Chapter 7. Product Quality

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7.1 Introduction

This Chapter addresses Product Quality. However, the information contained in this chapter can also be applied Services. Where the term “product” is used, it should be considered as “product or service”. However, the chapter content is more aligned to the production of products than the delivery of services (such as design).

Product Quality is the collection of features and characteristics of a product that contribute to its ability to meet given requirements. To determine product quality, first we must understand the requirements.

Example

If we were assessing the quality of three cars, a family saloon, a sports car and an off-road 4x4, first we must understand our customer requirements. If the customer requires a family car with superior safety features and reliability, then the family saloon would be the product with the highest quality.

In the nuclear industry, product quality is a key factor for ensuring nuclear safety. We must fully understand the need of the products, the product requirements, including any safety function or role in ensuring nuclear safety. Once we understand the requirements of the product, we can plan and undertake activities to verify the requirements have been met, thereby ensuring we have a quality product.

Ensuring appropriate product quality starts with quality planning. Quality Plans are used to define the actions, responsibilities and associated resources needed to ensure the successful delivery of a specific contract or product through its entire lifecycle. Quality planning through the design phase of a product ensures designs are appropriately reviewed and design changes are properly managed. In order to demonstrate that products meet their safety functional requirements it is necessary to demonstrate that sound proven robust design concepts, rules, standards and methodologies have been utilised.

The activities undertaken to realise the design during manufacturing or construction must be planned along with any inspection and testing to verify the products meet the design requirements. A product is monitored at each stage of its development to ensure that it meets the requirements and is safe. The level of inspection and testing used is defined in what grade/classification a product is given. Inspection and testing activities are typically planned using Inspection and Test Plans (ITP) to verify that all necessary activities are complete, and the product meets all the requirements.

7.1.1 Role of Quality Professionals in ensuring Product Quality

Quality professionals undertake a number of important activities in relation to ensuring Product Quality, such as:

- Assisting with the preparation and review of requirements, particularly in relation to Quality management requirements;
- Producing Quality Plans and monitoring their implementation;
- Helping to establish suitable criteria for the inspection, testing and acceptance of product;
- Reviewing Inspection and Test Plans and supporting document and records;
- Carrying out or overseeing product assessments including inspection and testing;
- Carrying out appropriate levels of assurance and oversight, including on-site and off-site inspections, surveillance visits and audits;
- Ensuring that licensees and suppliers establish and implement robust processes for the identification, mitigation and control of Counterfeit, Fraudulent or Suspect Items (CFSI);
- Assisting with the management of non-conforming products and concessions;
- Document and records management including long-term preservation;
- The promotion of a proactive nuclear safety culture including encouraging a questioning attitude.

7.2 Product Quality Planning

Adequate product quality planning is essential to ensure that products are designed and made to an appropriate standard including fulfilling their safety function. Quality planning is reflected in product specifications, Quality Plans, design documents and other documents such as Inspection and Test Plans (ITP) and test procedures. The extent of quality planning required varies depending on the complexity of the product and the safety significance of its component parts. Planning may need to be coordinated across organisational interfaces and involve the production of one or more Quality Plans for each organisation.

7.2.1 Quality Grade

Nuclear Licensees and their supply chain are encouraged to apply a graded approach to products and services. The graded approach ensures the effective use of resources through the deployment of appropriate levels of assurance and oversight, commensurate with the level of risk associated with failure of a product during service.

When applying a graded approach, Licensees would typically consider the following:

- The magnitude of the potential consequences if a product fails or an activity is carried out incorrectly;
- The significance and complexity of each product or activity;
- The hazards and the magnitude of the potential impact (risks) associated with the safety, health, environment, security, quality and economic elements of each product or activity.

For further information on the graded approach, see Chapter 3 (Leadership and Management).

In planning the levels of quality activities for products, the specifier should first consider the safety significance of the product, the level of quality assurance and quality control activities normally applied to the product for its intended use, the code/standard requirements and the possible difficulty of inspection and testing post manufacture or installation. All products are specified and designed to provide a required engineering functionality. This functionality has an influence on safety and so requires an appropriate Safety Category and Classification to be assigned, see IAEA SSG-30 [1]. This classification affects the design methods and standards, material selection, procurement process, manufacturing/construction and installation inspections as well as maintenance requirements and in-service inspections.

These factors are used to determine the Quality Grade to be applied to the product. The Quality Grade then sets out the minimum quality assurance and quality control measures, which must be applied to the product, and that are typically mandated through customer specifications [2].

7.3 Quality Plans

Quality Plans are used to define the actions, responsibilities and associated resources needed for the delivery of a specific contract or product. They are usually supported by other documents such as project management or execution plans (PMP/PEP), design documents, Inspection and Test Plans (ITP) and management system or product specific procedures. Complex items that are manufactured or constructed in stages or through assemblies may require several Quality Plans. The Quality Plan should describe all the arrangements in place to ensure the quality of the product being delivered through all stages.

Products are typically delivered under the controls of an organisations quality management system [3], which may be certified to international standards such as ISO 9001 [4]. Due to the complex nature of the nuclear industry, some products are delivered by more than one organisation (such as joint venture or consortiums) and in such cases, the Quality Plan is used to describe the implementation of the applicable management system arrangements for the delivery of the product.

Customers and Licensees normally include requirements for Quality Plans and Inspection and Test Plans (ITP) in procurement specifications. The Quality Plans may require customer or Licensee approval/acceptance prior to use and may need to include mechanisms for the notification and management of ITP control points (see section 7.5).

The scope of Quality Plans should address all the aspects outlined in this document along with the guidance on Quality Plans and their implementation in projects which can be found in international standards BS ISO 10005 [5] and 10006 [6].

7.4 Specifications, Codes & Standards

Specifications and requirements for products, including any subsequent changes, are expected to be in accordance with established standards and incorporate applicable requirements. Whenever codes and standards are specified the version should be defined; in that way there should be no ambiguity as to the requirements, particularly in nuclear projects which typically span many years and therefore possibly multiple revisions of the required codes and standards.

It is customary in the nuclear industry for designers to utilise other international codes and standards as part of the design process. These may also be supplemented or replaced entirely by the licensees' own standards. Differences in dimensional units or other factors may emanate from foreign designs and this aspect may well require further consideration.

Example

In the development of Sizewell B in the UK, which is based on a US PWR design, US design codes and standards [7] led to the production of specific UK manufacturing and construction specifications to replace US product standards. Similarly, Hinckley Point C in the UK is based on French design codes and standards [8].

It is important to recognise that international codes may set standards and requirements for construction details, workmanship, material specifications, inspection and testing requirements, which may be unfamiliar to the domestic manufacturing and construction work force or Regulator. Therefore, drawings and manufacturing/construction specifications should include all design, workmanship, inspection and testing requirements to be fulfilled during the delivery processes. However, it would also be expected that the designer highlight areas that might not represent 'normal' practice in order to establish the practicality of the proposal and ensure full understanding of the requirements.

When products are procured, the contractor should be fully knowledgeable with the relevant codes and standards used, and further, that Suitably Qualified and Experienced Personnel (SQEP) are employed in the relevant roles. For further information on the procurement of products and services, including their specification and oversight, please see Chapter 6 (Supply Chain Management).

