the extent of defects discovered; or
- Other measures used to assure that items discovered with defects are not processed any further until their ultimate disposition is determined.

Quality control personnel are not usually involved with the determination of the ultimate disposition of defective items. However, their responsibilities often include the initial measures to assure the separation and/or segregation to prevent any further processing or inadvertent use.

If the disposition of items with defects involves rework to remove the defects, repair to render the defects no longer defects, or other dispositions determined by the quality management system, quality control personnel may be called upon to re-inspect or re-examine the parts for defect resolution.

IV.3. QUALITATIVE AND QUANTITATIVE ACCEPTANCE CRITERIA

In all cases, quality control personnel cannot conduct their examination of items or activities without some specified acceptance and rejection criteria. These criteria may be qualitative or quantitative. Some examples of each follow.

IV.3.1. Examples of qualitative acceptance criteria

- No weld repairs;
- General good workmanship;
- Uniform coating or galvanizing;
- No rough edges;
- All labels and markings are legible; and
- All fasteners are at least finger tight.

IV.3.2. Examples of quantitative acceptance criteria

- No more than x numbers of porosity(s) greater than 1/32” in diameter per square inch;
- No surface defect greater than 10% wall thickness;
- No weld undercut > 1/32” per inch of weld; and
- No dimensional nonconformity under or overrun > 10% in any direction.

These are just a few examples of what could constitute a ‘defect’ that quality control personnel are required to identify. The source of the defect, the severity of the defect, and the ultimate

disposition of the defective items are not within the responsibility of the quality control personnel; only the identification and control of further processing.

IV.4. COMPETENCIES OF QUALITY CONTROL PERSONNEL

Since the examination techniques and the use of inspection aids and testing equipment and in many instances, the interpretation of observed results requires the application of judgement, quality control personnel need to have certain demonstrated competencies:

- The first of these is physical capabilities:

  - Demonstrated visual acuity — with or without corrective lenses is a necessity. Use of simple Jaeger J-1 eye test charts, administered by a certified practitioner is typical but technological advance in eye exams may be substituted if the management system allows;
  - Colour discrimination is also a requirement as many non-destructive examination methods rely upon colour and contrast discrimination; and
  - Sufficient physical capability is required as many types of after-the-fact verifications require some manual dexterity and ability for access to provide an adequate visual field of view;

- The second attribute is training and education:

  - All inspection techniques including simple visual and dimensional inspection require some level of formal instruction on adequate illumination, use of visual measuring devices, selection of appropriate measuring devices; and
  - More advanced non-destructive examination equipment such as magnetic particle testing (MT), penetrant test (PT), ultrasonic testing (UT) and Radiography require specialized training in the safe use of the testing equipment and interpretation of results;

- The third element of competency is testing:

  - Written and/or oral testing on the critical attributes and applicable precautions and limitations of the method being demonstrated;

- The fourth element of competency is demonstration of capability:

  - Training programmes for any quality control position require a capability demonstration; and
  - Using predetermined samples with known defects, the quality control personnel needs to demonstrate their ability to locate and evaluate the defects. This may be against qualitative and qualitative criteria appropriate for the method being demonstrated;

- The last element of competency is documentation of experience:

  - Related experience in activities subject to quality control are often used in evaluation of initial classification of inspectors. For example, a welder who has worked under a programme that included quality control has general knowledge of acceptable attributes of welding, this experience is direct and relatable and could

give him/her an advantage in examination and evaluation of defects in weldments; and

- Previous certifications in inspection and testing or completed formal education in inspection methods or related technologies can also be used to determine capability.

Proven quality control qualification programmes have followed a traditional model of classifying inspectors by different levels. This may not be a general requirement, but typically:

- A level 1 quality control inspector has completed the necessary training appropriate for the method they will be using and has less than five years' experience performing inspections under the supervision and control of a level 2 inspector. He/she is capable of recording results against relevant acceptance criteria. Final acceptance and evaluation of their results are by the supervising level 2;

- A level 2 inspector has more than five years combined experience and/or formal education in the method being certified, has completed the required training and can perform and evaluating the results and accepting the results of the method of quality control inspection being certified to. He/she is also able to supervise and accept the results of a level 1 inspector; and

- A level 3 inspector has more than ten years of combined experience and or formal education in the methodology being certified, is capable of training and testing and certifying level 1 and level 2 inspection personnel, writing inspection procedures and evaluating disputed results and making final determinations of defects. By organizational arrangement there is typically only one level 3 per inspection methodology in an organization to establish a path for appeals and ultimate decision making.

Other areas where specific technical skills associated with quality control are needed include non-destructive testing (NDT), metrology, statistical process control, or product specific quality control skills. The application of NDT techniques is dependent on the nature of the product and the associated specification.

Most commonly applied NDT techniques typically include:

- Visual inspection;
- Dye penetrant inspection;
- Magnetic particle inspection;
- Radiography; and
- Ultrasonic testing.

This list is not exhaustive and is only intended as a guide to the most common techniques that are applied and require some form of demonstrable competence in the technique.

APPENDIX V.
EXAMPLE OF SUPPLIER QUALITY PERFORMANCE ASSESSMENT

V.1. INTRODUCTION

This appendix gives an example of supplier evaluation[18] in one company. The purpose of the supplier evaluation is to increase quality of delivery provided by suppliers and to use the results of the evaluation in the qualification system and in awarding contracts.

Supplier evaluation can be performed for works such as products and services, as well as supply of materials. For material related to quality plans and supplier qualification, see Appendix III.

Specific criteria are defined for each product/service/material (merchandise) group[19].

V.2. SUPPLIER EVALUATION

V.2.1. Subject of the Evaluation

Service contracts, maintenance and work contracts normally are subject to supplier evaluation process considering a graded approach.

V.2.2. Evaluation Frequency

The contracts are evaluated after the expiry of the contract, where long-term contracts with the duration longer than one year are evaluated also continually on annual basis, after each anniversary date of the contract.

V.2.3. Evaluation Time

The evaluation is carried out after the end of each quarter. All the contracts which expired in the previous quarter or had the anniversary date will be included into evaluation.

It is also possible to include the contract into the evaluation process, which was already closed and evaluated; however, it is needed to take into consideration defects occurred during the warranty period.

V.2.4. Evaluators[20]

As an example, the following functions can take part in the process of evaluation of contracts:

- Buyer/procurement specialist;
- Unit manager[21];

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[18] The process of assessing supplier in terms of its compliance with Customer´s requests and contractual terms and conditions based on defined objective evaluation criteria and method of their evaluation.
[19] Merchandise group is a category of goods/services/works in terms of characteristic features and the method of their usage.
[20] Role or unit taking part in the supplier evaluation.
[21] Manager of the unit who requested concluding of a contract in the procurement process, or a person authorised by the manager. The unit manager ensures evaluation of the contracts on behalf of his/her unit.

- Contract manager[22];
- Safety and environment; and
- Quality assurance.

For materials:

- Buyer; and
- Material management specialist.

V.2.5. Evaluation Criteria[23]

V.2.5.1. Works and services

Evaluation of the quality of supplier´s contractual deliveries can be expressed in terms of the compliance with contractual requirements related to the contract subject-matter. The following quality items can be evaluated.

See example of evaluation criteria in TABLE 9.

TABLE 9. EXAMPLES OF CRITERIA FOR SUPPLIER EVALUATION

Quality items	Code	Weight*
• Quality Compliance (Compliance of the performance with the technical specification, presence of shortcomings, claims, supplier´s approach to problem solving, coordination of sub-suppliers, etc.)	PQ	50
• Compliance with Environmental Requirements (Impact of the supplier´s performance on the environment; fulfilment of the supplier´s notification obligations in line with the contractual requirements in the field of the environmental protection)	PE	20
• Staffing and Technical Equipment (Professionalism, education, skills, experience and number of supplier's personnel available for performance; quality, range and usability of the material and instrumental equipment of the supplier)	PM	30

* Percentage of the weight (Pi) may be defined differently depending on the merchandise group under evaluation.

The quality value is calculated as weighed average of evaluated items (Pi) that compose it. The formula (1) for evaluating of the criterion is as follows:

$$CQ = \sum_{i=1}^{n} p_i \cdot P_i \qquad (1)$$

Evaluation of a supplier's Industrial safety performance can be expressed in terms of compliance with occupational health and safety (OH&S) requirements, fire protection requirements, radiation protection and nuclear safety requirements.

[22] Manager stated in the contract as a person authorised to act on behalf of Customer in matters of delivery, or a person authorised by the Contract Manager.
[23] An evaluation criterion is a category of the supplier rating which is a part of the index vendor rating.

It is recommended to evaluate the following areas:

- Documentation (project documentation in terms of the safety, OH&S Plan, technological procedure, safe working procedure, training documentation, documents on professional qualification and health capability, work permits, etc.);
- Personal protective equipment (PPE) (allocation of the suitable personal protective equipment, technical conditions of the PPE, use of PPE by supplier´s employees);
- Technical conditions and usage of the working equipment (machines, devices, apparatus, equipment) and aids; and
- Observing of the safety requirements, rules, instructions and procedures during execution of works.

This criterion is not evaluated if the performance is provided outside the premises or if the performance is of intellectual nature.

Punctuality and completeness express the evaluation of suppliers' performance linked to observation of the contractual deadlines and completeness of performance. It is necessary to take into consideration a potential need of cooperation by customer in order to meet the deadline, utilization of urgency, as well as timeliness of complaint solving.

Procurement correctness expresses the approach of the supplier during procurement process, particularly acceptance of the standard contractual terms and conditions, transparency in price offer, etc.

V.2.5.2. Materials

Delivery reliability[24] expresses the share of the complete and timely deliveries of materials compared to the total delivery.

Procurement correctness expresses the approach of the supplier during procurement process particularly acceptance of the standard contractual terms and conditions, transparency in price offer, etc.

V.2.6. Evaluation range

V.2.6.1. Works and services

Fulfilment of the individual criteria/items is evaluated by allocation of the values from the following range: 1, 2, 3, 4, 5, N/A. The individual values have the following meaning.

Instructions concerning the evaluation of individual criteria are stated in TABLE 10.

TABLE 10. EXAMPLES OF VALUES FOR SUPPLIER EVALUATION CRITERIA

Value	Description	Score
5	higher than expected	110
4	full compliance with the contractual requirements	100

[24] An indicator, which reflects the ability of a supplier to deliver on time and completely

TABLE 10. EXAMPLES OF VALUES FOR SUPPLIER EVALUATION CRITERIA

Value	Description	Score
3	predominant compliance with the contractual requirements	70
2	partial compliance with the contractual requirements	40
1	non-compliance with the contractual requirements	0
N/A	evaluation not applicable	-

V.2.6.2. Materials

The criterion Delivery reliability is assessed by comparing the requested date of delivery falling within the evaluation period and the actual date of delivery of each item. If the actual date of delivery is max. 3 days later than the requested date of delivery, evaluation mark of such item will be 100. Otherwise, the evaluation mark of the respective item will be 0. In case the item was supplied in multiple deliveries, the latest date of actual deliveries is taken into account.

The criterion procurement correctness is evaluated in the same way as for works and services.

V.2.7. Evaluation of each criterion

Suppliers' evaluation is made by filling in the evaluation questionnaire, except for the criteria procurement correctness and delivery reliability. The criterion procurement correctness is evaluated by the buyer. The outcome of the criteria delivery reliability is calculated as the arithmetic average of the evaluation marks for individual items.

V.2.8. Calculation of index vendor rating

Index vendor rating[25] (IVR) is the result of the supplier evaluation process for the period under evaluation. Different weighted averages are used depending on the subject evaluated. Examples are shown in TABLE 11.

TABLE 11. EXAMPLES OF WEIGHT FACTORS FOR DIFFERENT SUBJECTS

Criterion	Code	Weight for services and maintenance	Weight for works	Weight for materials
Quality	IQ	40	30	N/A
Safety	IS	30	25	N/A
Punctuality and completeness/Delivery reliability *	LI	20	35	90
Procurement correctness	IC	10	10	10

[25] Overall indicator of supplier evaluation that expresses the level of performance provided during the evaluated period.

* refers to materials only

The formula (2) for the calculation of the supplier IVR is as follows:

$$IVR = Pq \cdot IQ + Ps \cdot IS + Pp \cdot LI + Pc \cdot IC \quad (2)$$

where (*Pq, Ps, Pp, Pc)* represent numerical values of 'weights' of the individual criteria.

(IQ, IS, LI, IC) represent points achieved in evaluation of the individual criteria.

Providing that evaluation of any criterion is not applicable, the formula for IVR calculation will automatically redistribute weights of the individual criteria so that the summary of weights equals to 100.

V.2.9. Actions with IVR

Based on the calculated IVR value, the evaluation mark is assigned to the supplier according to TABLE 12; depending on the evaluation mark the following actions may be taken against the supplier.

TABLE 12. EVALUATION MARK WITH IVR

IVR materials	IVR works and services	Evaluation mark	Potential consequent measures
>100≤110	>80≤110	Satisfactory	Prolongation of the contract • Advantage in the tender
>85 ≤100	>60 ≤80	Satisfactory with reservations	Asking the supplier to take corrective actions to improve the performance • Suspension of qualification
>0 ≤85	>0 ≤60*	Unsatisfactory	Including the supplier in the list of excluded suppliers • Termination / suspension of qualification

* Even if only one of the evaluated criteria has the evaluation mark lower than 60, it is possible to consider it a knock-out (KO) criterion and apply the measures against supplier which are linked to the final mark 'satisfactory with reservations' and 'unsatisfactory'.

V.2.10. Suppliers' IVR

If an association of suppliers is evaluated, the IVR is attributed to the supplier who delivers the largest number of items or who was authorized as the main supplier by the association. If the association of suppliers is based on equal position, IVR is attributed to each supplier.

V.2.11. Average IVR

After calculating the IVR for the current evaluation period, the average index vendor rating (AIVR) will be calculated as an average of all the achieved evaluation marks over the last three years.

V.3. KEY LEARNING POINTS

Introducing more specific and complex criteria for evaluation (see Table 13) can help to achieve more accurate results while using different competences in the evaluation process increases its objectivity. At the same time, it is always important to maintain the evaluation transparent.

