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IAEA SAFETY STANDARDS

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NUSSC comments resolution

Equipment Qualification ~~of Items Important to Safety~~ for Nuclear Installations

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DRAFT SAFETY GUIDE

New Safety Guide

CONTENTS

1. INTRODUCTION

BACKGROUND

1.1. This Safety Guide addresses the establishment, execution and preservation of the qualification of items important to safety in nuclear installations to provide confirmation of the reliable safety performance during operational states and accident conditions.

1.2. This Safety Guide provides recommendations on the qualification of items important to safety at nuclear installations to meet specific requirements established in IAEA Safety Standards Series No. SSR-2/1 (Rev. 1), Safety of Nuclear Power Plants: Design [1], No. SSR-2/2 (Rev. 1), Safety of Nuclear Power Plants: Commissioning and Operation [2], and No. GSR Part 4 (Rev. 1), Safety Assessment for Facilities and Activities [3].

1.3. Additionally, this Safety Guide interfaces with IAEA Safety Standards Series No. NS-G-1.6, Seismic Design and Qualification for Nuclear Power Plants [4], as currently it is the existing Safety Guide that provides recommendations on qualification of items important to safety specific to seismic design and qualification for nuclear power plants.

1.4. This Safety Guide additionally provides recommendations on the qualification of items important to safety at ~~other~~ different types of nuclear installations, to meet specific requirements established in IAEA Safety Standards Series No. SSR-3, Safety of Research Reactors [5], and No. SSR-4, Safety of Nuclear Fuel Cycle Facilities [6], if adequately adapted.

1.5. IAEA Safety Standards Series No. SSG-30, Safety Classification of Structures, Systems and Components in Nuclear Power Plants [7] provides recommendations on how to classify items important to safety on the basis of safety function and significance. Classification of equipment safety functions is important in defining the scope and methodologies to be used for executing qualification of items important to safety.

1.6. This Safety Guide takes into account recommendations from other IAEA Safety Standards that are relevant to the qualification of items important to safety. These include the Safety Requirements, IAEA Safety Standards Series No. GSR Part 2, Leadership and Management for Safety [8], and its supporting Safety Guides, notably IAEA Safety Standards Series No. GS-G-3.1, Application of the Management System for Facilities and Activities [9] and IAEA Safety Standards Series No. No. GS-G-3.5, The Management System for Nuclear Installations [10]. In addition, recommendations from Specific Safety Guides supporting Refs [1] and [2], notably IAEA Safety Standards Series No. SSG-34, Design of Electrical Power Systems for Nuclear Power Plants [11], IAEA Safety Standards Series No. SSG-39, Design of Instrumentation and Control Systems for Nuclear Power Plants [12] and IAEA Safety Standards Series No. SSG-48, Ageing Management and Development of a Programme for Long Term Operation of Nuclear Power Plants [13], are taken into account in this Safety Guide.

1.7. Additional guidance on the qualification of items important to safety is available from Member States and from other (international) organizations that develop nuclear and industrial codes and standards. Such publications provide specific implementation details and methodologies for qualification of items important to safety (see Annex).

OBJECTIVE

1.8. The objective of this Safety Guide is to provide a structured approach and guidance on the establishment and preservation of qualification of items important to safety to meet requirements established in IAEA Safety Standards.

SCOPE

1.9. This Safety Guide addresses the process for establishing and preserving qualification of items important to safety in nuclear installations to ensure reliable performance of the safety functions within anticipated service conditions.

1.9. a. Equipment qualification demonstrates the capability of items important to safety to perform their safety functions based on applicable functional, seismic, environmental, and electromagnetic interference parameters, over their full range from normal operating conditions up to and including design basis accident conditions.

1.10. Seismic qualification is part of the qualification process. However, this Safety Guide does not specify seismic qualification methods and processes in detail. Such detail is provided in IAEA Safety Standards Series No. NS-G-1.6, Seismic Design and Qualification for Nuclear Power Plants [4].

1.10.a Verification and validation of software is part of the equipment qualification process. However, this Safety Guide does not specify software verification and validation methods and processes in detail. Such detail is provided in Ref. [12].

1.11. The Safety Guide also provides guidance for assessing the capability of items to reliably perform safety functions in the event of severe accidents at the nuclear power plant.

1.12. Items important to safety in the scope include electrical, instrumentation and controls, electromechanical, active mechanical equipment with non-metallic parts and interfaces associated with this equipment (e.g. seals, gaskets, connections, mounting structures and their anchoring).

1.13. Non-active ~~Items~~ items important to safety ~~which~~ that safety function is demonstrated according to applicable codes (e.g. piping ~~, structures~~ and ~~passive mechanical~~metallic components) are outside the scope of this Safety Guide.

1.14. The main topical areas for which this Safety Guide provides guidance are the following:

— Qualification programme for items important to safety, for achieving compliance with the requirements established in SSR-2/1 (Rev. 1) [1];

— A systematic assessment carried out to provide reliable confirmation that items important to safety are capable to perform their safety function for operational states and for accident conditions, for achieving compliance with the requirements established in SSR-2/2 (Rev. 1) [2];

— Integration of qualification processes within the design, installation, commissioning, operation and maintenance of nuclear installations throughout their lifetime, for achieving compliance with the requirements established in GSR Part 2 [8];

— Preservation of qualification to ensure that the established qualified status of items important to safety remains valid for achieving compliance with the requirements established in SSR-2/2 (Rev. 1) [2].