International codes and standards tend to base design on the materials available within the country of origin. These materials may not be the standard, readily accepted or readily available norms in the home country.

The designer needs to specify materials that will meet the relevant requirements in a manner that is acceptable to the manufacturing organisation. Failure to communicate and agree these requirements will lead to formal design change requests later.

Changes in requirements subsequent to the completion of the design should be kept to a minimum as determining the implications for the design can require multi-disciplinary specialist knowledge and if there are numerous design changes, there is a risk that the specialists may not be aware of all the changes when making a decision. In addition, changes to agreed design may require approval by the Regulator and will likely have additional cost and schedule impacts. Design changes require robust configuration management controls, which should be included in the associated Quality Plan.

Example

Changing a material or component in one area may have a knock-on effect to another area. This means by trying to eliminating one problem, another problem may be created in another area of the project.

7.5 Inspection and Test

Inspection and Test Plans (ITP) for products (or Quality Control Plans for services) are used to identify all activities during product realisation that impact the quality of the product, including design, procurement, production, verification, inspection, Factory Acceptance Testing (FAT), installation and Site Acceptance Testing (SAT) and commissioning activities.

ITPs typically document the activities required to deliver the product in a sequential manner and include the acceptance criteria, control points and the associated evidence of completion (through records, signatures or operator stamps).

ITPs should detail at what phase of manufacturing inspection and testing are performed, the acceptance criteria, the evidence of conformity and who is to be present when the activity takes place to witness or oversee the activity. ITPs typically focus on inspecting during the manufacturing process, carrying out FAT and SAT.

It is also important that there are effective systems for identification of the status of items and for the recording & dealing with all non-conformances (see section 7.11). It is important to know exactly where materials come from and that they meet specifications; this is due to the large number of Counterfeit, Fraudulent and Suspect Items (CFSI), which do not meet requirements and jeopardise nuclear safety (see section 7.12). It is vital for ensuring nuclear safety that these items do not make their way onto nuclear sites and into structures, systems and components.

The level of detail included in ITPs should be commensurate with the Quality Grade (and therefore the associated Safety Category and Classification). Inspection and testing by itself is not sufficient to ensure the quality of a construction or manufacturing process, it is however important that inspection and test activities are properly planned and completed. ITPs primary purpose is to ensure all the inspection, verification and testing activities necessary to ensure the product meets the requirements are completed by the organisation delivering the product or service, however it also serves the purpose of providing the customer and/or Licensee/Regulator [9][10]/Third-Party with an overview of the activities and the opportunity to intervene or participate in the processes as required by their ultimate responsibilities. ITP activities usually include control codes or points, which are typically:

- **Hold Point**. Process cannot proceed past this point without formal release;
- **Witness Point**. Activity subject to external witnessing;
- **Review Point**. Evidence from activity requires review (and/or approval/acceptance).

Activities for inspection, testing, verification and validation need to be completed before the acceptance, implementation or operational use of products. The tools and equipment used for these activities need to be of the appropriate range, type, accuracy and precision.

7.5.1 Inspection & Test Plan Requirements

The following types of information should be included in (or referenced from) the Inspection and Test Plans:

- General information, such as the name of the installation, the product or system reference, the procurement document/contract reference, the document reference number and status, associated procedures and drawings.
- Identification of Special Process requirements (see section 7.6), including the use of SQEP operatives undertaking the work.
- A sequential listing of all inspection and testing activities. It needs to be clear at what stage of production each inspection and test activity is to be carried out.
- The products or items to be inspected and tested should be identified and referenced.
- The process and product monitoring and measurements to be applied.
- The procedure, work instruction, specification or standard (or the specific section, if appropriate) to be followed in respect of each operation, inspection or test. In addition, the facility for review of specific procedures for acceptance prior to use.
- The relevant acceptance criteria for each inspection and test activity.
- Any statistical control methods to be applied.
- Specification of who is to perform each inspection and test and provision for recording that each inspection and test has been performed satisfactorily.

- Specification of Hold Points beyond which work may not proceed without the recorded approval of designated individuals or organizations.
- Specification of Witness Points where an assigned individual or organization can check activities but where the work need not be stopped if the inspector is not present.
- Specification of Hold points for inspection and testing by an external organization that is independent of the installation, e.g. the Regulatory body, Licensee or a third-party inspector.
- The records, including Lifetime Records (LTR) that are generated for each inspection or test (See section 7.9).
- The number of products to be inspected or tested when multiple products or repeat operations are involved.
- The individuals or organizations that have authority for the final acceptance of the product.
- The criteria for the release of products.
- The criteria for package, deliverer and storage for coated products or products that shall be stored for a period of time (see section 7.10).

7.5.2 Test Requirements

Test requirements, including testing frequency and acceptance criteria, should be specified. The test requirements should be subject to the approval of the organization responsible for the specification of the product to be tested. Required tests should be controlled. Tests may include:

- Prototype qualification tests;
- Production tests (Factory Acceptance Testing (FAT), Load testing);
- Proof tests prior to installation or handover of equipment in the installation;
- Construction tests (Site Acceptance Testing (SAT));
- Pre-operational or commissioning tests;
- Operational tests.

The acceptance criteria should be based on the design documents or other relevant documents. Testing should verify that the safety function of a product has been maintained. Appropriate testing of computer software should be completed before reliance is placed upon the software for operations.

Testing instructions should specify the test objectives and should make provision for ensuring that prerequisites for the given test have been met, that adequate equipment is available and is being used, that necessary monitoring is performed, tests are performed by SQEP personnel and that suitable environmental conditions are maintained.

Test results should be documented and evaluated to ensure that testing requirements have been satisfied.

7.6 Special Processes

Special Processes are activities for product realisation where the resulting output cannot be fully verified by subsequent monitoring or measurement. For such processes, we are unable to fully verify the characteristics of the product without destroying the product as part of the evaluation (destructive testing) and as such, they present an increased risk to product quality.

Measures need to be established to assure that Special Processes are controlled and accomplished by SQEP personnel using qualified procedures in accordance with applicable codes, standards, specifications, criteria, and other special requirements. Special Processes must be validated and must demonstrate their ability to achieve desired results based on acceptance criteria that have been previously determined.

While not an all-inclusive list, processes that fall under this category include:

- Welding;
- Non-destructive examination (NDE);
- Heat treatment;
- Manufacturing practices (casting, forging, bending, forming, bonding, protective coatings and other processes).

While infrequent, disagreement can arise over what is a Special Process, but if the characteristics of a product cannot be 100% verified without destroying the product, this classification typically applies. In all cases, it is up to organization to define these processes as part of their Quality Plan and to address these processes as appropriate.

For these processes, the only alternative to destroying useable product is to ensure that the process is controlled to the degree that it is capable of producing only conforming product. To achieve this outcome, international quality management standard BS EN ISO 9001 [4] (or BS EN ISO 19443 [11]) address the control of these processes by requiring the organization to establish arrangements for the control and verification of procedures, personnel, equipment and other factors that may impact the process under consideration.