Proper evaluation of supplier's performance together with qualification process and results of quality assurance supplier's audits and other tools provide basis for keeping an up-to-date approved (qualified) suppliers list.

Keeping historical records regarding supplier's evaluation enables detecting improving or declining trends in their performance.

TABLE 13. EXAMPLE OF THE EVALUATION CRITERIA

CRITERION			
Punctuality and completeness			
	Scale	*Instructions for evaluation*	
1. Respecting the deadlines and completeness	• exceptional • yes • mostly yes • partially yes • no	<u>When selecting from the scale, assess the following aspects:</u>	
		• Observance of the contract dates • Customer's cooperation needed beyond the scope of the contract • Reminders by customer • Complaint settlement within the specified period	
		<u>The following situations can be included:</u>	
		exceptional	• Delivery of the whole performance scope in advance, which affected the performance result (i.e. if the earlier date was achieved based on customer's request or performance was delivered earlier on supplier's own initiative).
		yes	• Delivery of the whole performance scope on time (including the case when for reasons on the part of customer, the date of delivery was postponed in the form of an amendment to the contract).
		mostly yes	• Occurrence of a delay in case of several deliveries during the evaluation period. • Delay of partial terms (milestones), however the final deadline was met. • Customer’s cooperation needed for deadline observance (consulting, instructions...). • Reminders by customer needed (sporadic).
		partially yes	• Occurrence of several delays in case of several deliveries during the evaluation period. • Customer’s cooperation needed for deadline observance (participating in the execution of the contractual performances by customer workers, which was not agreed in the contract). • Delay in performance completion with a low-serious impact on operation or on continuing in further performance.
		no	• Delay in performance completion with an impact on operation or beginning of use, or on continuing in further performance. • A failure to complete the performance or a failure to deliver a complete performance.

<table>
<tr><td colspan="4">Quality</td></tr>
<tr><td></td><td>Scale</td><td colspan="2">Instructions for evaluation</td></tr>
<tr><td rowspan="5">2. Quality compliance</td><td rowspan="5">• exceptional
• standard
• with small reservations
• with serious reservations
• not acceptable</td><td colspan="2"><u>When selecting from the scale, assess the following aspects:</u></td></tr>
<tr><td colspan="2">• Observance of all performance requirements according to the contract
• Supplier's approach to problem and request solving (observance of deadlines, flexibility, communication)
• Defects and shortcomings during performance or during the warranty period
• Respecting the supplier's contractual duties related to subcontractors (e.g. a subcontractor used for contract performance without the customer’s consent or a subcontractor used for other part of performance or to a scope greater than specified in the contract; the permitted number of subcontractor levels exceeded; a failure to pay the subcontractor for the performance executed for customer)
• Performance of the subcontractors — shall be regarded as the performance done by the contractor
• Quality assurance system (QMS) requirements fulfilment (quality plan, applying of foreign material exclusion (FME) into the processes and practical application in the order) — evaluate only in case of quality category 1, i.e. subjects related to classified equipment or subjects with impact on nuclear safety
• QMS audit results and audit requirements fulfilment — this aspect shall be evaluated by the quality unit</td></tr>
<tr><td colspan="2"><u>The following situations can be included:</u></td></tr>
<tr><td>exceptional</td><td>• The subject was delivered in compliance with the contract and at the same time, the approach to problem and request solving was beyond expectation.</td></tr>
<tr><td>standard</td><td>• The subject was delivered in compliance with the contract (including the requirements on QMS) and at the same time, the supplier's approach to the fulfilment of duties and solving of problems and shortcomings related to the contractual performance was satisfactory (observance of deadlines, flexibility, communication, adherence to duties related to subcontractors).</td></tr>
<tr><td>with small reservations</td><td>• During the provision of performance or takeover of performance or during the warranty period, customer identified small quality defects and at the same time, the supplier's approach to the fulfilment of duties and solving of problems and shortcomings related to the contractual performance, or to the solving of complaints and remedy of defects, was satisfactory (observance of deadlines, flexibility, communication).
• In QMS there occurred some shortcomings e.g.: quality plans were assessed with comments, applying of FME principles by the supplier in the documentation and in the execution of the order was with comments.
• Based on the audit the supplier was ‘included with comments’.</td></tr>
<tr><td></td><td></td><td>with serious reservations</td><td>• During the provision of performance or takeover of performance or during the warranty period, customer identified small quality defects and at the same time, the supplier's approach to problem solving was unacceptable (observance of deadlines, flexibility, communication).</td></tr>
</table>

Quality			
	Scale	*Instructions for evaluation*	
			• Shortcomings in QMS e.g.: quality plan assessed with critical comments and request for redrafting, applying of FME principles by the supplier in the documentation and in the execution of the order was with critical comments. • During the provision of performance, customer identified serious shortcomings in quality, which the supplier removed. • To reach the required quality, customer's cooperation and collaboration exceeding the agreed scope was necessary. • The takeover protocol contained defects that do not prevent performance use and are not caused by customer. • Based on the audit the supplier was 'included conditionally'. • Defects were identified during the warranty period and at the same time, the supplier's approach to the solving of complaints and remedy of defects during the warranty period was **unacceptable** (observance of deadlines, flexibility, communication). • The supplier failed to adhere to any of the duties related to subcontractors.
		not acceptable	• During the provision of performance, customer identified serious shortcomings in quality. • Defects were identified during the warranty period, which were not eliminated. • Performance was not capable for take-over on the date of takeover due to existence of serious defects preventing performance use, in consequence, the performance was refused and was not taken over at all. The performance was taken over despite poor quality (price discount was applied, defects were removed by ourselves). • Shortcomings in QMS e.g.: quality plan assessed as unacceptable, applying of FME principles by the supplier in the documentation and in the execution of the order was assessed as unacceptable.
3. Staffing and technical equipment	• exceptional • standard • satisfactory with reservations • with reservations • not acceptable • N/A	<u>When selecting from the scale, assess the following aspects:</u>	
		• Competence, education, skills, experience and number of workers available to the supplier for the performance • Quality, scope and usability of material and technical equipment available to the supplier	
		<u>The following situations can be included:</u>	
		exceptional	• competence (education, practice) or provided capacities exceeded the minimum requirements of customer • the technical equipment used exceeded the minimum specified requirements of customer

Quality			
	Scale	*Instructions for evaluation*	
		standard	• during the contract performance, the supplier had adequate personnel and knowledge • during the contract performance, the supplier had adequate material and technical equipment
		satisfactory with reservations	• single or less serious shortcomings in personnel or qualification • single or less serious shortcomings in material or technical equipment
		with reservations	• repeated or serious shortcomings in personnel or qualification • repeated or serious shortcomings in material or technical equipment
		not acceptable	• during the contract performance, the supplier had non-satisfactory personnel and knowledge • during the contract performance, the supplier had non-satisfactory material and technical equipment
		N/A	• No performance was delivered during the evaluated period (from a general or open contract). • Performance was executed out of the customer's premises.
4. Environmental compliance	• yes • no, without a negative impact • no, with a negative impact • N/A	<u>When selecting from the scale, assess the following aspects:</u>	
		• The environmental impacts of supplier's performance execution • The fulfilment of the supplier's notification duties in accordance with the contractual requirements for environmental protection	
		<u>The following situations can be included:</u>	
		yes	• the supplier did not violate any duty and met all the contractual requirements for environmental protection
		no, without a negative impact	• e.g. failure to fulfil some of the notification duties (including the requirements for marking of chemical substances etc.)
		no, with a negative impact	• damage incurred to customer as a consequence of supplier's duty violation; • a fine imposed on customer by state administration bodies for the environment, which was caused by the supplier
		N/A	• No performance was delivered during the evaluated period (from a general or open contract). • Performance was executed out of the customer's premises.

<table>
<tr><td colspan="4">Industrial Safety (Nuclear safety, Radiation protection, Operational Health and Safety (OH&S), Fire protection (FP))</td></tr>
<tr><td></td><td>Scale</td><td colspan="2">Instructions for evaluation</td></tr>
<tr><td rowspan="8">5. Industrial Safety compliance</td><td rowspan="8">• exceptional
• yes
• mostly yes
• with reservations
• no
• N/A</td><td colspan="2"><u>When selecting from the scale, assess the following aspects:</u></td></tr>
<tr><td colspan="2">• Documentation (project documentation, OH&S plan, technological procedure, safe work procedure, training documentation, documents on professional qualification and health capability, work permits, etc.)
• Personal protective equipment (allocation of the suitable personal protective equipment, technical conditions of the PPE, use of PPE by supplier´s personnel)
• Technical conditions and usage of the working equipment (machines, devices, apparatus, equipment) and aids.
• Observing of the safety requirements, rules, instructions and procedures during works.</td></tr>
<tr><td colspan="2"><u>The following situations can be included:</u></td></tr>
<tr><td>exceptional</td><td>• the supplier ensured excellent provision of the safety requirements beyond the contractual requirements and legislative requirements (identified best practice), the supplier proposed /recommended implementation of the measures to customer to improve the safety</td></tr>
<tr><td>yes</td><td>• the supplier did not breach any duty and met all the requirements from the contract and respective legislative rules</td></tr>
<tr><td>mostly yes</td><td>• rare occurrence of small shortcomings with impact on safety with prompt reaction of the supplier (immediately removed), the shortcomings of the same kind do not repeat anymore</td></tr>
<tr><td>with reservations</td><td>• repeated occurrence of shortcomings with the impact on safety, occurrence of a recorded occupational injury due to insufficient ensuring of the safe contractual performance by the supplier</td></tr>
<tr><td>no</td><td>• damage to customer due to breaching of duties by supplier with the impact on safety; imposing of the penalty to customer by the supervisory authorities caused by the supplier, presence of shortcomings classified as ‘severe’, ‘very severe’, or ‘extremely severe’ in line with the contractual terms and conditions, occurrence of fire, registered occupational injury, including an occupational injury resulting in serious bodily harm or a fatal occupational injury due to insufficient ensuring of the safe contractual performance by the supplier</td></tr>
<tr><td></td><td></td><td>N/A</td><td>• No performance was delivered during the period under evaluation (from a general or open contract).
• The performance was done out of the customer’s premises.</td></tr>
</table>

<table>
<tr><td colspan="4">Procurement correctness</td></tr>
<tr><td></td><td>Scale</td><td colspan="2">Instructions for evaluation</td></tr>
<tr><td rowspan="8">6. Approach in tender and respecting contractual requirements</td><td rowspan="8">• exceptional
• yes
• with small reservations
• with reservations
• no</td><td colspan="2"><u>When selecting from the scale, assess the following aspects:</u></td></tr>
<tr><td colspan="2">• Behaviour/approach of the supplier during the tender
• Price offer transparency
• Observance of the standard contractual conditions
• Observance of deadlines related to contract conclusion</td></tr>
<tr><td colspan="2"><u>The following situations can be included:</u></td></tr>
<tr><td>exceptional</td><td>• e.g. the supplier provided information beyond the required extent or gave proposals for improvement of the technical or economic solution;</td></tr>
<tr><td>yes</td><td>• supplier´s approach to the fulfilment of requirements was satisfactory (meeting deadlines, flexibility, communication)</td></tr>
<tr><td>with small reservations</td><td>• supplier´s approach to the fulfilment of requirements was satisfactory with minor reservations (e.g. the supplier asked for extending the period, or an urgency was needed, or the supplier commented conditions which were not allowed for commenting, or some formal shortcomings occurred)</td></tr>
<tr><td>with reservations</td><td>• the supplier was a troublemaker when fulfilling the requirements (e.g. not respecting deadlines, the offer had several formal defects, or the supplier was not prepared and asked for explanation of information already included in the documents, or the supplier refused contractual terms and conditions which he did not comment when submitting offer)</td></tr>
<tr><td>no</td><td>• e.g. misuse of negotiation position in price-setting or in contractual terms and conditions, or unwillingness to agree on compromise solutions or disregarding of deadlines</td></tr>
</table>

APPENDIX VI.
EVALUATION, ASSESSMENT AND REVIEW OF QUALITY

VI.1. QUALITY EVALUATION APPROACHES

The simple management concept of plan-do-check-act (PDCA) model was modified by William Edwards Deming [21–23].

Deming, an American statistician, used the PDCA concept in contributing to the total quality management effort in post-World War II Japan. An organization plans its work (‘plan’) and then implements it (‘do’). While doing the work, checks of the work and the work processes are performed (‘check’). Gaps between the work/product and the governing procedures, specifications and customer satisfaction are also then identified (‘check’). Improvements to act on the gap between reality and the expectations are determined (‘act’). The improvements are planned and the PDCA cycle starts over. PDCA, sometimes referred to as PDSA (plan-do-study-act), remains the foundation of current day management systems.

Audits and assessments are part of the checking phase. Systematic, structured checks are performed to ensure that processes and the products and services from those processes meet the planned arrangements and customer requirements. The focus of audits and assessments is on the work processes and not on people. The plans and purpose of using audit and assessment results for improvement, and not punishment or blame, need to be defined and communicated to the organization.

For an assessment programme to be successful, senior management actions require to engage, enable, encourage, support and recognize employees for participating in assessments. Resources and time must be provided for staff participation. Often, self-assessment, internal and external independent assessments and management review are seen as the important processes for measurement, assessment and improvement [7].

VI.1.1. Self-assessment and quality system assessments

Self-assessments develop a culture where individuals are providing a critical evaluation of their own work in order to understand the method and its purpose. Assessments may be performed by a team or an individual with a focus on everyday work activities and practices that usually under the assessor’s control or are part of their everyday work activities. Assessments are narrow in scope and normally short in duration. A procedure or procedure checklist is usually used as the standard for compliance.

An example of a self-assessment is comparing a work activity, such as a motor oil change, against the procedure and/or a work order. Also, discussing in groups based on the experience obtained is useful to improve work. There may be occasions when people that perform a routine task vary from the procedure and requirements. A focused assessment is a tool to identify these variations. Results from assessments are indicators regarding to the health of a process or activity.

The purpose of an assessment programme needs to be defined and reinforced by senior management through communication and behaviours. Senior management provide support to the worker levels of the organization to select and perform assessments that are beneficial to the safe operation of the facility. Results from the assessment are to be shared as lessons-learned

and operating experiences. Instances of non-conformity and practices that may be averse to good quality need to be entered into a corrective action system.