1.15. This Safety Guide considers qualification aspects of other interfacing programmes and processes, including:

— Development and review of the safety analysis report;

— Modification processes for achieving compliance with the requirements established in SSR-2/2 (Rev. 1) [2];

— Other processes that affect qualification (e.g. supply chain, procurement, storage, maintenance, corrective action programme);

— Operational experience feedback (e.g. internal, external).

1.16. ~~The recommendations of this Safety Guide apply for new and existing nuclear installations.~~

1.17. This Safety Guide is intended for use by entities responsible for aspects of qualification of items important to safety for nuclear installations. This publication also provides guidance for regulatory authorities to support their licensing and inspection activities related to qualification.

STRUCTURE

1.18. Section 2 provides guidance regarding qualification concept and process. Section 3 provides recommendations for specifying the design inputs needed to support qualification process. Section 4 provides guidance on establishing qualification. Section 5 provides recommendations for preserving qualification. Section 6 provides guidance on the evaluation of the effectiveness of equipment qualification programme. Section 7 provides guidance on programmatic interfaces and integration of qualification within other safety programmes and processes.

1.19. The Annex provides a list of international nuclear and industrial standards that can be used for qualification of items important to safety, which have a strong relationship with the major topical areas of this Safety Guide. International nuclear and industrial standards are typically reviewed by their applicable regulatory bodies that specify conditions for their implementation.

2. QUALIFICATION CONCEPT AND PROCESS

BASIC CONCEPT

2.1. Paragraph 4.48 of SSR-2/2 (Rev. 1) [2] states:

> "Appropriate concepts and the scope and process of equipment qualification shall be established, and effective and practicable methods shall be used to upgrade and preserve equipment qualification. A programme to establish, to confirm and to maintain required equipment qualification shall be launched from the initial phases of design, supply and installation of the equipment. The effectiveness of equipment qualification programmes shall be periodically reviewed."

2.2. Paragraph 4.49 of SSR-2/2 (Rev. 1) [2] states:

> "The scope and details of the equipment qualification process, in terms of the required inspection area(s), method(s) of non-destructive testing, possible defects inspected for and required effectiveness of inspection, shall be documented and submitted to the regulatory body for review and approval. Relevant national and international experience shall be taken into account in accordance with national regulations."

2.3. The qualification should demonstrate that the item important to safety will be capable of performing its intended safety function(s) under the full range of anticipated service conditions of the nuclear installation (operational states and accident conditions), internal and external events.

2.4. The qualification should address combinations of anticipated service conditions, including synergistic effects, where identified.

2.5. Qualification of items important to safety is a necessary condition for prevention of ~~some types of~~ common cause failures caused by the item not being qualified for the intended function required to perform during anticipated service conditions.

2.6. The qualification activities should provide confidence that an item is designed, manufactured, installed, commissioned, operated, and maintained such that the item is capable of performing its required safety functions, when necessary, and in the specified service conditions, throughout their qualified life, with due account taken of plant conditions during maintenance and testing.

2.7. Within the context of qualification, items important to safety should be considered as ~~a structured~~an integrated assembly of one or more interconnected components or assembly, each with dedicated functionality and specified interfaces to perform or contribute to one or more safety functions.

2.8. The item important to safety to be qualified should be representative of the item that will be installed in the nuclear installation and its application.

2.9. The qualified configuration should include the items themselves and its interfaces.

2.10. The equipment qualified configuration should also include software, hardware description language, and process interfaces, if any.

2.11. The qualification should address all factors affecting the suitability of systems and components for intended safety functions. This include a suitability of systems or components for performing the safety functions under the effects caused by anticipated service conditions during plant states and events not excluded by the design of a nuclear installation (e.g. seismic, internal flooding, electromagnetic phenomena, arcing, lightning). For example, internal fires, explosions, tornadoes or hurricanes are not considered in the qualification since designs generally protect the items from these events.

2.12. Qualification should be considered as an essential part of the whole lifecycle of items important to safety.

QUALIFICATION PROCESS

2.13. The qualification process for items important to safety comprises three phases:

— Design inputs;

— Establishing qualification;

— Preserving qualification.

2.14. These three phases of the qualification process and the relationship of activities within each phase are described in this Safety Guide.

Qualified life

2.15. The qualification process should establish the qualified life of items important to safety that are subject to significant ageing degradation mechanisms ~~or~~ and expected to function within the harsh environment. Such mechanisms can degrade the functional capabilities of items to perform required safety functions during anticipated service conditions.

2.16. Parameters and any modelling of anticipated ~~in-service ageing degradation~~environmental conditions used to establish the qualified life should be specified.

2.17. A qualified life is ~~not required for items located in a mild environment for all operational states and which has no significant ageing degradation mechanisms.~~required for equipment in harsh environments, and which have significant aging degradation mechanisms. These components are considered non-serviceable after the beginning of a design basis accident.