Example

Due to structural transformations during welding, it is difficult to determine if the welding is continuous, base material and welding material are properly mixed, no internal holes exist, no cracks exist, etc. Although non-destructive testing methods exist, they cannot confirm 100% that the weld is adequate. A test for proving that weld is OK would be a destructive

one; destroying the weld destroys the product. Therefore, welding process must be validated.

Special Process may require verification through independent third-party processes utilising organisations certified to ISO/IEC 17020 [12] and/or ISO/IEC 17025 [13]. Verification of Special Processes using independent certified laboratories may be included as a requirement through customer specifications.

7.7 Metrology & Calibration

7.7.1 Measuring & Test Equipment

In line with BSEN ISO 9001 [4] and BSEN ISO 19443 [11] where measuring or test equipment (MTE) is used for any inspection, testing, verification and validation activity which may affect safety, the MTE should be of the suitable range, type, accuracy and precision. In addition, tools, gauges, installed instrumentation and other inspection and MTE (including testing software and devices) should be of the appropriate range, type, accuracy and measuring precision. Depending on the Quality Grade and type of product, statistical tools such as Measurement System Analysis and Gauge Repeatability and Reproducibility studies may be considered necessary to validate and verify the measurement capability of MTE.

It is possible for MTE to be damaged during handling and it is also possible for the readings given by the instrument to drift with usage of the instrument or with age. If measurements are carried out by a faulty MTE then the conformity of the product to the specifications also becomes questionable. The MTE should therefore be calibrated at the time of purchase and thereafter at regular intervals, with frequency depending upon their use. Some MTE may also need to be calibrated before every use.

The use of MTE should uniquely be identifiable for traceability purposes and when used in inspection, testing or verification of a product, the item(s) of MTE used should be recorded to ensure containment of products affected by faulty MTE can be performed.

Example

If an item of MTE is found to fail its periodic calibration, we would need to be able to trace and identify all products that used that item as part of the products inspection, testing or verification activities since its last successful calibration. We would have to perform quarantine/containment activity, as the products would have to be considered as 'Suspect' (see section 7.12) until further verification of their conformity can be confirmed.

Calibration can be performed by the organisation performing the measurement in accordance with approved procedures, or by an independent/third-party testing and calibration laboratory. Testing and calibration laboratories used should operate appropriate management systems that may require certification to international standards such as

ISO/IEC 17025 [13]. Certification requirements of testing and calibration laboratories may be included in customer specifications.

7.7.2 Calibration Process

A process should ensure the MTE is calibrated and traceable to National Standards [14]. The calibration process is applied to all MTE, which may affect safety (e.g. radiological measuring equipment, operational process measuring equipment and measuring equipment used for maintenance).
The calibration process should include:

- Specification of the measurements to be made and the accuracy required, and the specific MTE to be used.
- Identification, calibration and adjustment of all MTE and devices that could affect product quality, at prescribed intervals or prior to use, against certified equipment having a known and valid relationship to nationally or internationally recognized standards. If no such standards exist, the basis used for calibration should be documented.
- Establishment, documentation and maintenance of calibration procedures, including details of the type of MTE, its unique identification number, its location, the frequency of checks, the check method, the acceptance criteria and the actions to be taken when results are unsatisfactory.
- Verification that the MTE has the required accuracy and precision.
- Identification of MTE with a suitable indicator or approved identification record to show its calibration status.
- Maintenance of calibration records for MTE.
- MTE is such that its accuracy and fitness for use are maintained.
- Protection of MTE from adjustments that may invalidate its accuracy.
- Methods for adding MTE to and removing it from, the calibration programme, including the means to ensure that new or repaired products are calibrated prior to their use.
- A process to control the issue of MTE to SQEP authorized individuals.

A process should be established for the control of MTE that is out of calibration, including its segregation to prevent its further use and the identification and evaluation of any consequences of its use for previous measurements made since the last calibration date.

Testing hardware, such as jigs, fixtures, templates or patterns, and testing software used for inspections should be checked prior to their use in production and in the installation. They should be rechecked at prescribed intervals and account should be taken of any recommendations of the manufacturer/supplier. The extent and frequency of these checks should be established, and records should be maintained as evidence of control with hardware that has been approved for use being accurately identified. Where the test results

for a product are required to be submitted to a Regulatory authority for approval, it is necessary for the authorities to recognize the laboratory that has performed the tests.

7.7.3 Inspection Validation

Some inspection processes, particularly Non-Destructive Testing (NDT), may require independent validation through qualification of the process and personnel to ensure they are effective and deliver the assurances required on safety-related and safety-critical products. Inspection validation or qualification is a formal process for gaining confidence that inspection can meet its objectives and will detect defects and ensure products meet requirements. The process covers the entire inspection process by independently examining individually and in combination the elements of the MTE, the inspection and testing procedures and the SQEP personnel. Inspection validation is usually performed by independent third-party organisations certified to ISO/IEC 17020 [12] and/or ISO/IEC 17025 [13] and it may form part of the licensee's Safety Case, see IAEA GSR Part 4 [15], and be required by customer specifications. Safety Case is a term used to encompass the totality of the documentation developed by a designer, licensee, or duty holder to demonstrate high standards of nuclear (including radiological) safety and radioactive waste management.

7.8 Certification and Qualification

Certification is defined by international standard BSEN ISO/IEC 17000 (Conformity assessment; Vocabulary and general principles) as "third-party attestation related to products, processes, systems or persons".

Product certification is required to demonstrate that a specific product meet a defined set of requirements and is carried out by third-party certification bodies that are independent of the consumer, seller or buyer, and are acceptable/recognized by purchasers, importers and Regulatory authorities.

Many national standards bodies provide third-party product certification services, which include placing their certification mark on the product, along with the reference number of the standards used as the criterion for testing the product. In some countries, product certification is also carried out by trade or industry associations, government institutions or private certification bodies.

The product certification authorities usually permit the use of a mark on the product to demonstrate that the product meets a defined set of requirements, such as safety, fitness for use and/or specific interchangeability characteristics that are usually specified in related standards or specifications. The mark is normally found on the product or its packaging; it also carries a reference to the number of the relevant product standard against which the product is certified. Ideally, a product certification mark should demonstrate to the consumer that a product meets the generally accepted standard for that product.

Example

In the European Union, CE marking is applied to products that meet the conformity assessments of the relevant directives [16]. “CE” is the abbreviation for “conformité européenne”, French for “European conformity”. CE marking is not a quality mark, it refers to the safety rather than to the quality of a product. CE marking is mandatory for the product it applies to, whereas most quality marking is voluntary.

7.8.1 Accreditation of a Conformity Assessment Body

Accreditation is an internationally accepted system that recognizes that a conformity assessment body (laboratory, inspection body, product certification body or system certification body) is able to provide its services in a professional, reliable, and efficient manner.

To demonstrate that the essential safety requirements are satisfied, equipment is subject to conformity assessment. The higher the category and therefore the greater the hazard, the more demanding are the requirements.