Training needs to be available within the organization on the scope and purpose of self-assessments. The training could include a methodology for selecting an assessment area as well as how to perform the assessment. Behaviours of those doing the assessment as well as those being assessed are an integral part of it. Assessments are a tool for improvement and not as a mechanism to place blame.

VI.1.2. Management review

The involvement and commitment of senior management provides the foundation of a successful management system. Positive leadership from the highest level of the organization is essential for a culture that improves based on lessons-learned from within and from outside the organization.

The schedule, status and results of these activities will be part of frequent, regularly held management reviews. Corrective analysis and subsequent actions for nonconformities and areas/activities that are potentially of poor quality will be monitored at the highest level of the organization. Management review will consider performance measures such as completion time of cause analysis and timeliness in completing subsequent actions. Improvement areas are identified as a part of the review. Management review will also include periodic review of trends such as repeat findings, common topics, common occurrence areas, common causes and good practices.

In regard to audits and assessments, senior management will select the areas and processes to be audited and assessed (See next). In some organizations, a core set of functional areas such as operations or radiation protection will be the subject of an annual audit. Other areas will be selected based on performance indicators and operating experiences.

VI.1.3. Independent assessment and internal and external quality audits

Internal quality audits are performed by an independent group on processes and work activities. These audits focus on procedure compliance, process output and customer satisfaction. The results of audits often include identification of good practices, opportunities for improvement and non-conforming or potentially non-conforming conditions. Audit results are analysed for resulting actions to improvement the process thus preventing recurrence of the findings.

Compliance-based audits are focused on whether a (quality related or any other) process is being performed in accordance with formalized instructions such as guidelines, standards, procedures, specifications and policies. Customer-focused audits are based on the satisfaction and needs of the customer or those that are impacted by the output from a process. Risk-based or risk-informed audits focus on whether the effort is put to the most significant activities from organizations risks point of view.

Three types of audits/assessments/evaluations exist:

- Internal audits (first party) — Auditors performing internal audits are employed by the organization being audited. These auditors can be employees of or contractors to the power plant operator. The auditors are trained and certified in accordance with quality requirements of the organization. The focus of these audits are processes internal to the organization;

- Supplier audits (second party) — A supplier audit is when an organization audits a supplier of products and services to ensure that the supplier is providing the works within the requirements of the contract. The purchase documents contain the quality requirements for the supplier, for example in form of a quality plan - or inspection and testing plan. An example is where a facility audit team may audit the fabricator of transformer bushings to ensure that the parts and work practices are in-compliance with the purchasing documents; and

- Independent audits (third party) — An organization requests an independent audit when it desires to either show high quality by using a third party. Sometimes, the aim may also be to be certified to a standard or surveillance of continued conformance with it (such as ISO 9001) [16]. Independent auditors from an inspection organization or a certification body perform the audit. For certification and re-certification purposes, the certification body normally needs to be accredited by a national accreditation body.

The audit workflow most often includes assembling the team of auditors, detailed planning, informing of the party to be audited (also a request by the originator may have been received), performance of the audit using a pre-defined rubric or checklist, the detailed documenting of conclusions and, if necessary, allowing for a response and follow-up. Auditors are suitably trained, experienced and qualified persons independent of the process or area to be audited. The individuals to be audited can be the owner(s) of processes, users of processes or those whose work is affected by a given process.

Audit results are documented and can include findings which indicate the deviations from expectations or non-conformances. Improvement, or corrective actions in the audited area, is normally made by means of the closure of findings and subsequent review of the effectiveness of their implementation, typically during the next scheduled audit, but sometimes earlier in the case of severe findings.

VI.1.4. Independent oversight

Independent oversight at corporate level provides senior management — up through the chief executive officer — with an ongoing perspective of actual status, risks or compliance in the corporate organization. Independent oversight is normally carried out by an internal audit or internal compliance function that is independent of operations and other functions. This is mostly done by performing evaluations, inspections, investigations, audits and assessments of performance based on legal and other relevant requirements, and thus by identifying gaps and areas for improvement. Independent oversight works as an additional barrier to quality assurance in defence-in-depth against all kinds of deviations.

The mission of independent nuclear oversight is to identify opportunities for improvement in sustained performance in nuclear facilities and activities, provide independent nuclear safety assessment (if not defined elsewhere), give standpoints into causes and contributors of deviations, non-conformances or events, to promote continual improvement as well as support achieving excellent results in the areas defined in its scope.

Independent nuclear oversight provides plant and the company management with an independent assessment of the operational performance to identify areas for improvement and propose corrective actions. It cooperates with external experts on key aspects of nuclear plant performance, reliability and nuclear safety. Independent nuclear oversight personnel conduct evaluations, inspections, investigations, audits and assessments of performance to verify

nuclear safety standards and regulatory requirements are met and to identify shortcomings and areas for improvement.

APPENDIX VII.
SAMPLE TOOLS FOR ANALYSIS OF QUALITY, RISKS, NON-CONFORMANCES AND CORRECTIVE ACTIONS

This appendix presents a collection of techniques and tools that are usually used in quality management. It is no way pre-emptive, and several variants, combinations and development of the presented toolbox have been and may be used. The following focuses upon presenting techniques in controlling quality, tracing causes of quality deviations or non-conformances and modelling their logic. In some cases, the search mechanism also involves propagation of causal factors to undesired events, i.e. forward search for different types of task analyses.

The techniques presented are commonly used also in process quality development, reliability engineering, safety and availability analysis and root cause analyses [47]. In their most advanced forms, these analyses use statistical and probabilistic methods.

Each technique/tool is described by use of a short verbal description including the origin, then the main uses, properties (verbal/graphical or qualitative/quantitative), nature of the tracking mechanism and, finally, some references are given. The tools are divided into three groups: 1. structured identification/questioning techniques, 2. logic modelling tools, and 3. quantitative tools.

VII.1. STRUCTURED QUALITATIVE ANALYSIS (IDENTIFICATION, QUESTIONING AND PROBLEM SOLVING) APPROACHES

VII.1.1. Failure mode and effects analysis

Failure mode and effects analysis (FMEA) is a qualitative technique developed in late 1940s by US Armed Forces. It is generally used as engineering quality design tool to aid reliability analysis, e.g. fault tree drafting. It follows both forward and backward logic, as it begins with presenting different plausible failure modes and then studies their potential causes and consequences.

A tabular format is normally used to document FMEA. By use of FMEA, an analyst may decide whether it is relevant to tackle the causes or consequences or both. Similarly, criticality of the faults may be assessed. In such cases the analysis may be called FMECA, where C stands for criticality to be used to prioritize the improvement needs. Typical features of FMEA are presented in Table 14.

TABLE 14. TYPICAL FEATURES OF FMEA

Main uses / scope	Quality and reliability system design
Qualitative / quantitative	Qualitative (may support semi-quantitative criticality screening and quantitative reliability analysis)
Verbal / graphical	Verbal tabular representation of the faults with their potential causes and consequences (sometimes with their criticality for risk screening)
Tracking mechanism	Forward and backward logic from different fault modes to their causes and consequences

References [48–52] contain procedures for performing FMEA.

VII.1.2. Hazard and operability study

Hazard and operability study (HAZOP) is a qualitative structured qualitative analysis to study system design robustness against deviations that challenge it. The technique was developed by Imperial Chemical Industries in the UK in 1960s for chemical plant risk analysis. A table is used to structure the work, including questions about the potential causes, consequences and potential management actions of deviations.

Typical keywords deviations for a process are e.g. NO (e.g. flow), too much/little (flow, force, temperature …), reverse (flow …), too high/low (temperature, etc. …). A task analysis variant to study human actions is sometimes called Human HAZOP. HAZOP has proved very successful in analysis of continuous processes and may be extended to management ones. The search profile is on a slightly higher level than that of FMEA, as faults lead to deviations (and other consequences). Typical features of HAZOP are presented in Table 15.

TABLE 15. TYPICAL FEATURES OF HAZOP

Main uses / scope	Process deviations (mostly used for continuous processes)
Qualitative / quantitative	Qualitative (may support semi-quantitative criticality screening and quantitative reliability analysis)
Verbal / graphical	Verbal tabular representation of deviations with their potential causes and consequences (sometimes with their criticality for risk screening)
Tracking mechanism	Forward and backward logic from different fault modes to their causes and consequences — profile slightly higher than that of FMEA

References [53–56] provide information on HAZOP.

VII.1.3. Root cause analysis of five whys

An example of the backward tracking techniques, also known as root cause analysis, the one of five whys is taken as an example. The idea is simple: for a problem or a defect, repeat five times WHY tracking all the time back to causes. At least the fifth WHY could lead you to root causes, although things to improve may be found along the way. There are many variants, that basically do the same thing (why-because analysis, etc.). The technique was developed by Toyota car manufacturing. It is expected that the underlying causes reveal organizational deficiencies, although as the analysis is not very prescriptive. Typical features of root cause analysis of five whys are presented in Table 16.

TABLE 16. TYPICAL FEATURES OF ROOT CAUSE ANALYSIS OF FIVE WHYS

Main uses / scope	Problems and defects
Qualitative / quantitative	Qualitative
Verbal / graphical	Verbal – a tabular representation may be given
Tracking mechanism	Backward (root cause tracking) logic from different problems or non-conformances to their causal factors

Reference [57] provides information on five whys.

VII.1.4. Other structured questioning techniques

There is a host of other structured questioning techniques to aid in identifying causes, contributors and consequences of risk factors in processes and organizations. Examples of such techniques are management oversight and risk tree (MORT), various human action analyses of procedure-based actions such as action error analysis (AEA) (using keywords like no action, wrong sequence, and wrong action of different types) and various types of barrier analysis.

References [58, 59] provide further information.

VII.2. LOGIC MODELLING APPROACHES

VII.2.1. Fault tree

Fault tree is a logical model based on the mission failure logic, i.e. its consequence (or so-called TOP event, since it is presented on the highest level of the tree,) event represents failure of a system, mission, component, etc. Fault tree was developed in 1962 at Bell Laboratories in the USA to support Minutemen ballistic missile control system design evaluation. It is a graphical tool that supports well reliability and causal logic analysis.

Normally AND/OR logic gates are used, although more complex K/N (e.g. 2/4) and other logical conditions may be inserted. Fault tree is probably the most widespread logic model to support quality and reliability evaluations, and it is often used in combination with FMEA. A reliability model using success logic otherwise similar to fault trees (that use failure logic) is called reliability block diagram. Typical features of fault tree are presented in Table 17.

TABLE 17. TYPICAL FEATURES OF FAULT TREE

Main uses / scope	Analysis of logic behind fault events, reliability analysis
Qualitative / quantitative	May be used both as logic model without quantification, but as logical model suits well quantitative probability estimation
Verbal / graphical	Graphical representation of fault logic
Tracking mechanism	Backward logic from the main fault even (TOP event) to its causes through logic gates

References [60–62] provide further information on fault trees.

VII.2.2. Event tree

Decisions trees are one form of event trees representing branching (e.g. uncertainty points) for decision making situations. Typical features of event tree are presented in Table 18.

TABLE 18. TYPICAL FEATURES OF EVENT TREE

Main uses / scope	Analysis of logic behind leading to consequence events, mission reliability analysis
Qualitative / quantitative	May be used both as logic model without quantification, but as logical model suits well quantitative probability estimation

TABLE 18. TYPICAL FEATURES OF EVENT TREE

Verbal / graphical	Graphical representation of logic where normally the lower branching point represents failure of a phase/function
Tracking mechanism	Backward logic from the main fault even (TOP event) to its causes through logic gates

References [60–62] provide further information on decision trees.

VII.2.3. Fishbone and similar causal diagrams

Causal diagrams are a tool to represent and model backward tracking logic from problems and other non-conformances to their causes. The most famous of them is undoubtedly Ishikawa diagram, sometimes also known as fishbone diagram. The approach was developed in the 1920s by Kaoru Ishikawa and then applied systematically in the 1960s in Kawasaki shipyard. There is a myriad of variants, but in many of them the causes are distributed in the following classes: machine (equipment, technology); method (process); material (raw material, consumables, information …); human (physical or knowledge work), and measurement / medium (inspection, environment). Also, the following are often used: mission / environment; management / leadership and maintenance. Typical features of fishbone diagrams are presented in Table 19.

TABLE 19. TYPICAL FEATURES OF FISHBONE DIAGRAMS

Main uses / scope	Analysis of causes behind fault events
Qualitative / quantitative	Qualitative representation of causes – a variant with criticality investigation exists
Verbal / graphical	Graphical representation of causes
Tracking mechanism	Backward logic from the main event to root causes

References [63, 64] provide further information.

VII.2.4. Process influencer diagrams

Process influencer diagrams (turtle diagrams) are nowadays frequently used to model and improve business processes. Their use originates in the Ford automotive company. Turtle diagrams present the process inputs and outputs in terms of relevant requirement what it comes to what needs to be received and delivered (sometimes this is illustrated as “what the turtle eats and what its internal process produces out of it”). Although many variants exist, normally material and human resources are presented as influencers with methods and measurements used. The technique is widely used throughout the industries. It is one of the leading principles of ISO 9001 [16] with the Deming’s PDCA (plan-do-check-act). Typical features of process influencer diagrams are presented in Table 20.

TABLE 20. TYPICAL FEATURES OF PROCESS INFLUENCER DIAGRAMS

Main uses / scope	Analysis of factors influencing processes
Qualitative / quantitative	Qualitative representation of causes – may be quantified by use of other tools
Verbal / graphical	Graphical representation
Tracking mechanism	Mainly forward logic (influencers of processes)

VII.2.5. Influence diagrams

Influence diagrams were developed in the 1970s to represent influencers in decision analysis. Different types of nodes (e.g. decision, uncertainty and value nodes) and arcs are used in the denotation. The mode itself is generic lends to many uses, but often it is used as part of mathematical representation of decision logic (often Bayesian network). Related tools are decision tables and trees. Typical features of influence diagrams are presented in Table 21.