7.8.2 Equipment Qualification

Equipment Qualification (EQ) provides documented evidence that products are able to perform their safety-related functions reliably, on demand and in normal and abnormal conditions, or even in the event of an accident. EQ is often required by Regulatory bodies to demonstrate through independent qualification that safety-related and safety-critical products will operate as intended to meet the parameters of the Safety Case, see IAEA GSR Part 4 [15]. EQ also enables early detection of errors and weaknesses, which helps to prevent costly rework and saves time. EQ is usually performed by independent third-party organisations certified to ISO/IEC 17020 [12] and/or ISO/IEC 17025 [13] and may be required by customer specifications.

7.9 Traceability

Traceability of products to their source materials (including design information, specification, standards, and raw/construction material), production processes, inspection and testing and installation configuration (including non-conformance, concessions and production permits) is vital in ensuring product meet their requirements. Traceability requirements may include physical marking of products with unique identification or serial numbers, traceable back to the products’ history. The levels of traceability required are typically commensurate with the products’ safety function and associated Quality Grade and may be specified in customer specifications.

Traceability and associated records are a key factor in the mitigation of Counterfeit, Fraudulent and Suspect Items (CFSI) (see section 7.12).

7.9.1 Records

As-built records and Lifetime Records (LTR) should provide an actual, fully referenced account of the work and configuration of the product and should be produced in a timely manner as the information becomes available.

For the purposes of verification of production detail (particularly for Special Processes and areas that cannot be readily inspected or will become inaccessible, concealed or covered once complete) detailed referenced information (including photographs) should be retained and used as part of the as-built records. As-built records are an important aspect of future verification and maintenance and as such suitable and adequate provision should be made for their retention (see Chapter 8 – knowledge and Information Management).
In the event of a "latent defect" (a defect present which has not/cannot be detected until it results in an incident) the as-built evidence is be key for problem solving, containment and correction activities.

Production, management and retention of records has received various levels of attention during projects and has often been found to be an area of where practices are inadequate. Records requirements are often poorly specified and are sometimes not available due to the time delays in their production.

Example

In April 2019, the UK regulator (ONR) raised a Level 3 Regulatory Issue #7042 on Licensee NNB Genco for their HPC site due to adequate management their contractors' provision of LTR relating to civil construction activities and a Level 3 Regulatory Issue #2061 in 2014 relating to LTR on their Nuclear Steam Supply System (NSSS).

7.10 Storage, Handling, Packaging & Delivery

Provision needs to be made for preventing damage, deterioration, or loss of products. Products should be stored in a manner that provides for their ready retrieval and protection. Storage should be controlled to prevent the deterioration of degradable material, such as elastomer seals, O-rings and instrument diaphragms with measures included within a procedure which may require acceptance by the customer prior to completion.

Storage practices should be adopted to ensure that:

- Corrosive chemicals are well segregated from equipment and metal stock;
- Flammables are properly stored;
- Radioactive material is properly controlled;
- Stainless steel components are protected from halogens, sulphur and direct contact with other metals, in particular carbon steel;
- Relief valves, motors and other equipment are stored on their bases;

- Containers (boxes, barrels and crates) are stacked to reasonable heights and in accordance with instructions of the vendor and storage instructions;
- Parts, materials and equipment are repackaged, or protective caps are reinstalled to seal items on which previous packaging or protective caps have deteriorated or been damaged or lost while in storage;
- Elastomers and polypropylene parts are stored in areas where they are not exposed to light;
- Machined surfaces are protected;
- Products include Foreign Material Exclusion (FME) and are protected from the ingress of foreign materials and contaminants to prevent Foreign Object Damage (FOD);
- Material, equipment and storage facilities are properly protected from rodents and environmental conditions (e.g. temperature, humidity, ultra-violet radiation);
- Static/idle rotating equipment is regularly rotated;
- There is suitable segregation of safety related and non-safety-related components.

Physical means of identification should be used to the extent possible, and the identification should be transferred to each part of an item that is to be subdivided.

The handling and storage process should include arrangements for shelf-life management. For example, an item whose shelf life has expired should be discarded unless an engineering evaluation is conducted, and engineering approval is obtained prior to use of the item. For critical, sensitive, perishable, or high value items, special arrangements, such as the provision of protective enclosures, an inert gas atmosphere and moisture and temperature control, should be specified and put in place. These measures may also be applied to installed items that are subject to extended out-of-service conditions.

The handling and storage process should also cover field storage of consumables such as lubricants and solvents to ensure that they are properly stored and identified.

Items removed from storage should be protected. In the handling of items, factors such as weight, centre of gravity, size, certification and regular inspection of hoisting or lifting equipment, chemical reactivity, radioactivity, susceptibility to physical shock or damage, electrostatic sensitivity, sling location, balance points and method of attachment should be considered. Special handling tools and equipment should be provided, controlled, and inspected periodically as necessary, to ensure safe and adequate handling.

Items removed from or placed into storage, including surplus material returned to storage, should be promptly documented so that the store inventory is kept accurate. The store record system should indicate the locations of materials and parts in all designated storage areas. Access to storage areas should be controlled.

Maintenance should be performed on items held in storage as required. Maintenance typically includes periodically checking energized heaters, periodically changing desiccants, rotating shafts on pumps and motors, and changing oil on rotating equipment and other maintenance requirements as specified by the Original Equipment Manufacturer (OEM) which should also be included within the accepted procedure.

7.11 Non-Conforming Product & Concessions

A health nuclear safety culture should be adopted and promoted in all organisations in the supply chain, such that all personnel are positively encouraged to report openly any potential non-conformances no matter how they have arisen. Generally, a 'questioning attitude' should be fostered within the organisation. For further information on nuclear safety culture, see Chapter 3 – Leadership and Management.

The identification, reporting and resolution of deviations or non-conformances should not be seen as negative but as an indication that the achievement of the customers' requirements is of prime importance. The control of any deviation from the specification is fundamental to the achievement of quality and therefore the integrity of the item. During the realisation processes deviations or non-conformances may occur. Deviations or non-conformances are unplanned departures from the requirements and can be identified through a number of mechanisms including inspection, testing, checking, self-assessment, audit or technical query. They can occur at any level within the supply chain.

It is important that there are appropriate arrangements including processes and procedures to record non-conformances and confirm the actions taken to address any issues resulting from a non-conformance. The arrangements for management of non-conformities must enable the identification, segregation, control, recording and reporting of non-conformances against processes, procedures, or specifications.

Non-conformances should be categorised in accordance with a graded approach, evaluating the severity and the impact on safety, so that they can be appropriately investigated, reported and have corrective actions implemented and verified to eliminate the cause(s), commensurate with the associated risks.

Where a non-conformity cannot be reworked to meet the specified requirements, a concession may be applied to either use the product as-is or repair the product to an agreed standard. A concession application to the customer is a formal request for approving the use of a product that does not meet one or more specified requirements. Decisions involving repair or concession should be made at appropriate levels of design authority and include assessments on fit, form and function as well as operational impacts, and for significant products may need Regulatory agreement due to the potential impact to nuclear safety. The arrangements should also include preventative actions to eliminate the cause of potential

non-conformances or read-across improvements across similar processes or product families.

All organizations within the supply chain should, as part of their quality management arrangements, operate consistent arrangements (flowed down from the Licensee) for the categorisation and disposition of deviations and non-conformance. Each level of the supply chain should ensure that their suppliers have adequate arrangements for the identification, categorization, and disposition of deviations for items or services. These should include obtaining the approval of the customer for the deviation in the form of a concession or procedure for re-work. Reporting requirements should be detailed in customer specifications and associated procedures. Deviations that are significant to nuclear safety may require reporting to the Regulatory body.

All decisions and dispositions should be recorded for future reference and trending. Non-conformance reports and any concession applications are vital in configuration management and must be included in as-built records and LTRs.

7.12 Counterfeit, Fraudulent or Suspect Items

Counterfeit, fraudulent, and suspect items (CFSI) present a real risk to nuclear safety and mitigations must be put in place to ensure they do not make their way into products installed in nuclear facilities.

The International Atomic Energy Agency (IAEA) has adopted the following definitions:

- **Genuine**. Products produced and certified without intent to deceive.
- **Non-conforming (sub-standard)**. Products that do not meet intended requirements or function and may be provided by legitimate suppliers without intent to deceive (see section 7.11).
- **Suspect**. Products where there is an indication or suspicion that they may not be genuine.
- **Fraudulent**. Products that are intentionally misrepresented with intent to deceive, including items provided with incorrect identification, falsified or inaccurate certification. They may also include items sold by entities that have acquired the right to manufacture a specified quantity of an item but produce a larger quantity than authorized and sell the excess as legitimate inventory.
- **Counterfeit**. Products that are intentionally manufactured or refurbished or altered to imitate original products without authorization in order to pass themselves off as genuine.

(Source - INTERNATIONAL ATOMIC ENERGY AGENCY, Managing Counterfeit and Fraudulent Items in the Nuclear Industry, IAEA Nuclear Energy Series No. NP-T-3.26, © IAEA, Vienna (2019) page 2.)

CFSI can infiltrate the supply chain at any stage and Product Quality measures must be used to enable their identification and control (see associated Chapter 6 – Supply Chain Management).

Example

In South Korea in 2012, eight companies were accused of supplying 60 forged quality control certificates to Korea Hydro and Nuclear Power (KHNP) since 2002. The affected equipment comprised mainly fuses, switches and cooling fans. Another case discovered in 2013 involved false test certificates for safety-related cabling. One hundred people were indicted in 2013, including some senior management at KHNP.

In a parallel case, prosecutors investigated KHNP's procurement functions and uncovered corruption among suppliers, brokers and company personnel. Over 7500 reactor parts were replaced at nuclear power plants on the orders of the Nuclear Safety and Security Commission at an additional cost of about $90 million.

World Nuclear Association - Supply Chain Working Group: Countering Counterfeit, Fraudulent and Suspect Items in the Nuclear Supply Chain

References [17], [18], [19] and [20] provide valuable information about the risks and management of CFSI.

7.13 Further Reading

7.13.1 Design

The design management for a nuclear facility must ensure that the structures, systems and components important to safety have the appropriate characteristics, specifications, and material composition. This is necessary so that the safety functions can be performed, and the plant can operate safely with the necessary reliability for the full duration of its design life.

The design management needs to ensure that the requirements of the operating organization are met, and that due account is taken of the human capabilities and limitations of personnel. The design organization needs to supply adequate safety design information to ensure safe operation and maintenance of the plant and to allow subsequent plant modifications to be made, and recommended practices for incorporation into the plant administrative and operational procedures (i.e. operational limits and conditions). It is important to design for all future users. A design is useless if it cannot be manufactured, installed, commissioned, maintained, and decommissioned.

Wherever possible, structures, systems and components important to safety should be designed according to the latest or currently applicable approved standards; shall be of a design proven in previous equivalent applications; and should be selected to be consistent

with the plant reliability goals necessary for safety. Where codes and standards are used as design rules, they need to be identified and evaluated to determine their applicability, adequacy and sufficiency and should be supplemented or modified as necessary to ensure that the final quality is commensurate with the necessary safety function.

The design concept should incorporate appropriate protection systems and monitoring systems to enable the component or structure to be maintained within its safe operating envelope for the duration of the life of the installation and adequate arrangements need to be in place for maintenance, inspection, and testing of the monitoring systems to ensure that the safety functional requirements continue to be met.

It is important to verify that safety significant components and structures are constructed from materials with well-established properties and behaviour.

The potential degradation mechanisms that could occur should be established at the design stage and appropriate materials chosen. This is part of reviewing the suitability of components and materials for their long-term use and the environmental conditions they are going to be placed in. Material properties used in analyses should be demonstrably conservative such as lower bounds from either generic databases or specific data that represent the component manufacturing and fabrication conditions.

Example

The steels specified for use in pressure boundary components and other structures important to safety need to have a well-established history of usage. If any unforeseen behaviour change or degradation mechanism is identified, the licensee should review and if necessary, update the relevant safety case.

The material composition, manufacturing process, operational history, pressure, temperature, irradiation, creep, fatigue, and corrosion mechanisms may result in degradation in the material properties assumed at the design stage. Appropriate provision should be made for the measurement of relevant properties of fully representative materials across the full range of environmental conditions expected throughout the identified lifetime of the plant. For example, many nuclear sites are situated on coastlines, which exposes materials to a higher risk of corrosion. Therefore, materials that are less likely to corrode would be chosen at the manufacturing stage. Measures such as pickling, passivation or galvanization may be carried out to protect the materials.

Example. Books of Technical Rules and Specifications

Books of Technical Specifications and Books of Technical Rules have been drawn up by EDF with reference either to design and manufacturing codes, or to European standards. Compliance with the requirements of the Book of Technical Rules is deemed to comply with

BS EN ISO 9001, the requirements from IAEA safety standard GS-R-3, and the EDF General Quality Assurance Specification.

Design References

- IAEA Safety Standards Series No. SSR-2/1 [21]
- ONR, Safety Assessment Principles for Nuclear Facilities, 2014 [22]

Civil Structures

Civil structures, typically constructed from structural steel or concrete, use idealized stress models to determine characteristic "stresses" that can be used to select the size of structural elements or the disposition of reinforcement. This process is known as structural analysis and certain classes of civil engineering structures can benefit from a detailed stress analysis, e.g., concrete vessels and containment. However, reinforced concrete presents particular difficulties for the stress analyst because it does not behave elastically. In structural analysis due consideration is given to uncertainties in material properties and verification of the methodology and loading data.

7.13.2 Pressure Equipment

In order to know how the UK Pressure Equipment Regulations (PER) will apply to specific items of pressure equipment, the manufacturer will need to classify the equipment according to its perceived level of hazard. Equipment of a relatively low hazard will be required to be manufactured according to 'sound engineering practice' (SEP). Equipment that is classified as a higher hazard than SEP is required to meet the relevant essential safety requirements of the PER and, on that account, to be CE marked. It is allocated, in ascending order of that hazard, to one of Categories I, II, III, or IV.

Inspection & Test plans (ITPs) are key, during manufacturing and construction, to provide the means to verify compliance with requirements. These contain the required control measures to be carried out (for example, a particular inspection or testing activity such as a dimensional check or pressure test).