TABLE 21. TYPICAL FEATURES OF INFLUENCE DIAGRAMS

Main uses / scope	Conditional logic representation of the influencers of decisions or other events
Qualitative / quantitative	In many cases the goal is quantitative i.e. to analyse the probability (Bayesian network), but the notation itself is generic
Verbal / graphical	Graphical representation of a causal network leading to the consequence event
Tracking mechanism	Conditional forward logic of influences to the main consequence event i.e. value event

References [65] provides more information.

VII.3. QUANTITATIVE OR SEMI-QUANTITATIVE QUALITY TOOLS

VII.3.1. Pareto Analysis

Pareto analysis is one of the tools traditionally seen as basic quality control tools (with quality checklists, fishbone diagrams and statistical control charts). It has been developed based on the principles set forward by Italian economist and engineer V. Pareto at the beginning of the 20th century to model the distribution of wealth in society. The Pareto principle (80–20) is widely used to express the idea that with 20 percent of work you normally reach 80 % of benefits. This means that by eliminating 20 % of problem causes you eliminate 80 % of defects. This principle of ‘Pareto optimality’ includes the thought of not spending resources in aspiring towards perfection and it is the cornerstone of the graded approach. In decision theory, Pareto distributions are used. One of the uses is to study how much resources or funds may be used to reach optimal improvements. Typical features of Pareto analysis are presented in Table 22.

TABLE 22. TYPICAL FEATURES OF PARETO ANALYSIS

Main uses / scope	Analysis of optimal decisions/measures with regards to process improvements
Qualitative / quantitative	Quantitative or semi-quantitative
Verbal / graphical	Graphical (quantitative)
Tracking mechanism	Based on the results of identified causal factors (not relevant)

Reference [66] describes Pareto analysis.

VII.3.2. Control charts

Control charts are a quality control tool developed by W.A. Shewhart in the Bell Laboratories USA in the 1920s, and further enhances by W.E. Deming. The idea is to measure outputs of (stable) processes and judge based on the variation if improvements are necessary. Normally, this is the case if scrap is produced (i.e. twice the standard deviation is exceeded). Control charts are the most used tool in statistical process control, and they allow well-defined and stabilized processes to be built. There are other statistical analysis tools used together with the control charts, like data scatter charts and trend analyses etc. What is common is the attempt to understand if the process is problem free and behaving as expected. Typical features of control charts are presented in Table 23.

TABLE 23. TYPICAL FEATURES OF CONTROL CHARTS

Main uses / scope	Analysis of process behaviours from statistical process control point of view
Qualitative / quantitative	Quantitative
Verbal / graphical	Graphical (see next)
Tracking mechanism	Deviation from the median/mean (in Gaussian curve)

References [21–23, 67] contain further information on control charts.

APPENDIX VIII.
QUALITY ASSURANCE AND QUALITY CONTROL IN PROCESS DURING DIFFERENT LIFE CYCLE STAGES OF AN NPP

VIII.1. GENERAL

The nature and extent of quality assurance and quality control activities will be determined by the requirements associated with the process and the particular stage of the life cycle of an NPP. NG-T-1.3, Development and implementation of a process-based management system, [13] provides a substantial list of processes that are often defined for the various stages of a nuclear power plant life cycle.

These processes are shown in the TABLE 24, where the abbreviations used for the stages are: G: general; S: siting; DE: design; C: construction; CO: commissioning; O: operation; D: decommissioning.

TABLE 24. EXAMPLE OF PROCESSES IN EACH STAGE OF NPP LIFE CYCLE

Process	G	S	DE	C	CO	O	D
Control of documents	✓						
Control of products	✓						
Control of records	✓						
Communications	✓						
Managing organizational change	✓						
Procurement and purchasing management (control of non-conforming items) and supply chain oversight	✓						
Vendor/supplier (field) oversight		✓		✓	✓		
Licensing and permits	✓						
Strategic, business and initiative planning	✓						
Risk management (technical, financial, etc.)	✓						
Financial management (tax, payroll, accounts payable)	✓						
Human resource management	✓						
Training and qualification	✓						
Design management			✓	✓	✓	✓	✓
Configuration management			✓	✓	✓	✓	✓
Project management	✓						
Monitoring and measurement	✓						

TABLE 24. EXAMPLE OF PROCESSES IN EACH STAGE OF NPP LIFE CYCLE

Process	G	S	DE	C	CO	O	D
Assessment (independent assessment, self-assessment, assessment of the management system, etc.)	✓						
Site selection (includes environmental assessment)		✓					
Construction management				✓			
Commissioning management					✓		
Operations management						✓	
Work management and maintenance						✓	
Equipment reliability					✓	✓	
Waste management (conventional and radioactive)		✓	✓	✓	✓	✓	✓
Fuel management (procurement, fuelling, IAEA interface, high level waste disposal)				✓	✓	✓	✓
Industrial health and safety management	✓						
Radiation protection management			✓		✓	✓	✓
Outage management			✓			✓	
Security management	✓						
Emergency preparedness and fire protection management			✓	✓	✓	✓	✓
Decommissioning management			✓				✓
License management, including management of requirements	✓						

The following sections address specific topics and the stages of the life cycle and indicate how and to what extent quality assurance and quality control activities can be applied.

VIII.1.1. Member State and its nuclear regulatory body

GSR Part 1 [68], GSR Part 3 [69] and GSR Part 7 [70] set out requirements that need to be addressed by governments and regulatory bodies, and therefore need to be addressed in their management systems along with the generic issues set out in GSR Part 2 [12]. The government or its nuclear energy programme implementation organization (NEPIO) and nuclear regulatory body may determine other business activities that need to be addressed in the management system. Development of a process based system as set out in NG-T-1.3 [13] is a useful way to go about meeting this requirement.

During subsequent development of the nuclear programme the regulator will need to determine their approach to oversight of licensees and their contractors and thus generate their own management and quality assurance arrangements. Internal management of regulatory decision-making and internal checking will need to be addressed in the quality assurance/quality control arrangements. More detail can be found in various Guides and Reports such as [71–79].

VIII.1.2. Owner and Operator/ Licensee

From the initial decision to start developing a nuclear power plant project, the owner, operator and licensee needs to be developing a management system.

The safety requirements that they have to meet are included in GSR Part 1 [68], GSR Part 3 [69], GSR Part 4 [80] and GSR Part 7 [70]; whilst the management requirements in GSR Part 2 [12] apply to all.

The owner and operator, later becoming a licensee, need to determine what other activities need to be addressed in the management system. This will almost inevitably involve key stakeholders such as financiers, designers, vendors, main contractors, engineering organizations, environmental agencies, security authorities, power grid companies.

The owner, operator and licensee, in discharging their responsibility, require to specify and supervise the work of contractors, including architect engineer and potential owner's engineering organizations and possibly main suppliers, to ensure that they are adequately implementing their delegated activities (see VIII-3 and phase of life VIII-2 to VIII-7). At this stage, they thus responsible for developing their own quality assurance and quality control functions.

NP-T-3.21 [20] is specifically written for operation and maintenance activities but provides good guidance that can apply generically on the topic of supply chain management. It notes that an important aspect of safe operation is ensuring that safety related components operate as intended, thereby ensuring that they perform their intended safety function (see NP-T-3.21 Section 1.1.2). To facilitate this, operators need to ensure that items procured for safety related systems meet their original design requirements and the procurement function for nuclear facilities plays a key role in ensuring nuclear safety.

Beyond ensuring that the required parts are available when needed for operation and maintenance activities, the procurement function helps to ensure that the correct equipment and components are installed in the correct locations in the plant, helping to maintain proper configuration management and safety functions. NP-T-3.21 [20] also states that procurement has a direct connection to product costs, in that the costs of materials, spare parts, inventory, staffing and processes required to support procurement all add to facility operating charges (see NP-T-3.21 Section 1.1.3). The large number of items to be procured necessitates a planned, graded approach to procurement activities, with safety related items receiving more attention.

Additional details on procurement and contracting are provided in the IAEA on-line nuclear contracting toolkit[26].

GS-G-3.1 [7] and GS-G-3.5 [10] include guidance on:

- Determining the criteria and methods necessary to ensure that the operation and control of processes are effective;
- Carrying out design verification and validation;
- Work planning (inspection and testing requirements);
- Identification of the status of work; and

[26] See https://www-legacy.iaea.org/NuclearPower/Infrastructure/NuclearContractingToolkit/index.html

- Specification of reviews required upon completion of the work.

The former guidance in 50-C/SG-Q[27], Guide Q4 Inspection and Testing for acceptance [5] remains appropriate. It identified that inspection and testing, whether performed by the responsible organization or by a supplier, take place at three identifiable stages. These are:

- Receiving inspection and testing, prior to commencement of work;
- In-process inspection/monitoring, during performance of the work; and
- Final inspection and acceptance testing, upon completion of the work.

To facilitate these, an inspection and testing plan can be prepared and used in order to control verification activities and provide a record of their satisfactory execution. Inspection and testing plans need to identify the sequential inspection and testing elements necessary to demonstrate conformance with requirements, the means by which they are to be verified and the relevant acceptance criteria. One also needs to bear in mind that taking into account the financial risks involved, many checks, tests and inspections are better carried out outside the NPP fence at workshops.

More detail can be found in various guides and reports [28] such as INASG-25 A Framework for an Integrated Risk Informed Decision Making Process [81], GSG-7 Occupational Radiation Protection [82], RS-G-1.8 [83], TECDOC-1580 [84], TECDOC-1581 [85], TECDOC-1600 [86], GSG-11 [87], DS475 [88], Safety Report No. 65 [89], Safety Report No. 74 [90], and Safety Report No. 83 [91].

In terms of quality assurance, GS-G-3.1 [7] and GS-G-3.5 [10], especially Section 4 Resource Management and Section 5 Process Implementation in both, are relevant.

Similarly, for quality control, GS-G-3.1 [7] in full plus GS-G-3.5 [10] paragraph 5.12 and 5.13 Control of Products; paragraphs 5.14 to 5.23 Inspection and testing ; paragraphs 5.24 to 5.30 Measuring and testing equipment; and paragraphs 5.31 and 5.32 Control of records are relevant.

VIII.2. SITING

It is very important at very early stages[29] of siting to establish a project work plan of what needs to be studied, in what depth, who will undertake the study, where and/or how the information will be obtained, and what use is going to be made of information. NS-R-3 [92], SSG-35 [93] and NG-T-3.7 [94] with supporting guides provide detailed information on these aspects related to an NPP.

Typical activities within the siting activity that could involve quality control are:

- Checking on generic information extracted from other sources;
- Checking of base surveys;
- Testing and analysis of site investigation samples; and

[27] This publication is superseded by GSR Part 2
[28] Information obtained from IAEA 'Safety Standards' committee papers.
[29] SSG-35 [95] Fig 1 identifies five stages in the operating lifetime of a nuclear installation: 1 -Site Survey, 2 - Site selection, 3 - Site Characterization, 4 - Pre-operational (e.g. up to approval of the final safety analysis report) and 5 - Operational (e.g. re-evaluation at PSR stages).

- Confirmation of output reports that form the basis for ongoing stages in the operating lifetime.

Where information is drawn from previous studies, e.g. for existing nuclear facilities in the proximity, or from national or academic resources, consideration needs to be given to the level of reliability that can be attributed due to changes in underlying knowledge or standards in the intervening time.

Attention needs to be made particularly to outputs which in later design stages form assumptions or inputs to safety reports. It will be prudent for the government, its NEPIO or the owner organization to establish processes for data management including record requirements at this stage, with consideration being given to formats etc., to facilitate transfer of information between participant organizations e.g. building information modelling (BIM) [95] and [96] approaches, Lifetime record requirements; NG-T-3.7 [94] Section 3.1.4 provides guidance.

VIII.2.1. Management systems

GSR Part 2 [12] is applicable while GS-G-3.5 [10] Appendix III addresses the management system for the site evaluation of a nuclear installation, supplementary to, and needs to be read in conjunction with, the generic recommendations provided in GS-G-3.1 [7].

The management system needs to integrate with the security system set out in NSS-19 [97] and guidance such as NSS-23-G [98] on security of information. In security terms siting is Phase 2 (Phase 1 having been the establishment of the national nuclear security regime). In security the quality assurance/quality control activities may be labelled as security assurance / security checks. Similarly, environmental and land-use planning management requirements needs to also be integrated.

Guidance can be found in GS-G-3.5 [10] Appendix III Management system for site evaluation for a nuclear installation, 50-C/SG-Q[30] [5] Safety Guide Q9 Quality assurance in siting and SSG-35 [93] S7 Application of the Management System.

Specific requirements are to be found in:

- NS-R-3 (Rev. 1) [92] supported by the likes of SSG-9 [99], SSG-18 [100], SSG-21 [101] and SSG-35 [93] along with other safety series guides;
- Establishing the nuclear security infrastructure for a nuclear power programme: implementing guide NSS No.19 [97]; and
- Security of nuclear information NSS No. 23-G [98].

VIII.2.2. Quality assurance

NS-R-3 (Rev.1) [92] includes requirements for quality assurance and makes reference to GS-R-3 [6] and revision to GSR Part 2 [12].

VIII.3. DESIGN (INCLUDING RESEARCH AND DEVELOPMENT)

SSR 2/1 (Rev. 1) [35] Section 3 Management of Safety in Design sets out requirements for design activities whilst Section 4 gives the requirements for specific plant systems. This all has

[30] This publication is superseded by GSR Part 2

to do with ensuring that the safety design principles such as defence-in-depth, diversity and redundancy are put in practice.

It is noted in SSR 2/1 (Rev. 1) [35] that:

- (Requirement 2 and paragraph 3.2) The design organization[31] management system shall include provision for ensuring the quality of the design of each structure, system and component, as well as of the overall design of the nuclear power plant, at all times. This includes the means for identifying and correcting design deficiencies, for checking the adequacy of the design and for controlling design changes;

- (Requirement 2 and paragraph 3.4) The adequacy of the plant design, including design tools and design inputs and outputs, shall be verified and validated by individuals or groups separate from those who originally performed the design work. Verification, validation and approval of the plant design shall be completed as soon as is practicable in the design and construction processes, and in any case before operation of the plant is commenced; and

- (Requirement 3 details in paragraph 3.6) The operating organization shall establish a formal system for ensuring the continuing safety of the plant design throughout the lifetime of the nuclear power plant.