7.13.3 Welder Qualification

Welder certification is based on specially designed tests to determine a welder's skill and ability to deposit sound weld metal. The welder's tests consist of many variables, including the specific welding process, type of metal, thickness, joint design, position, and others. Most often, the test is conducted in accordance with a particular code. The tests can be administered supported by national or international organization, such as British Standards (BSEN ISO) or American Welding Society (AWS), or American Society of Mechanical Engineers (ASME), but manufacturers may specify their own standards and requirements as well. Most certifications expire after a certain time limit and have different requirements for renewal or extension of the certification. In the USA, welder qualification is performed

according to AWS, ASME and API standards, which are also used in some other countries. In Europe, the European Committee for Standardization (CEN) has adopted the ISO standards on welder qualification (BSEN ISO 9606). In Europe welders are usually certified by third party Inspection Bodies or Personnel Certification Bodies. Welders involved in the manufacture of equipment that falls within the scope of the Pressure Equipment Directive must be approved by a competent third party, which may be either a notified body or a third-party organization recognized by a Member State.

Once a welder passes a test (or a series of tests), their employer or third party involved will certify the ability to pass the test, and the limitations or extent they are qualified to weld, as a written document (welder qualification test record, or WQTR). This document is valid for a limited period (usually for two or three years), after which the welder must be retested.

7.13.4 Qualification of Manufacturing Processes

Some manufacturing processes are to be qualified, such as procedures for manufacturing of certain parts and the operating procedures for permanent assemblies. It should also be noted that only staff possessing the required skills may be assigned to a quality related activity. Other staff requiring qualification include:

- Welders;
- Welding operators;
- Tube to tubeplate expansion operators;
- NDT operators.

Qualification operations for staff and procedures are not quality related activities.

7.13.5 CE Marking – Conformity Assessment

A manufacturer must follow a conformity assessment procedure in order to place CE-marked products on the market. The company may select from among the modules listed below, depending on the modules that are permitted or required by a particular European Union directive and the product's perceived risk level. Some products may require a combination of these modules:

- Internal control of production (module A);
- European Union-type examination (module B);
- Conformity to type (module C);
- Production quality assurance (module D);
- Product quality assurance (module E);
- Product verification (module F);
- Unit verification (module G);
- Full quality assurance (module H).

Notified bodies are designated by European Union Member States to carry out conformity assessment tasks according to the directives. A list of them is published in the Official Journal of the European Union. The notified body could be a third-party organization, such as an ISO 9001 certification body or testing body, or a product certification body accredited by the national accreditation bodies of member States of the European Union.

Guidance on CE Marking [23] and the new UKCA marking [24] is provided on the GOV.UK website. The UKCA marking became part of UK law on 31 December 2020 at the end of the Brexit transition period. UKCA marking is mandatory in the UK although until 31 December 2024 the CE mark is accepted as a valid alternative.

7.13.6 Quality Assessment System for Electronic Components

The International Electrotechnical Commission (IEC) Quality Assessment System for Electronic Components (IEQC) is a comprehensive, worldwide approval and certification programme that assesses electronic components according to quality requirements. The supplier's declaration of conformity under third-party supervision is an essential element of the system. Details of the scheme can be obtained at https://www.iecq.org/certification/ [25].

Conformity assessment generally consists of the following activities:

- Inspection;
- Testing and calibration;
- Product certification;
- System certification;
- Accreditation.

While each of the above activities is a distinct operation, they are closely interrelated. The reliability of the results of any of the activities depends on many factors, such as the competence of the assessment body, methods followed and the appropriateness of the standard against which the product is evaluated. The certification of structural nuclear safety related work should thus only be entrusted to appropriately qualified and experienced people.

Case study 1. NNB GenCo General Quality Assurance Specification & Quality Related Activities

For the UK EPR Project, requirements pertaining to Quality are expressed in contractual terms in the "General Quality Assurance Specification"(GQAS), reference ECUK100053. This specification is based on ISO 9001:2008, and includes additional requirements placed on the contractor to meet the needs of the nuclear industry. In particular to the following activities and requirements:

- Identification of Quality Related Activities (QRAs);
- Qualification of staff and technical equipment/processes;
- Technical inspection;
- QRA Performance Report.

A QRA is defined in the GQAS as "an activity, the failure of which can lead to a product non-compliance with the nuclear safety requirements".

Examinations and tests are carried out to check that a QRA has obtained the required result, and these examinations and tests form part of the "technical inspection". Examinations and tests are not considered to be QRAs except when justified by safety considerations. QRAs designed to ensure metallurgical quality are distinguished from those that guarantee equipment functionality. Depending on the safety considerations involved, an overall QRA may be broken down into several basic QRAs that are subject to individual technical inspections.

The method by which the requirements of the various clauses of the GQAS are implemented depends on the safety considerations involved.

The manufacture of materials, which are for use in level N1 nuclear pressure equipment and are subject to technical qualification, comprises the following QRAs:

- Melting process;
- Forming by hot or cold working;
- Forming by casting;
- Specified heat treatments;
- Non-destructive Testing (NDT).

Case study 2. Regulatory issues at Olkiluoto 3

During 2006, STUK (the Finnish regulator) appointed an investigation team after having noticed that the management of those participating in the construction of Olkiluoto 3 unit (the first ever EPR) did not fully comply with their expectations concerning good safety culture. Key findings were:

- Major problems with project management, in particular with regard to construction work, but not nuclear safety.
- The project should be provided with a strong safety culture.
- The large number of subcontractors had insufficient guidance and supervision to ensure smooth progress of their work. A particular problem was the supervision of subcontractors' performance level and the guidance provided for them.

- Recommendations both to the buyer Teollisuuden Voima Oy (TVO) and to the vendor company Consortium FANP-Siemens (CFS) and also room for improvement in the practices of the regulatory body (STUK).
- Design took longer than planned confusing the work schedules of sub-contractors.
- CFS did not understand the Finnish requirement for the design to be accepted by TVO and STUK before manufacturing commenced.
- Communication of requirements on quality and quality control, from CFS to subcontractors, had occasionally been deficient; essential quality requirements and any possible extra costs arising had not been clearly specified at the stage of the invitation to tender.
- Issues were found with the construction of the reactor island base slab and the reactor containment steel liner and in a later report with the emergency diesel generators (EDG). The EDG issues were mainly related to traceability and quality of the many components involved.
- The required standards have been maintained although in some cases only after corrective measures. The observed difficulties at the construction stage had therefore not influenced the safety of the power plant when it will be ready to operate.

Corrective measure were subsequently agreed with TVO and CFS and within STUK. Claims that welding issues occurred during construction have been refuted by STUK.

Case study 3. Regulatory issues at Flamanville 3

The table below show the issues that have arisen and been reported by the French nuclear regulator ASN at ASN's supervision of Flamanville-3 reactor in their Inspection News (IN) letters [26]

Table 1. Regulatory issues at Flamanville-3 reactor

Topic	Issue	EDF / ASN Response	NQK Comment
IN 1 - Apr 2008			
Safe system of Work	Inadequate consideration of crane fall on adjacent existing reactor safety structure	Design in safety structure to prevent fall.	
Concreting	Cracking to foundation block concrete – shrinkage – poured early Dec 2007	Repair by resin injection.	
Concreting & Management supervision	Rebar not fixed as drawings. Inadequate technical supervision by contractors and monitoring by EDF	EDF corrective actions (not defined) in place before concrete poured.	Correction time not defined

Topic	Issue	EDF / ASN Response	NQK Comment
Overview	Subcontractors' technical skills and safety culture	ANS believe EDF need to reinforce lead and monitoring of activities until shown satisfactory.	
IN - 2 June 2008			
Concreting & Management supervision	Rebar not fixed as drawings. Inadequate technical supervision by contractors and monitoring by EDF	Repeated issue – EDF to •suspend concreting of safety related structures •analyse malfunctions and corrective action required •Improve service provider technical control •Improve own monitoring activities • Improve own discrepancy management procedures	See IN 1 Topic 3 Led to ASN Regional Head being questioned in press conference
IN - 3 June 2008			
Concreting & Quality Management System	Authorise resumption of concreting after: •Improved technical control by service providers •Closer monitoring by EDF •Introduction of 3rd party supplementary tech inspection of concrete reinforcement operations •Clearer management of deviations •Training of all on site – improve safety culture •Strengthening Bouygues (principal civil and structural construction contractor) quality team	EDF to submit monthly report on implementation of action plan.	See IN 2 Topic 1 IN 4 shows work had been suspended for 23 days
IN 4 - Nov 2008			
Liner plate welding	Use of different welding method from those defined in technical specification	EDF •submit technical justification, •Propose additional weld testing •ASN review and accept proposals	5 June to 28 Aug i.e., +12 weeks disruption
IN 5 - Feb 2009			
Liner plate welding & Management supervision	1 Deviations from technical specification requirements •Use of different welding method from those defined	ASN asked EDF to suspend irreversible operations that would be incompatible with additional weld inspections.	See IN 4 Over 9-week loss on programme

Topic	Issue	EDF / ASN Response	NQK Comment
	• Climatic conditions during welding • Welding data package available to welders 2 Inadequacies against Order of 10 Aug 1984 • Qualification of the pre-manufacturing shop on site • Monitoring of welding operations and NDT of welds • Quality management system of company responsible for welding 3 High rate of weld repairs	ASN after two-month examination of case asked for existing welds – • additional data particularly on representative weld tests • 100% inspection of certain weld types • For new welds – • Action plan to improve weld quality • Monthly report on implementation of plan • 6 month report on effectiveness • 100% inspection of welds till confirmed significantly improved	before allowing for additional activities
Safe system of Work	Changed methods in excavation of sea outfall tunnel – consideration of effects on existing reactor	ASN ask EDF to undertake safety analysis	
Supplied items	Pipes for essential service water system not to production standard	EDF undertake additional investigations and resultant scrapping of pipes	
IN 6 - July 2009			
Liner plate welding & Management supervision	Radiography shows weld repairs now <10%.	EDF suspend radiography tests but maintain monitoring operations	See IN 4 & 5 (Issue 1)
Civil engineering operations	• Inspectors/tech support agency alert to EDF that Reactor Building foundation raft required significant number of tasks before going ahead with concreting. • Subsequently non-conformances identified in insufficient concrete poured, modifications to formwork during operations.	ASN consider major programme pressures having negative impact on quality of works. EDF asked to take measures to avoid repeat.	See IN 3
IN 7 - Feb 2010			
Concreting	Inadequate roughness and use of chemical not designed for construction joints	ASN asked EDF to • stop use of the product • make an inventory of all methods used to treat construction joints on site	

Topic	Issue	EDF / ASN Response	NQK Comment
		• analyse the consequence of the chemical usage • produce a comprehensive qualification procedure for methods of treating construction joints.	SEE IN 10 – (Feb 2011) regarding report.
Control of deviations from civil engineering standards	Many deviations from Standard ETC-C design and construction rules noted.	ASN asked EDF to • More rigorously identify and justify all such deviations • Check all deviations (to date) have been correctly identified.	
Cooling system manufacturing & supplier control	Reactor coolant system and secondary system components: • Deviations identified, cases examined and additional tests inspections led to defective steam generator component being replaced by alternate already manufactured but differing characteristics. • Tasks of those responsible for quality needed clarified.	ASN asked AREVA NP to improve • decision making procedures, • supplier approval and monitoring, • move forward in area of regulatory documentation	
IN 8 - June 2010			
Installation of concrete prestressing sheaths	After ASN requested EDF ensured procedures for installing prestressing complied with requirements, EDF reported prestressing sheath in the inner containment wall positioned outside tolerances.	• ASN studying EDF report justifying acceptability of non-conformances. • EDF must now advise ASN of all subsequent concreting lifts in the inner containment wall.	
Mechanical assembly installation – housekeeping	Cleanliness requirements not being complied with on site.		
Cooling system manufacturing	Joint inspection with STUK – detection of deviations in manufacture of coolant pipes for Olkiluoto 3 EPR project – same manufacturer for Flamanville 3.	ANS determined that AREVA NP action plan was inadequate to allow manufacture of equipment for Flamanville to begin. Required information on: • Quality of risk analysis • System of internal inspections • Formalisation of quality related actions	Refs to IN 6. for further details

Topic	Issue	EDF / ASN Response	NQK Comment
		• Detailed quality / manufacturing plan	
IN 9 - Aug 2010			
Liner manufacture - welding	• Ergonomic of welding position causing new problems • Radiographic testing not keeping up with welding	EDF had already temporarily suspended new welding, reminded of 2009 action plan and begun radiography of all questionable welds. Repairs had been completed. ASN determined 2008/2009 response not adequate and EDF to apply operating feedback to all welding activities on site.	See IN 4,5 & 6
Safe System of Work – underground cabling to Flamanville 2	Worker on Flamanville 3 site drilled through 400kV underground cabling to Reactor 2 @ Flamanville 2 (shut down at the time for refuelling). EDF inquiry identified lack of information to construction workers + poor cable identification	ASN to take more actions to control major risks prior to construction	
Component suppliers & supervision	Identified room for improvement in EDF project organisation related to • Monitoring by EDF • Validation of list of activities concerned by quality		
IN 10 - Feb 2011			
Feedback on construction joint issues report	Report by EDF assessed by ASN/IRSN	ASN conclusion need further take account of situations on site e.g., difficulty of application & cleaning.	See IN 7 Topic 1
IN 11 - Sep 2011			
Installation of concrete prestressing sheaths	EDF notified new non-conformance issues	ASN requested suspension of installation. Concerns at: • Increase training and awareness of safety culture • Increase monitoring by EDF • Impact analysis of anomalies incl cumulative account. EDf to produce Action Plan	See IN 8 Delay approx. 1-week ASN released hold on concreting