Traditionally, these activities, undertaken generally by engineering personnel, may not be always labelled as quality assurance/quality control but fulfil the same purposes.

GS-G-3.5 [10] Appendix IV addresses the management system for the design of a nuclear installation, supplementary to, and needs to be read in conjunction with, the generic recommendations provided in GS-G-3.1 [7].

Management needs to be particularly thoughtful to requirements relating to interfaces between different disciplines, systems and down through the tiers of the supply chain. Clear responsibilities including a design authority need to be established. Discipline and system-based design reviews are likely to be found at different key programme points related to such interfaces.

Consideration needs to be given to control of modifications and additional build which occur during the operational stage. Additionally, consideration needs to be given to how periodic safety reviews (PSRs) to justify continuing operation are undertaken and thus managed, as they involve design. SSG-25 [102] provides guidance on the topic.

VIII.4. CONSTRUCTION

The IAEA definition of construction [103] is wider than even many in the nuclear industry recognize:

[31] The design organization is the organization responsible for preparation of the final detailed design of the plant to be built.

> "The process of manufacturing and assembling the components of a facility, the carrying out of civil works, the installation of components and equipment and the performance of associated tests."

As such, activities occur both at off-site facilities and on-site. Manufacturing of long-lead items such as steam generators and pressure vessel begin normally immediately from signing the main contract.

Recommendations and guidance for construction are set out in SSG-38 [104] Sections 4 Management System and 5 Management.

In the background it is recognized that even if the design and commissioning are fully compliant with all safety requirements, a high level of safety can only be achieved when the construction is carried out with high quality and care, since commissioning cannot test all aspects of the design. Therefore, all construction activities have a potential impact on safety, even though there may be no nuclear material present during the construction (see SSG-38 paragraph 1.4).

It is recognized that some owner's site preparation activities, such as geological investigation, may be carried out before a license has been granted (e.g. based on environmental permits). Arrangements need to be put in place by the potential applicant for a license to ensure that, if the results of these activities are to be incorporated into the permanent works or can have an influence on them, they are planned, executed, monitored and documented to standards equivalent to activities that would later be carried out under the license (see SSG-38 paragraph 2.10) [104].

Regardless of contractual arrangements the licensee has to be able to demonstrate control over all activities that deliver safety, and thus needs to put in place an oversight process that covers the management of activities by the contractor or any subcontractors, and the activities themselves (see SSG-38 paragraph 2.2). SSG-38 [104] paragraph 5.20 states the technological expertise of the suppliers/contractors needs to be verified by the licensee and/or the main contractor organization, before the procurement requirements are specified. Augmented monitoring and inspections, if necessary, needs to be employed to verify that new manufacturing techniques and new types of equipment meet relevant design requirements.

All the guidance of GS-G-3.1 [7] applies whilst expanded by GS-G-3.5 [10] especially Appendix V. The latter GS-G-3.5 [10] Appendix V.3 suggests that the organization needs to formally appoint an individual to be responsible for construction activities. Experience has shown that it is important that the construction management have good interfaces with design authority(ies), suppliers and the operating organization (licensee).

As manufacturing and fabrication may take place in disparate unrelated places by different organizations and predominantly off-site prior to erection/installation, project management becomes a critical activity. SSG-38 [102] paragraph 2.10 recommends that a design schedule, including verification of acceptance criteria and engineering work, commensurate with the authorization process, needs to be drawn up by the design organization or main contractor, and it needs to be verified by the licensee prior to the start of construction, so that late procurement will not adversely affect the construction process. This needs to include licensing planning.

Before construction starts, a review of readiness needs to be carried out by the licensee or its construction organization to verify that the design is sufficiently complete and that all engineering documents are available, and to identify any areas where the design is incomplete. The design organization or the main contractor needs to develop an action plan covering any

remaining design and engineering work, and the necessary resource requirements needs to be agreed with the licensee and monitored by the licensee as construction proceeds.

Changes to the action plan need to be agreed only if safety would not be compromised by any time and cost pressures resulting from the late completion of design work. Design changes that could have an impact on safety and licensing need to be minimized after construction starts and need to be recorded by means of a well-defined process, so that demonstration of the safety of the as built design is achievable.

It is expected from SSG-38 [102] paragraph 5.51 that temporary devices and equipment used during manufacturing, installation, inspection and testing need to be controlled and documented. It is important that as-built information is promptly generated and made available to all relevant parts the overall organization.

During installation and setting-to-work/inactive commissioning the overall management system and supplier/contractor/sub-contractor quality plans need to recognize that additional license requirements are likely to become applicable or need to be established and phased in emergency management plans, training of operators, transport arrangements.

Both the management system and the project plan need to be clear on the change of stage into verification and testing/setting to work and subsequently into inactive and active commissioning. These may occur at different times for different structures, systems and components. SSG-38 [102] paragraph 5.43 recommends that the licensee and the construction organization or the main contractor need to develop and agree a process to verify the completion of construction activities and the transfer of completed work. The test plan and the acceptance criteria need to be documented such that they can be independently assessed.

VIII.5. COMMISSIONING

SSR-2/2 (Rev. 1) [105] sets out the requirements for commissioning activities, several of which are related to quality. It is noticeable that several of the requirements are similar if not identical to some of those in GSR Part 2 [12]. It is quite normal for licensees to have their full range of safety, design and operational assurance arrangements in place by the start of active commissioning; whilst quality systems activities, such as scheduled audits continue.

SSR-2/2 (Rev. 1) [105] Requirement 30 Core management and fuel handling introduces the issue of design and procurement of fuel. This involves significant quality issues prior to loading and also a safe reactivity management programme under a strong management system for quality. Further information can be found in DS488 Design of the Reactor Core for Nuclear Power Plants [106] (in drafting replacing NS-G-1.12 [107]); DS487 Design of Fuel handling and Storage Systems for Nuclear Power Plants [108] (updating NS-G-1.4 [109]).

The former guidance in 50-SG-QA11[32] Quality assurance in the procurement, design and manufacture of nuclear fuel assemblies (1983) [110] can still provide helpful thought.

SSR-2/2 (Rev. 1) [105] Section 8 Maintenance, Testing, Surveillance and Inspection provides the detail supporting Requirements 31 and 32. Requirement 32: Outage management may relate to both Commissioning and the Operational stage (see VIII-6).

[32] This publication is superseded by GS-G-3.5

SSG -28 [111] provides detailed guidance:

- Section 2 The Commissioning process;
- Section 3 Organization and Management of Commissioning;
- Section 4 Implementation of the Commissioning Programme;
- Section 5 Documentation for Commissioning; and
- Appendix Fuel Loading.

SSG-15 [112] provides guidance on Nuclear Fuel which applies from the time fuel elements are taken out of reactor, through storage on site, until transported to reprocessing or disposal.

All the guidance of GS-G-3.1 [7] applies whilst expanded by GS-G-3.5 [10] especially Appendix VI.

VIII.6. OPERATION

SSR-2/2 (Rev. 1) [105] sets out the requirements for operational activities many of which will have already been addressed for commissioning though may need enhancing. It is noticeable that several of the requirements are similar if not identical to some of those in GSR Part 2 [12]. As stated for commissioning (see VIII-5), it is expected that licensees would have their full range of safety, design and operational assurance arrangements in place as well as quality assurance activities.

GS-G-3.5 [10] provides guidance on how to satisfy management system requirements for nuclear installations. This guidance includes examples of how to apply both quality assurance and quality control to processes that apply during operation.

During operations, processes are often defined in procedures such as technical specifications which define limits and conditions which require operational controls to be measured using safety systems; and these then require maintenance, inspection and testing with associated quality activities.

It is common for licensees to have two parallel assurance routes; first quality assurance teams who undertake management system audits and surveillances reporting to top management, and secondly internal inspectors who mirror the activities of regulators and report to facility management. See also Section 3.1 and Appendix VII.

Arrangements may need enhancing during outages or modifications.

Section 7 of [105] gives the requirement for Plant Operations; it provides the detail supporting Requirements 26 to 30.

Section 8 of [105] gives the requirements for Maintenance, Testing, Surveillance and Inspection; it provides the detail supporting Requirements 31 and 32.

The following Specific Safety Guides and Nuclear Safety Guides are applicable to operational activities:

- NS-G-2.1 Fire Safety in Operation of Nuclear Power Plants [113];
- NS-G-2.4 Operating Organization for Nuclear Power Plants [114];
- SSG-50 Operating Experience Feedback for Nuclear Installations [115]; and

- NP-T-3.21 Procurement Engineering and Supply Chain Guidelines in Support of Operation and Maintenance of Nuclear Facilities [20].

VIII.7. DECOMMISSIONING

Whilst the technical activities change from operation into decommissioning, the overall management approaches are likely to be very similar, albeit radiological risk reduces and thus from a quality grading perspective the level of quality assurance and quality control activity may reduce. There are, however, some stages such as removal of spent fuel or declaration of a site as free from radiological risk, which will require intense activities.

GSR Part 5 Predisposal Management of Radioactive Waste [116] and GSR Part 6 Decommissioning of Facilities [117] define key requirements with guidance in SSG-47 Decommissioning of Nuclear Facilities, except Facilities using NORM and Medical, Industrial, Research and Disposal Facilities [118] (superseded WS-G-2.1 [119] and WS-G-2.4 [120]); alongside GSR Part 2 [12] and the guidance in GS-G-3.5 [10] Appendix VIII Management system for the decommissioning of a nuclear installation.

In GSR Part 5 [116] the following are applicable:

- Requirement 4: Responsibilities of the operator sets out various ‘quality’ activities specifically in paragraph 3.11 which requires the establishment of a management system (Referencing GS-R-3 [6]), whilst paragraph 3.12 requires the establishment and maintenance of a strong safety culture by means of an effective management system and a demonstrated commitment to safety on the part of senior management;

- Requirement 21: System of accounting for and control of nuclear material calls for active surveillance and controls, in such a way as not to compromise the safety of the facility.

In GSR Part 6 [117] the following are applicable:

- Requirement 2: Graded approach in decommissioning; which calls for the type of information and the level of detail in the decommissioning plans and supporting documents, to be commensurate with the type, scale, complexity, status and stage in the lifetime of the facility and with the hazards associated with the decommissioning;

- Requirement 6: Responsibilities of the licensee for decommissioning which includes:

  - Establishing and implementing an integrated management system. If the licensee changes during the lifetime of the facility, procedures shall be put in place to ensure the transfer of responsibilities for decommissioning to the new licensee;
  - Fostering a safety culture in order to encourage a questioning and learning attitude towards safety, and to discourage complacency.

- Requirement 7: Integrated management system for decommissioning requires that the licensee shall ensure that its integrated management system covers all aspects of decommissioning;

- Requirement 10: Planning for decommissioning includes:

- Appropriate records and reports that are relevant to decommissioning (e.g. records and reports of events) shall be retained by the licensee throughout the lifetime of the facility.

- Requirement 14: Radioactive waste management in decommissioning includes:

- The licensee shall ensure traceability for all waste generated during decommissioning. The licensee shall maintain up to date records of the waste generated, stored in the facility, or transferred to another authorized facility, specifying its quantities, characteristics, treatment methods and destination.

VIII.8. TRANSPORT

Requirements for transport of new fuel, spent fuel and waste, be it by road, rail, sea or air, and associated quality assurance and quality control activities need to be considered. Clear boundaries could be defined when activities pass from operators to transporters and vice-versa. For some very large facilities a distinction may need to be made between internal movement and off-site transportation. The IAEA Transport Regulations (SSR-6) [121] with guidance (SSG-26 [122] and SSG-33 [123]) provide technical requirements to be met. Some of the requirements also address quality assurance and quality control aspects. It is noted that the term quality control is used in the text (see paragraph 680 of SSR-6 [121] in relation to packaging, and paragraph 817 in relation to sources).

In transport the terms defined in SSR-6 [121] include:

- Compliance assurance shall mean a systematic programme of measures applied by a competent authority that is aimed at ensuring that the provisions of these Regulations are met in practice;
- Management system shall mean a set of interrelated or interacting elements (system) for establishing policies and objectives and enabling the objectives to be achieved in an efficient and effective manner;
- Radiation protection programme shall mean systematic arrangements that are aimed at providing adequate consideration of radiation protection measures.

Paragraph 306 of SSR-6 [121] sets out that a management system is required. SSR-6 [121] introduction references TS-G-1.4 [11] and TS-G-1.5 [124] which were written based on the 2005 edition of the Regulations for the Safe Transport of Radioactive Material (TS-R-1) [125], which preceded SSR-6 [121].

Management systems

- All aspects of GSR Part 2 [12] apply to transport with guidance in TS-G-1.4 [11] (based on GS-R-3 [6]). Specific transport guidance is included in TS-G-1.5 [124];
- SSR-6 [121] with advisory material in SSG-26 [91] especially Section III.

Quality assurance

- TS-G-1.4 [11] Sections 2 The Management system, 3 Management responsibility, 4 Resource Management, 5 (part) process implementation, 6 Measurement, assessment and Improvement;
- SSG-26 [91] especially Section VIII Approval and Administrative procedures.

Quality control

- TS-G-1.4 [11] S5 (part) process implementation;
- SSG-26 [86] especially Sections V Requirements and Controls for transport, 6 Requirements for Radioactive Material and for Packaging and Packages and S7 Test Procedures.

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ANNEX I.
LIBERTY SHIP BRITTLE FRACTURES

Lack of adequate quality assurance and quality controls result in fatal flaws due to workmanship.

I-1. QUALITY THEME

Workmanship errors made by poorly trained welders resulted in fatally flawed critical welds causing significant loss of life and property.

I-2. CIRCUMSTANCES

In 1940, at the start of World War II, the UK and other allied combatants had depleted vital war materials and sustenance to continue to fight. The USA, not yet in the conflict, had stockpiles and the manufacturing capacity to resupply many of the strategic resources but had few maritime ships to move the necessary volume of material. On the planning boards was a British designed emergency class freighter. The design of that freighter was rather primitive and utilized traditional plate and rivet construction. However, the American shipyards proposed all-welded steel construction and modular techniques that allowed dispersed construction and relatively non-maritime construction tooling. As all shipbuilding yards and construction firms were engaged in building military hardware and weapons, the US government contracted with many industrialists to build a fleet of these vessels as soon as possible.

While never having built a ship in his career, industrialist Henry J. Kaiser, the builder of the Hoover Dam and the Bay area bridge, won the contract and began building the ships and the new shipyards with the available work force. Shipyards and sub-assembly suppliers sprung up across the USA although mainly on the West Coast. Any available able-bodied workers — many housewives, farmers, and mechanically-minded labourers — were pressed into service as welders, fitters and shipyard workers. Ships began pouring out of new shipyards wherever there was a navigable river and floating to larger facilities that allowed final assembly into complete merchant freighters. No sea trials or extensive shakedown cruises to expose latent defects were taken as the need was so urgent. Eventually over 2700 of these Liberty ships were built but in 1941–1942.

At least 12 of these ships, heavily laden with life-saving supplies, inexplicably failed and sank on their maiden voyages through the North Atlantic. Eventually over 25% of these ships failed to complete their resupply missions and over 1500 exhibited some amount of brittle fracture weld failure. Some like the USMC Schenectady, failed in the shipyard 24 hours after completion even before accepting cargo. The premature celebration at the emergency response of the American industrial machine quickly turned to idea of possible sabotage, war-profiteering, and poor quality of American goods.

Henry Kaiser began an immediate investigation into the causes of the failures. The outcome of this investigation showed some immediate problems that needed to be addressed and remedial steps were immediately applied.

I-3. DISCOVERY AND DIRECT CAUSES

The discovery mechanism was obvious. The first ships were lost on their maiden voyages and some ships failed even before leaving their anchorages.

The main contributor to the failure of the Liberty ship hull failures was identified as the failure of the steel in the heat affected zone of the large transverse welds used in the hull. While the concept of null ductility temperature fractures was known and understood, the design of the hulls and the materials used were not viewed as being susceptible in the ocean environment. However, the saline North Atlantic water in the winter months could result in brittle fracture due to the lack of conditioning or design of the weld joints.

The original British design utilized plate and rivet construction which is self-relieving of stresses at the joints. After the American design change to all welded construction, almost all failures occurred in the heat affected zone of the large welds that were near square holes or penetrations of the hull due to superstructure openings or geometry. The corners of these openings provided stress risers while the poor welding quality created large heat affected zones or just plain unsound welds.

Traditional large ship construction techniques before 1940's was by means of large plates and rivets. This type of lapped joint construction allowed some natural stress relief at the rivet joints and was more forgiving of sharp transition that a straight welded but seam. The initial fix for this issue involved the addition of gun-wale reinforcements and straps at critical points to prevent flaw propagation. Many Liberty ships finished their planned short lifetimes successfully with only these repairs. Eventually, near war's end, a Liberty ship could and would be built in as little as 21 days.

I-4. CONTRIBUTING FACTORS

The root causes of these failures were investigated and the resultant actions to prevent recurrence became the basis in the US of what was known as Shipyard quality control and is the first significant step to what is now considered as modern quality assurance and quality control.

As the investigation deepened, the workmanship and the quality of the welding became more questionable. Brittle fracture could not explain all the failures. The use of a non-traditional workforce was probed. Although an initial assessment of the physical capability was made before assignment as a welder, the extent of training and capability demonstration was severely lacking. A very short hands-on demonstration and cursory overview for a short trial period was thought to be enough. Joint preparation was rudimentary (flame cut, not ground to profile, poor fit-up, etc.) along with no protection of the welding environment from external factors such as rain and contamination made sound welds improbable. However, due to the wartime incentives and shift premiums given, the only outcome tracked was ‘feet of weld completed’.

Without rigorous training on the latent defects that could be induced during the welding process, slugging of welds with unfused electrodes or garbage, introduction of inclusions and porosity, lack of constant control of hand welding to control the embrittlement of the base material in the heat affected zone, and poor joint designs, were just a few of the results of an inadequate training programs. Many welders were unaware that even a few imperfect inches of weld could endanger a complete circumferential hull weld. The span of control of supervisors also contributed to the problems as poor practices were not often observed, stopped or corrected. Even the incentive process for the whole work force and concentration on speed of completion versus quality of final assembly worked against a defect free construction.

Another element that was examined was weld soundness. Non-destructive examination and volumetric investigation were well known and established in the laboratory. Magnetic particle testing, liquid dye penetrant, x-raying of welds, material testing for discontinuities, even

ultrasonic investigation was well-known by the 1940's. However, routine application on the assembly line or in the shipyard was thought to be un-necessary, since these ships were viewed as temporary solutions and almost disposable.

This might have been true for traditional, overly conservative construction of hulls using plates and rivets, but the inherent risks in large weldments and behaviour of highly stressed, nominal materials in the worst expected environments was not yet appreciated. The manufacturing of aluminium, plastics and their behaviour in harsh environments was just beginning to be appreciated. After identifying certain critical points in the construction, routine visual inspection, magnetic particle and liquid penetrant inspection and, even radiographic examination was built into the ship building process.

It was also found that over-inspection by independent inspectors who checked the work product separate in time and space was the most efficient and effective way to provide in process checks. While the workers and the supervisors could specialize in production, the quality control inspectors provided independent, skilled inspections using weld gauges, calibrated measuring and testing equipment, and even performing non-destructive examination.

I-5. CORRECTIVE ACTIONS TAKEN

- Crack-stopping straps and gunwale reinforcements were installed and stopped crack propagation;
- Welders were adequately trained and subject to capability demonstrations;
- Design of hull openings were redesigned to eliminate sharp corners and make transitions more rounded;
- Greater care and attention were taken in weld joint preparations and fit-ups;
- Care was taken to control weld progression to try to minimize the heat affected zone;
- Greater attention was given to material properties and their null ductility temperatures — brittle fracture concerns became prominent;
- Changes to designs were reviewed to assure that no latent defects were incorporated — even by relatively simple changes. Stress risers were eliminated where possible;
- Quality control overview and inspections separate in time and space became routine and valued;
- Defect identification and corrective actions were implemented before continuing works;
- The establishment of Quality Assurance provided valuable overview of complex, critical activities and assured more successful outcomes;
- Routine surface and volumetric testing of weldments was instituted;
- Drawing and procedures were given greater distribution to all involved parties.

I-6. LESSONS LEARNED

- Workers need to be adequately trained and understand the consequences of the processes and activities that they can control;
- Training a non-traditional workforce in the results of ‘slugging’ welds, poor environmental conditions such as rain and snow result in weld porosity and inclusions, and non-adherence to welding process steps and process affects the heat effected zone of large welds resulting in unsound welds;
- Processes like welding that can result in hidden or latent defects in critical constructions need to be routinely tested and examined non-destructively in the field;

- Critical activities such as welding require routine and intrusive overview by independent in space and time competent inspectors;
- Non-conforming items need to be identified and corrected before moving on to subsequent steps;
- Quality control using appropriate tools and personnel are an integral part of critical construction.
- Designs need to consider new materials and technologies and need to address all expected and even extreme environmental conditions;
- New designs need some form of review and verification before declaring success;
- Reliance on a first of a kind design before adequate validation often results in poor results;
- Incentives need to be tied to workmanship and defect free outcomes. 'Feet of defect free weldment per hour' is a much more appropriate performance indicator than just 'feet of weld per shift';
- Activities that have become so complex and of such duration that they are beyond the capabilities of a single individual to measure and monitor need an overall plan -a quality assurance activity - to guarantee the required outcomes.

I-7. GOOD PRACTICES AS A RESULT

Correcting the contributing factors resulted in the application of many more skills and techniques. Many more process steps and checking needed to be controlled. Better drawings and written procedures were required. While the supervisors and the workers could pay attention to the new needs, someone needed to provide some overview that all the pieces and parts were working to result in a quality product.

Bringing together all the disparate parts from many sub-suppliers also required careful checking before incorporating subassemblies into the whole. Certain individuals were assigned to overview and check that all the necessary steps were being taken. This became the first real manifestation of quality assurance with a focus on processes and activities versus just product quality. The end effect of each of these contributors was not difficult to discover nor hard to correct. The corrective actions that needed to be taken and verified resulted in a quality system that we can now recognize as a quality management programme.

While Henry Kaiser and the Liberty Ship hull failures are often used as case studies, the entire US quality management system development was a direct result that continues to influence nuclear construction to this day. While timely completion and quantity of items or activities is important, quality in the final product is the only true measure of achievement. When nuclear naval propulsion was initiated following the war, cumulating in the USS Nautilus, these lessons learned from the Liberty ships became part of the nuclear construction programme and spilled over into spaceflight and other high risk, high consequence endeavours. In turn, the US nuclear power plant construction processes and practices are a direct result of the naval nuclear propulsion program. The more one studies these events, and more importantly, their remedies, the more clearly one can discern the roots of modern quality assurance and quality control.

ANNEX II.
FAILURE TO ADEQUATELY CHECK CALIBRATION OF TORQUE WRENCHES RESULTS IN TOTAL REINSPECTION OF NPP STRUCTURAL BOLTING

II-1. APPLICABLE QUALITY CONTROL OR QUALITY ASSURANCE PRINCIPLE(S)

Choice of suitable equipment, value of routine operability checks, integrity of quality records, competency of inspection personnel.

II-2. CIRCUMSTANCES

The primary mechanical construction subcontractor at a large multi-unit US nuclear power plant under construction was required to adhere to AISC 7th edition bolting requirements for the installation of structural steel fasteners (A325). The installation specification required such fasteners to be installed and tightened to several hundred-foot pounds of torque. Production crews were issued Snap-On brand, snap tight torque wrenches which indicate when specified tightness has been achieved by making an audible click and then spinning free. The quality control inspection forces would then follow along separate in time and space and over-check a sample (usually one out of six or eight) of bolting with a Snap-On brand torque-o-meter type wrench which has a dial indicator that measures break-away torque and displays the maximum achieved tightness before the fastener begins to spin. Minimum values were specified for the installation torque and minimum and maximum inspection values. Actual recorded inspection values were not required or recorded nor were the sampled fasteners at each connection required to be recorded. Due to the heavy use and skill of the craft labour, the Snap-on brand snap type torque wrenches were returned to the tool crib at the end of work each week for a 'calibration' and operability check. A quality control technician was assigned to verified continued integrity and operability and functionality and 'test' each wrench against a known tightness threaded fastener. The wrench was then hand rotated as it would normally be used in the field and was considered acceptable if it audibly 'clicked' at the minimum torque value per the setting on the adjustable setting collar of the device. Occasionally, the continued tightness of the test fastener was verified using a Torque-o-meter indicator wrench. Each wrench was identified with a unique serial number and assigned tool number. Upon successful completion of the check, a unique inspection report was completed which indicated the expected value of check and a column indicating the result was recorded as 'Accept' or 'Reject'. As there were no repairable or adjustable parts for any of the snap-type wrenches, a wrench failing this weekly check was scrapped by destruction by severing the operation head from the integral handle. Since these are relatively primitive measuring devices and designed and fabricated for rough duty, there were few failures. This entire activity conformed to standard steel construction practices of the time and the quality assurance requirements and quality control practices. Hundreds of installation wrenches and thousands of fasteners for structural steel, pipe hangers, and mechanical equipment were installed under the described processes.

II-3. METHOD OF DISCOVERY

During a routine quality assurance audit of the mechanical erection subcontractor by the NPP licensee, it was noted that several recent weeks' worth of the 'calibration' records were photocopied including the signature of the only quality control technician in the tool crib and the notation of expected values and the results (ACC or REJ). The quality control technician was interviewed and freely disclosed that hundreds of wrenches were checked weekly, almost all were always acceptable, almost all had the same expected 'setting', and any rejects were scrapped and thus, removed from any future usage. As he was the only technician who performed this check, he was the only one accountable for the check and the results. Upon

further investigation, he felt that he could generate one ‘master’ sheet listing the expected value, the expected result, and the Acceptable result, and his signature. After xeroxing a sufficient number of copies, he was able to only enter the unique tool number and the date and produce a final calibration form recording what was accomplished for any one wrench. There was neither evidence to indicate that any wrenches were returned to service that had not been acceptably checked nor evidence that any inoperative or out-of-calibration wrenches were subsequently used. The Torque-o-Meter indicating wrenches used by the quality control inspectors for over checks were subject to greater care and attention than the production wrenches (as inspection instruments) and were returned to the manufacturer quarterly for recertification. No indications of on-site adjustments or ‘calibration’ checks were required or were found. Upon recheck by the manufacturer, all inspection Torque-o-Meter indicating wrenches were found acceptable and in calibration against a secondary standard traceable to NIST.

II-4. CONTRIBUTING FACTORS

Upon further review, it was discovered that, except for a general indoctrination and orientation on general quality assurance requirements, the tool crib quality control technician had not been specifically trained on the necessary integrity required in quality records and, the calibration checks, and their documentation were considered to be permanent quality records. Unique and direct recording of results were required. More review also disclosed that quality assurance records personnel responsible for reviewing and filing these calibration check records in the file room had noted the shortcuts taken by the tool crib quality control technician but did not recognize that this was not an acceptable practice.

There was no second verifier involved who may possibly have raised and issue with the practices being used.

Additional investigation of the site practices pertaining to the checking of the snap-type torque wrenches with the manufacturer, revealed that since there were no adjustments or repairs possible for these devices, any checking for ‘calibration’ were meaningless. The only type of verification of acceptable settings required and elaborate test bench with a mechanical lead screw device and a certified scale to assure a loading that did not depend on direct human input for results. What was being conducted was merely a demonstration that the wrenches were operable but there was no direct correlation to the actual tightness achieved by use of the snap-type wrenches. The appearance of precision by using the snap-type wrenches was no better than the skill of the craft in applying reasonable force on the bolting using a standard open-ended hand wrench. The specification of ‘reasonable force using a typical unassisted hand wrench’ was the standard in many other types of high-risk construction endeavours such as aviation and marine construction. As a result of this recommendation from the manufacturer, the weekly checks were discontinued and all wrenches or any style or type were returned to the manufacture for a factory check quarterly.

II-5. CORRECTIVE ACTIONS TAKEN

As a result of discovering that quality records supporting the acceptable installation of safety related, non-safety related and seismic systems, structures and components did not possess sufficient evidence of uniqueness or integrity, all fasteners installed by hundreds of work crews over the course of two and a half years were re-inspected using calibrated, indicator type torque wrenches by qualified mechanical and structure quality control inspectors and the results of all items sampled (at a much higher sample rate than originally) were recorded.