Topic	Issue	EDF / ASN Response	NQK Comment
Concreting	EDF identified "rock pockets" in some walls. Result of •Difficulty of pouring in complex shapes with dense reinforcement •Cleaning prior to pouring incorrectly performed and inspected.	ASN require EDF •Produce report on quality of affected walls, after repairs completed •Identify if complex concreting could have led to defects for which visual inspections are not possible •Define appropriate preventative measures •Present operating experience feedback / lessons learnt prior to next complex concrete operations	This appears what in UK would be called honeycombing See IN 13 Topic 2 Appears recurring theme in civil and mechanical welding constructability in design.
IN 12 - Mar 2012			
Installation of concrete prestressing ducts – corrective actions	Action plan presented by EDF to ASN.	ASN inspections show adequate implementation of the various technical and management measures to ensure proper construction.	See IN 8 Topic 1 & IN 11 Topic 1
Polar crane brackets Manufacture	Welding defects identified in factory prior to painting and again during additional on-site inspections	ASN has requested additional inspections of other brackets EDF undertaking inspections and developing.	Delay to concreting of lift in inner containment wall
Concreting	EDF additional information on "rock pockets".	Accepted by ASN	See IN 11 Topic 2
Tank. Pool and liner welding operations	EDF must pay careful attention to: •stainless steel sheet metal contamination risks •to ensuring adequate control of sheet metal welding operations, particularly during repair work.	ASN continuing to monitor execution of these and proper implementation of tank lining procedures for spent fuel pool tanks.	
Reactor vessel head repair	AREVA NP informed detection of two significant quality non-conformances during manufacture of reactor vessel head. Relate to	ASN asked AREVA NP to •Conduct detailed assessment of the potential impact on construction quality of the head.	About 9 months between two issues.

Topic	Issue	EDF / ASN Response	NQK Comment
	• Initial detection of welding defects • Subsequent detection during subsequent repair operations. Proposed solution consisted of reworking several manufacturing steps	• To propose specific measures to ensure quality of repairs. After assessment, ASN allowed AREVA to proceed with repairs. Operations being undertaken under direct supervision of ASN & inspection authority appointed by ASN. ASN will assess acceptability of reactor vessel head after completion of all repair and manufacturing operations	Continued work at manufacturing risk.
Pipe manufacturing **Procurement and Product quality**	During manufacturing inspection (Mar 11), AREVA NP detected small metal tears and scratches on the internal surface of certain auxiliary pipes. AREVA NP proceeded with repairs. • (Sep 11) ASN ordered suspension of repair operations due to non-consideration of requirements to improve radiation protection performance of future reactor. • (Nov 11) repairs resume dafter AREVA NP proposed measures. • (Nov 11) EDF inspectorate informed ASN of inadequacy of weld repair operations performed by AREVA NP sub-contractor. Related to tools used and inspections conducted. • (Dec 11) ASN inspection / suspended pipe manufacturing operations. • (Feb 12) resumed manufacturing.	ASN consider these non-conformances illustrate essential for manufacturers to stipulate specific requirements to suppliers and ensure they are met.	
IN 13 - Oct 2012			

Topic	Issue	EDF / ASN Response	NQK Comment
Polar crane supports Manufacture	EDF advised ASN of decision to have all polar crane supports remanufactured	Manufacturing in progress	See IN 12 Topic 2
Concreting	• EDF previous reports of localised honeycombing issues. • EDF report of "empty spaces" behind recesses accommodating gates of reactor building pools – arose from activities prior to implementation of additional measures. Identified following experience feedback from Okiluoto. EDF have undertaken repairs, inspected by ASN.	ASN attentive to final construction quality, after inspection and repair, of reactor pools	See IN 11 Topic 2
Reactor vessel head repair	As first step, AREVA NP proposed large scale repair solutions, including eliminating all welds of 50 out of 105 adaptors	After inspections and feedback, ASN approved continuation on remaining 55 adaptors. At end of second phase, AREVA NP to undertake complete inspection of closure head base metal under removed welds.	See IN 12 Topic 5 Continued work at manufacturing risk.
Steam Supply System components **Care & Maintenance during Transport and Site installation**	ANS asked AREVA NP to carry out risk analysis of Transport and Site installation phases. Inspection showed Improvements needed in: • Identification of documents drafted by manufacturers, defining precautions needed. • Definition and compliance with conservation conditions in buildings between installation and commissioning; notably related to temperature and relative humidity.	After review, by ASN and Pressure equipment assessors, of AREVA NP's measures ASN will state its position regarding continuation of on-site assemble operations	
IN 15 – Nov2013			
First nuclear pressure equipment (NPE)	AREVA informed ASN that the first of the 3-way valves, in the Safety Injection System, had been installed upside down.	In early September 2013, AREVA NP proposed ASN a method for identifying and correcting all the shortcomings in the technical	

Topic	Issue	EDF / ASN Response	NQK Comment
installation operations	The analysis of the causes of the deviation revealed that it resulted firstly from human and organisational-related factors and secondly from shortcomings in the specification of the requirements applicable to the installation operations and their monitoring.	documentation used for the first installation sequence, such that each requirement to be met during the operations is correctly specified, with a document certifying the results of the required inspections. This method will also be applied for the subsequent sequences.	
Suppliers - Manufacturing	ASN conducted an inspection of the quality and monitoring of the manufacturing activities for the core external instrumentation. ASN considers that EDF needs to apply greater rigour when validating the specifications proposed by the instrumentation supplier and must see to the consistency of all the documents describing the characteristics, whether required or obtained, of this instrumentation. This inspection also revealed that some of the manufacturing stages are not monitored with sufficient rigour: certain surveillance activities will therefore have to be repeated so that EDF can decide on the quality of the manufactured instrumentation.		

7.14 References

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[4] ISO 9001 - Quality Management Systems — Requirements

[5] ISO 10005 - Quality Management – Guidelines for Quality Plans

[6] ISO 10006 - Quality Management – Guidelines for Quality Management in Projects

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[8] EDF RCC-M and RCC-E codes

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[11] ISO 19443 - Specific requirements for the application of ISO 9001:2015 by organizations in the supply chain of the nuclear energy sector supplying products and services important to nuclear safety (ITNS)

[12] ISO/IEC 17020 - Conformity Assessment – Requirements for the operation of various types of bodies performing inspection

[13] ISO/IEC 17025 - General Requirements for the competence of testing and calibration laboratories

[14] Examples of National Standards include UKAS for the UK or NIST for the USA.

[15] INTERNATIONAL ATOMIC ENERGY AGENCY, Safety Assessment for Facilities and Activities, IAEA Safety Standards Series No. GSR Part 4 (Rev. 1), IAEA, Vienna (2016). Available at: https://www.iaea.org/publications/10884/safety-assessment-for-facilities-and-activities

[16] Directives relating to CE products can be found on the website of the European Union. Each directive includes the conformity assessment procedure to be followed. EU guidance on CE marking is provided at: https://single-market-economy.ec.europa.eu/single-market/ce-marking_en

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Revisions

Revision date	Description	Contributors	Editors
March 2019	Sections on Quality Planning and Quality Plans rewritten to align with BS ISO 10005:2018 and BS ISO 19443:2018. Hypertext links checked and updated. ASN inspection findings from Flamanville updated.	Richard Hibbert, Mike Underwood, Iain McNair	Bob Dixon
January 2023	Content and format updated by NNG.	NNG Steering Group	NNG Steering Group