Quality control supervisors and design engineers reviewed all results and accepted the final results.

All personnel on site responsible for preparing, reviewing, and processing all quality records were re-trained on the specifics required for quality records and a sample of other similar activities were reviewed by the licensee's quality assurance staff and the federal regulator's inspection specialists.

These reviews found that essentially all fasteners in question were acceptable and only a few questionable connections required any rework. This re-inspection, rework, and reviews resulted in thousands of man-hours of delay and schedule slippage as a result of poor training and sloppy quality control activities.

II-6. LESSON(S) LEARNED

- Critical activities that require verification also require the generation of records sufficient to demonstrate that they have been acceptably performed. All personnel are necessary to be trained to understand the essential controls to assure quality records retain their integrity;

- Certain activities also have critical aspects that require actions but not all of these actions could be performed unless a full understanding of the aspects being verified, and the applicability of results are well understood;

- Relatively simple routine quality control actions and incorrect actions can have far-reaching and expensive ramifications;

- Even quality control may actually perform work and if the activity is quality affecting, and the impact of errors can remain undetectable, a second verification separate in time and space could be performed. Another quality control inspector was assigned to perform an overcheck of the production wrench check until it was determined that the check was not necessary.

II-7. GOOD PRACTICE(S) AS A RESULT

- Be absolutely convinced that all quality activities are fully understood and appreciated by those performing them.

ANNEX III.
THE APPLICATION OF QUALITY ASSURANCE AND QUALITY CONTROL METHODOLOGIES IN NUCLEAR FUEL MANUFACTURING

III-1. INTRODUCTION

The manufacturing of nuclear fuel assemblies and their associated component parts represents as complete an example of the application of quality assurance and quality control techniques that could be found in any manufacturing environment. Nuclear fuel assemblies have to operate in very demanding and exacting conditions.

The environment in which they operate is extremely difficult and consists of high temperatures, high pressures and high fields of radiation. In most reactors the cycle the fuel assembly has to withstand is 4-5 years. As such the level of quality that need to be attained is some of the highest likely to be found in any application.

Within a PWR reactor a nuclear fuel assembly faces operation in challenging conditions. To give an example of those conditions typically pressure in the primary reactor circuit is an excess of 150 Bar. The temperature within the pressure vessel will in places exceed 300 degrees Celsius and water is pumped around the cooling circuit at around 9 tons per second. In that environment the performance of the product is absolutely critical and a failure within a reactor can have extensive financial consequences in terms of reactor close down and clean.

Consequently, the ownership of quality within a fuel manufacturing plant needs to belong to the entire plant manufacturing organization. Typically, 75% of all rejects in a fuel manufacturing plant link to behaviours in human actions. The remaining 25% can be linked to direct machine faults, so every small detail of fuel manufacturing can influence product quality and can make the biggest difference.

III-2. NUCLEAR FUEL SPECIFICATIONS

The specifications for fuel manufacturing are usually derived by the fuel vendors who are usually the reactor manufacturer. They own the safety case requirements and set the specifications to enable the safety case for reactor operation to be met and maintained. The specifications are usually bespoke and unique to the particular fuel type or fuel vendor.

Fuel assembly designs vary but basically, they consist of fuel pellets which are sintered mix of materials. The pellets are loaded into fuel rods. They are held under compression with a spring and then plug is inserted in the end of the rod welded and sealed. The rods are loaded into a fuel assembly.

Once all the rods are loaded into the assembly matrix it is subject to final assembly where top nozzles are fitted, and the assembly checked for dimensional integrity. In many respects the fuel assembly is simple in terms of numbers of components, but the requirements placed upon the pellets rods and final assembly are extensive.

A fuel pellet is quite a small component, sizes vary between reactor type and design but to give an example a typical PWR pellet could be around 9 mm in diameter and 10 mm in length. It could be subject to 70 to 80 different checks to establish that the quality attributes have been met.

Similarly, fuel rods will be subject to 70 to 80 different attributes to be checked to ensure conformity with drawings and dimensions.

Fuel assemblies may be subject to 35 to 40 different dimensional checks to establish their integrity against the drawings.

III-3. THE REQUIREMENTS PLACED ON FUEL ASSEMBLIES

The requirements placed on fuel assemblies are extensive and rigorous and the product is necessary to comply with three key principles which are usual in nuclear safety related products and services:

- The product needs to be demonstrably manufactured within a stable process window which has been pre-qualified by the manufacturer;
- The product needs to meet the specified requirements and dimensions; and
- All the attributes that are product quality related to manufacturing, measurement, inspection and analysis need to be demonstrably documented and certified.

Failure to provide full demonstrable compliance with any of the three areas would render the product as non-conforming.

To some extent the special requirements placed on nuclear fuel assemblies are the same as any high-quality manufactured product that you would purchase for any particular given application. The expectations are:

- That the product is safe;
- That it is reliable;
- That it meets the performance requirements placed on it;
- That it is capable of being given with a long warranty; and
- That it gives value for money.

However, one key factor needs to be considered. A fuel assembly is part of the reactor safety case, so the attainment of quality is intrinsic to meeting that safety case and ensuring the appropriate levels of nuclear safety are met and maintained.

Nuclear fuel assemblies need to ensure that:

- Containment of nuclear material is maintained at all times;
- The assembly is of the right size and shape;
- It performs well within the reactor;
- It produces the required amount of energy and is delivered on time; and
- It is supplied with a warranty and is good value for money.

The customers within the nuclear power industry set high expectations of quality to achieve these requirements.

To give some indication of the high levels of quality expected of nuclear fuel assemblies, typically the expectation is that the failure rate does not exceed more than 1 in 1 million fuel rods.

III-3.1. Process Qualification

Controlling the process during manufacture is equally as important as ensuring the dimensional and material integrity of the individual components. Process control provides assurance that the product has been manufactured correctly to the drawing and specification requirements throughout the manufacturing process. In order to control the process, the product quality processes need to be qualified.

Process qualification establishes the window of the process which produces product of the requisite quality. The principle is that, if any subsequent product is manufactured within the qualified window, then that product needs to conform to the appropriate specification. If it cannot be established that product has been manufactured within the qualified window, then that product could not be deemed acceptable even though it may have acceptable analytical and dimensional results. This is because for some product attributes verification is done on a sample basis. The use of sampling techniques can only be justified when the process for manufacture has been qualified and the product has been manufactured within the qualified window. In essence, product cannot be accepted purely on quality control results alone. The quality assurance aspects of process qualification need to also be met, this demonstrates that the appropriate combination of quality assurance and quality control techniques ensures a wholly assured product of the highest quality is manufactured.

So, what is process qualification and what do you need to do to achieve that? Initially you need to identify those process parameters which affect product quality attributes. You need to then test those process parameters to define the operating window which will produce product that meets the specification requirements. This is known as prequalification and is used to establish the parameters which will be used to subsequently qualify the process.

Once that window is established a formal qualification exercise is carried out using the data from prequalification. Trial batches of product are produced under tightly controlled conditions using sets of parameters to prove the window established during prequalification. Having established a qualified window those parameter ranges are locked down on the plant. The established parameters form the basis of all future manufacturing unless further qualification is carried out. The qualification requirements are typically recorded on Process Data Sheets which define the plant settings and operating window.

Extensive use of plant monitoring equipment is then utilized to ensure that the plant is operating within the qualified window and sampling provides the assurance that the product that is manufactured is meeting the acceptable criteria laid down in the fuel vendor’s specification.

The application of control charts and control limits are used throughout the plant to monitor and provide assurance of the continuing manufacturing integrity of the process.

III-4. PELLET MANUFACTURING

Pellets are made in large numbers; something in the order of 10,000 pellets per assembly is not untypical. Typically, assessments of less critical dimensional attributes, such as pellet length and pellet end geometry dimensions, are checked on a sample basis, but to a high level of accuracy.

Pellet composition attributes established by analysis are also carried out on a sample basis, so maintaining a stable process within a qualified window is vital to provide that assurance that those pellets can be accepted on a sample basis. This reduces the amount of inspection and

analysis which would be costly and time consuming but maintains an appropriate level of product assurance and quality.

Some pellet attributes are critical to the performance of the fuel assembly in the reactor. For example, 100%-dimensional inspection is carried out on pellet diameter. This is usually carried out as an in-line activity using equipment such as a laser micrometre. This is a non-destructive technique so 100% inspection is feasible particularly in an automated fuel plant.

All pellet data needs to be continuously checked and monitored. This gives an indication of the adequacy of process control and is used for conformity purposes and also to provide feedback to the manufacturing process. Any indications of process drift are then addressed and fed back into the process thus eliminating potential batch rejection due to manufacturing variations. Variation within a qualified process needs to be tightly controlled. Process stability and process capability needs to be tightly monitored and controlled to ensure consistent product quality.

Quality control checks serve two purposes:

- They give demonstrable evidence that the process is stable and under control; and
- They give demonstrable evidence that the product meets the specification.

Again, this emphasizes the relationship between quality assurance aspect in the form of process control, and quality control aspect in the form of product and dimensional measurement. They two aspects combine to give the full range of assurance of the product.

III-5. FUEL ROD MANUFACTURING

The rod manufacturing process typically specifies a series of attributes requiring a 100% inspection as well as qualification of critical processes such as welding and rod handling. Qualification of the welding process is critical, as the welds on a fuel rod represent a potential weak point if they do not achieve the requisite level of quality.

Typically, the key areas of rod integrity which need to be established are:

- The integrity of the welds;
- The integrity of the pellets following the loading process;
- That pellets of the correct enrichment or sequence of enrichment have been correctly loaded; and
- That the dimensional accuracy of the rod has been maintained.

The surface integrity of the rod is equally important. Consequently, not only does the rod have to be dimensionally acceptable, but there is a cosmetically acceptable standard as well. This is primarily to ensure that the corrosion resistance of the rod is not compromised through surface crevice corrosion as a result of scratches or through corrosion invoked by contamination from foreign sources or from fingerprints. The environment within a reactor pressure vessel is a highly aggressive one from a corrosion aspect. Therefore, surface integrity is vital. The consequence of poor surface integrity or contamination could lead to rod failure within the reactor and contamination of the cooling water circuit.

III-6. FUEL ASSEMBLY MANUFACTURING

Final fuel assembly manufacturing involves pulling the completed fuel rods into a skeleton or assembly matrix in a defined and exact manner. The assembly is then subjected to a number of

dimensional checks to establish that the assembly dimensions fall within a prescribed window which is critical to reactor installation.

In addition to establishing the dimensional envelope of the assembly, the surface integrity is absolutely paramount. A detailed visual inspection of as much completed assembly as possible is carried out. This is to ensure that there are no potential corrosion sensitive surface imperfections left on the assembly as a result of the assembly process. Typically, the surface imperfections result from the assembly process where the rods are pulled through grids which maintain the exact dimensional positions of the rods within the assembly.

III-7. CERTIFICATION

To support the manufacturing and inspection processes and to give the correct levels of assurance of the integrity of the assembly and its component parts, an extensive certification process is undertaken during all phases of manufacturing of the fuel assembly. It needs to be stressed that the certification of assemblies is absolutely critical to provide demonstrable assurance of the performance of the assembly in its subsequent operational phase. Dimensional and analytical conformance of product to drawing and specification requirements in itself is not sufficient to provide the correct level of assurance of a completed fuel assembly.

III-8. KEY QUALITY ASSURANCE AND QUALITY CONTROL ASPECTS OF FUEL MANUFACTURING

If now we consider some key aspects of quality assurance and quality control you will be able to see that each of them plays a contributory part in assuring the integrity and quality of a nuclear fuel assembly and its components.

III-8.1. Process Control

Process control is a fundamental principle in fuel assembly manufacturing. It is a critical requirement in all three phases of fuel manufacturing. The manufacturing process has to be shown to be stable within a qualified window. The window will have been developed by specific plant testing and analysis designed to establish the manufacturing window which produces product attributes with the correct levels of quality.

III-8.2. Control Charts

Control charts are an essential tool to ensure a process is adequately monitored and provides data to assure its stability. They are also used to identify trends where the process is showing potential instability which could result in the process deviating from the qualified window and associated parameters.

III-8.3. Process qualification

Process qualification is the method by which the operating window of the process, which provides the requisite quality of product, is established. Process control establishes a stable process. Monitoring that process is typically carried out through control charts and these activities need to be carried out to demonstrate the process is within a process qualification window. If these activities are collectively established and controlled correctly then the product needs to meet the specification requirements.

III-8.4. Non-destructive testing

Non-destructive testing (NDT) is used extensively in a number of areas of the manufacturing process. The exact type of NDT does vary but is typically one on the following techniques:

- Visual inspection carried out by suitably qualified and experienced operatives or by automated image analysis;
- Dimensional inspection carried out by suitably qualified and experienced operatives or by automated inspection systems;
- Radiography is carried out using a qualified process, typically this is automated. The subsequent radiographic images are assessed by a suitably qualified and experienced operative or by a qualified automated image analysis process; and
- Ultrasonic Testing is carried out using a qualified process, typically this is automated. The subsequent test data is evaluated and sentenced by a qualified automated data analysis process.

Other specialist NDT techniques may also be employed to assess specific attributes such as enrichment of loaded pellets.

III-8.5. Sampling

Sampling is typically used where the high volume of pellets produced make sample inspection a practical option when combined with process control.

Typically, analytical testing of pellets is done on a sample basis to ensure the specification requirements have been met for the pellet composition. The sample needs to be taken as defined in a sampling plan at a recognized frequency based on statistical analysis.

III-8.6. Witnessing

Witnessing is frequently used by fuel vendors and utility customers to provide additional oversight and assurance of the manufacturers' internal arrangements. Typically witness plans are prepared and agreed prior to manufacturing commencing. They need to be based on a combination of historical data but take cognizance of current data from the plant.

III-8.7. Calibration

All measurement equipment which influences process control or provides data for the assurance of product quality needs to be correctly calibrated. The equipment needs be calibrated at appropriate intervals, calibrations need to be recorded and validated and made available for witnessing by customers if required. Any piece of product quality equipment which is not adequately calibrated will result in the data from that equipment being considered invalid. Consequently, the product affected will be considered as non-conforming.

III-8.8. Non-conforming product

Non-conforming product needs to be properly identified and segregated from conforming product within the plant and processes. This is a fundamental requirement that needs to always be met, and the adequacy of these arrangements never has to be called into question. Consequently, on a fuel manufacturing plant, product and process traceability are paramount and need to be maintained at all times. If product and process traceability are lost, then the integrity of that product will be called into question and will be rendered non-conforming.

III-8.9. Subjective standards

Subjective standards are used where an element of subjectivity is required on the part of the inspector. Subjective standards are not used where automated assessment is carried out, for examples when using image analysis software or equipment of that type the equipment is usually calibrated using qualified standards. Subjective standards are used to eliminate as far as possible subjective judgement on the part of an inspector. They are intended to provide objective guidance to an inspector to enable him to make an objective judgement. The subjective standards are usually prepared by the manufacturer and acceptance/rejection of a feature/discontinuity is agreed with the customer. Typically, in fuel manufacturing, they are used in all stages of the manufacture.

The subjective standards will consist of a series of images of fuel rods with unusual marks or surface imperfections. Similarly, in the pellet manufacturing area, subjective standards can also be used to assess unusual pellet surface irregularities or imperfections. They also provide an assessment of an acceptable size of a defect or discontinuity where automated systems are not used.

III-8.10. Destructive testing

Destructive testing is used primarily to establish the integrity of welds on an end plug on a fuel rod. The typical destructive testing that is carried out is burst testing. That is where a sample is pressurized to assess whether the weld integrity is sufficient to prevent the rod failing in service.

III-8.11. Analysis

Analysis of pellets is a destructive testing technique which establishes that the pellet attributes have been established during the qualified process. Analysis of pellets is extensive and requires the services of specialist analytical laboratory. The analytical techniques need to be correctly qualified, and where specified these techniques need to be independently accredited.

III-9. SUMMARY

Nuclear fuel manufacturing provides a good example of where quality assurance and quality control are used together to provide the assurance of product quality to the highest level. Assurance that the product meets the specified attributes in itself is not sufficient.

It needs to be complementary assurance that manufacturing was conducted within a stable process operating to qualified parameters which enabled to product to consistently achieve the specified requirements.

The product and process assurance coupled with the appropriate certification are required to demonstrate that the product meets all the specified requirements.

The level of assurance is necessary as the product is part of the safety case for the reactor and as such the confidence in the product quality of any nuclear fuel assembly be established without question.

ANNEX IV.
QUALITY CONTROL ACTIVITIES DURING MANUFACTURING AND CONSTRUCTION PHASE OF AN NPP - EXPERIENCE FROM FINLAND

IV-1. GENERAL

Quality control is the part of quality management focused on fulfilling quality requirements as defined in ISO 9001:2015 [IV-1]. Surveillance and verification activities are one of the core activities under the licensee's responsibilities (ISO 19443:2018 [IV-2] chapter 8.4.1 and 8.6).

IV-2. INDEPENDENCE OF QUALITY CONTROL ACTIVITIES

It is of paramount importance that the conformity assessment is performed in such way that, the party performing control and inspection activities is independent from design and execution.

According to good practices of quality control (example NQA-1 [IV-3]), those verifying activities affecting quality shall have sufficient authority, direct access to responsible levels of management, organizational freedom, and access to work to perform this function, including sufficient independence from cost and schedule when opposed to safety function considerations.

The principles of ISO/IEC 17020:2012 [IV-4] are followed and focus shall be given to impartiality of quality control activities such as:

- Inspection activities shall be undertaken impartially;
- The inspection body shall be responsible for the impartiality of its inspection activities and shall not allow commercial, financial or other pressures to compromise impartiality; and
- The inspection body shall identify risks to its impartiality on an ongoing basis. This shall include those risks that arise from its activities, or from its relationships, or from the relationships of its personnel. However, such relationships do not necessarily present an inspection body with a risk to impartiality.

IV-3. QUALITY CONTROL AND INTERFACES WITH QUALITY ASSURANCE

Quality control activities share a large number of interfaces with quality assurance activities, for both are integral part of overall quality management.

Quality assurance develops frameworks in which verifications and controls performed by quality control are defined. The goal of quality control is to verify fulfilment of requirements during manufacturing, construction, installation and commissioning while the goal of quality assurance is to improve development and test processes so that defects do not arise when the product is being developed.

Quality control aims to verify if defects are identified in the manufacturing phase or in the finished product. Quality control, therefore, is a reactive process while quality assurance aims to prevent defects with a focus on the process used to make the product. It is a proactive quality process. quality assurance establishes a good quality management system and the assessment of its adequacy with periodic conformance audits of the operations of the system while quality control finds and eliminates sources of quality problems through tools and equipment so that requirements are continually met.

Quality control activities are intertwined with management of product nonconformities and both processes are dependent on each other.

IV-4. QUALITY CONTROL AND INTERFACES WITH SAFETY CULTURE

A systematic management of safety culture is essential to ensure that all activities are done according to requirements, quality and safety targets are met, safety is continuously developed, and ultimately, to ensure nuclear safety during all lifecycle phases of a nuclear power plant.

The results of quality control activities are a source of input for safety culture planning and development. If in the course of an inspection or surveillance activity, a nonconformity or observation is identified which root causes are directly or indirectly connected to safety culture activities, the staff involved in such activities are responsible for reporting such an event to their direct supervisor.

IV-5. QUALITY CONTROL AND INTERFACES WITH CONFIGURATION MANAGEMENT

Quality control activities are based on the principle of product freeze. The evaluation of fulfilment of requirements always needs to be based on design previously approved by all relevant parties. If, in the course of an inspection or surveillance activity, the freezing of the design is unclear or ambiguous, the staff involved in such activities are responsible for reporting such an event to their direct supervisor and to the quality control manager. The inspection or surveillance activity needs to be stopped until full clarification of design integrity is achieved.

The result of quality control activities may influence in the product configuration management.

IV-6. DESCRIPTION OF QUALITY CONTROL ACTIVITIES

The control of production and associated services relates to activities, which can directly affect product quality, such as manufacturing, installation, commissioning, tests, maintenance and which can result or take place through the following processes as applicable:

- Design;
- Manufacturing;
- Site activities including construction;
- Installation; and
- Commissioning.

Production and services provisions are carried out under controlled conditions, these controlled conditions include:

- The availability of information that defines the characteristics of production or service, such as applicable design, specification, and necessary processes, procedures and instructions;
- The organization and coordination activities, example: resource planning for employees as well as equipment, coordination of transport activities, planning of the infrastructure and work environment;
- The use of suitable equipment;
- Required inspection and test activities specific for production and services are planned, performed, controlled and traced for compliance with established acceptance criteria,

and as applicable, using adequate tools and equipment regarding e.g. range, type, accuracy and precision;
- Verification is carried out to ensure that the production and services are performed satisfactorily, and that risks, claims and emergency situations are appropriately managed;
- The availability of the status of inspections and tests performed on production and services; and
- As applicable, handling, transportation, storage, maintenance and operation of the products comply with the specified requirements to prevent their damage, loss, deterioration or inadvertent use.

Purchased and manufactured products have a vital role in the construction of an NPP and meeting of requirements set in specific component technical specifications for products needs to be ensured by supplier at all times by systematically monitoring conformity of the products. This means, for example, manufacturing and construction monitoring and reporting of nonconformities.

During inspections where the quality control inspector or its representative participate as witness point or hold point, they are entitled to stop any kind of inspection if there is evidence available showing that the requirements won't be most likely fulfilled.

IV-6.1. Quality Control during Manufacturing

The licensee has to verify the progress of the works in order to examine and inspect the quality of materials and the work carried out and to survey testing of materials, structures, system and components in any work place of the supplier or sub-suppliers.

The supplier(s) and/or manufacturer will establish and maintain a documented inspection system capable of producing objective evidence that all materials, manufactured parts and assemblies comply with quality requirements stipulated in the standards and contracts.

Inspection and testing plans (ITPs) are issued by the supplier and/or manufacturer and verified by relevant engineering unit. The inspection system needs to, as a minimum, include procedures used for controlling the following functions:

- Free access to the manufacturing or installation facility;
- Availability at inspection points of applicable drawings, instructions and other relevant documents and prompt removal of superseded documents;
- Maintenance and calibration of suitable inspection and test equipment;
- Inclusion of the necessary technical inspection and test details to meet the specified requirements and regulator's rights of involvement at the manufacturing works;
- Incoming materials, in process and final inspection and inspection of packing and marking;
- Means of identifying inspection status throughout manufacturing;
- Provision of complete inspection and test records; and
- Provision of all certificates according to national and international standards

IV-6.2. Quality Control during Construction and Installation

IV-6.2.1. Civil Works

For structures and buildings, the mandatory national laws and regulations for civil works are the basis for all inspections.

For safety classified civil works, specific requirements are defined by the local regulator. For non-safety classified civil works (e.g. turbine island), as defined in YVL Guide E.6 [IV-5], the concreting or injection works of non-nuclear safety structures normally starts after licensee's inspection.

IV-6.2.2. Mechanical

For safety classified components and prior to commencing the construction/installation/erection and related follow up activities, the following documents (as a minimum) are to be issued by supplier(s):

- Supplier(s) and/or subcontractor(s) approval file;
- Inspection and testing plan (ITP);
- Prerequisite for welding operation (e.g. welding plans);
- Testing organization file;
- Inspection organization file.

For the equipment in the scope of European Union (EU) Directives (including non-safety classified equipment), e.g. Pressure Equipment Directive (PED) 2014/68/EU or other legislation, the manufacturer or the notified body (depending on PED requirements) responsible for the manufacturer/ components/ parts, is required to draw up their own report in situ.

For welding quality control activities, personnel need to be qualified and have accreditation depending on the inspection and/or test to be performed.

IV-6.2.3. Electrical and Instrumentation and Control

For electrical and instrumentation works, the mandatory national laws and regulations are the basis for all inspections.

IV-7. RECORDS AND REPORTING

The results of quality control activities are reflected in approved records, such as but not limited to ITPs, product nonconformity reports, end of manufacturing reports and end of installation reports.

During inspections where the quality control inspector or its representative participates as witness or hold point, they are entitled to report any kind of deviation such as safety concern, observation, open point or non-conformance. They are responsible for making sure that the deviation is appropriately registered in the inspection report as well as entitled to notify their management according to the applicable discipline.

The evidence resulting from inspection activities needs to be unambiguous and traceable at all time, including but not limited to all the links to personnel performing inspections, criteria for inspections, notifications, related non-conformities, open points and regulator's decisions.

These reports need to be accessible by any inspection body, i.e. sub-suppliers, supplier, owner and authorities, in the purpose of any relevant inspection proceedings.

IV-8. MANAGEMENT OF MEASURING AND TEST EQUIPMENT

In order to ensure the conformity of the product as defined in ISO 9001:2015 [IV-1] clause 7.1.5, the licensee needs to implement a process for management of measuring and test equipment.

This process could include the following:

- Calibration requirements;
- Calibration intervals;
- Identification and traceability of measuring and test equipment;
- Responsibility for controls for measuring and test equipment
- Maintenance of calibration records; and
- Handling and storage of measuring and test equipment.

IV-9. SUSPECT, FRAUDULENT AND COUNTERFEIT ITEMS

A suspect item is one in which there is an indication by visual inspection, testing, or other information that it may not conform to established industry-accepted specifications or national/international standards. A counterfeit item is a copy or substitute without legal right or authority to do so or one whose material, performance, or characteristics are knowingly misrepresented by the vendor, supplier, distributor, or manufacturer (NP-T-3.26 [6]).

When a fraudulent and/or counterfeit item is identified the main steps are tracking, regulatory reporting, training, communication and information sharing.

Measures to ensure products are authentic and reduce the risk of introducing counterfeit or fraudulent items include:

- Procedures for detection and prevention of counterfeit and fraudulent items;
- Instructing staff on the issue of counterfeit and fraudulent items, and providing information on incidents of suspected counterfeit items that have been received or experienced by others; and
- When an item suspected of being counterfeit or fraudulent is identified, measures including segregation and control of the suspect item as nonconforming material.

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ABBREVIATIONS

AEA	action error analysis
AISC	American Institute of Steel Construction
AIVR	average index vendor rating
ANI	authorized nuclear inspector
ANSI	American National Standards Institute
AS	Aerospace Standards
ASME	American Society of Mechanical Engineers
BIM	building information modelling
BS	British Standard
BSI	British Standards Institution
CAP	corrective action programme
CFR	code of federal regulations
DIN	Deutsches Institut für Normung (German Institute for Standardization)
ENSI	Eidgenössisches Nuklearsicherheitsinspektorat (Swiss Federal Nuclear Safety Inspectorate)
EU	European Union
FAT	factory acceptance testing
FME	foreign material exclusion
FME(C)A	failure mode and effects (criticality) analysis
HAZOP	hazard and operability study
IMS	integrated management system
ISO	International Organization for Standardization
ISO/TC	International Organization for Standardization/Technical Committee
ITNS	important to nuclear safety
ITP	inspection and testing plan
IVR	index vendor rating
MORT	management oversight and risk tree

MS	management system
MT	magnetic particle testing
NDE	non-destructive examination
NDT	non-destructive testing
NEPIO	nuclear energy program implementation organization
NIST	National Institute of Standards and Technology
NPP	nuclear power plant
NQA	nuclear quality assurance
OH&S	occupational health and safety
PDCA	plan-do-check-act
PED	pressure equipment directive
PDSA	plan-do-study-act
PPE	personal protective equipment
PSR	periodic safety review
PT	liquid penetrant testing
PWR	pressurized water reactor
R&D	research and development
QA	quality assurance
QAG	quality assurance grade
QC	quality control
QMS	quality management system
QP	quality plan
SQEP	suitably qualified and experienced person
STUK	Säteilyturvakeskus (Radiation and Nuclear Safety Authority)
UT	ultrasonic testing
USS	United States Ship
YVL	Ydinturvallisuusohjeet (regulatory guides on nuclear safety)

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20-01337E

International Atomic Energy Agency
Vienna
ISBN 978–92–0–107020–3
ISSN 1011–4289