2.17.a Items in a mild environment not subject to significant aging degradation mechanisms are typically serviceable and therefore regular compliance to the design specification requirements and adherence to the maintenance program is considered adequate.

2.18. An item important to safety that is located in the harsh environment should be maintained within

its qualified life while installed in service or in while in storage prior to installation. The qualified life of the item may not be required to cover the lifetime of the nuclear installation, as it may need to be periodically replaced~~The qualified life of an item established in initial qualification may not be required to cover the entire lifetime of the nuclear installation~~.

Qualification methods

2.19. Appropriate qualification methods should be applied in accordance with the different equipment types, such as:

~~— Structures;~~

— Pressure boundary active components with non-metallic parts;

~~— Fuel and reactor pressure vessel internal components;~~

— Other mechanical equipment with non-metallic parts;

— Electrical, instrumentation and control equipment.

2.20. The qualification methods should ensure traceability of as-built conditions to:

— Tested or analysed equipment;

— Tested or analysed configurations.

2.21. Internationally recognized methods for qualification are: type testing, analysis, operating experience or combination of these methods. These methods should be supplemented by new knowledge based on previous qualification test results and experiences and/or scientific publications. The Annex provides a list of applicable standards which may be considered for qualifying items important to safety. The specific methods of qualification for any particular type of item may include the application of more than one method of qualification (for example seismic, environmental, and periodic functional testing).

Preservation of qualified status

2.22. The qualified status of the item important to safety should be preserved during lifetime of the nuclear installation and should take into account actual operating environmental conditions, progress in the knowledge and understanding of degradation mechanisms.

2.23. The qualified life of items important to safety should be reassessed periodically during the lifetime of the nuclear installation.

~~2.23.~~2.24. A review of qualified status should be conducted whenever changes in actual service conditions have been identified as deviating from expected conditions under normal operational states and postulated accident conditions.

2.24.a The review of qualified status should also be conducted due to other reasons; e.g. equipment

design or installation changes, changes in licensing basis of the nuclear installation, parts changes, component material changes, component failures, uncontrolled maintenance, life extension review.

~~2.24. The qualified life of items important to safety should be reassessed during the lifetime of the nuclear installation.~~

2.25. During the service life of the nuclear installation, extensions of the qualified life of an item may be considered, where justified and documented.

QUALITY ASSURANCE

2.26. Quality assurance for equipment being qualified includes a variety of elements of a program such as equipment design, production, qualification (e.g. test, analysis, combined test and analysis and experience), installation, plant surveillance and maintenance, periodic testing and documentation).

2.26.a All qualification activities should be consistent with requirements of an approved management systems for safety according to Ref. [8].

2.27. All qualification activities should be performed in accordance with approved procedures and controls.

2.28. Data acquisition tools used during type testing should be calibrated against traceable standards with documentation supporting such calibration.

2.29. Traceability should be established between the testing documentation, conclusions from each qualification test and each installed system and component subject to qualification in order to ensure that the test configuration corresponds to the installed configuration.

2.30. All non-conformities and deviations identified during the qualification activities should be corrected, justified and documented.

DOCUMENTATION

2.31. Documentation on qualification includes different documentation types such as qualification specification / plan, qualification analysis and test procedures, qualification analysis and test reports, qualification analysis and test data, qualification summary report, plant specific equipment qualification files (e.g. equipment qualification reports, environmental, seismic and electromagnetic compatibility (EMC) evaluations), qualified life evaluations, plant field testing and analytical evaluations, equipment modifications and changeouts, and surveillance / maintenance records.

Equipment specification and requirements specifications should be an input for the assessment of the initial qualification status of the equipment.

2.32. The qualification status of items should be properly documented and maintained in an auditable form while the item is in service or in storage for installation~~throughout the lifetime of the nuclear~~

~~installation~~.

2.33. The items initial qualification status should be documented in a preliminary suitability assessment report describing which further qualification steps are needed. Further qualification steps should be described in the qualification programme.

2.34. Test specifications or analysis reports should be prepared for each type of qualification (i.e. electromagnetic, chemical components, chemical composition analysis, compatibility, environmental qualification, seismic qualification, functional qualification and aging through functional cycling). For example, non-destructive chemical composition of certain components could be of paramount importance to its safety functions and safety margins.

2.35. If type testing comprises multiple qualification types, a test report should be prepared for each type of qualification.

2.36. A qualification summary report evaluating all results from various types of qualification processes should be prepared.

2.37. The qualification summary report should be the basis for the suitability analysis if needed. A suitability analysis documents the basis for concluding that the qualified item is now suitable for the ~~range~~ specific application of the installation and ~~of intended~~ safety functions to be implemented ~~in the nuclear installation~~.

2.38. Documented evidence and records should be organized in a clear and traceable manner allowing for independent verification.

TRAINING

2.39. The personnel involved in qualification activities should be trained to possess adequate skills, ~~and~~ knowledge and attitude, and should be included in the equipment qualification programme.

2.40. A systematic approach to training should be used to design, develop, implement, and evaluate the training provided.

2.41. Key training elements for personnel implementing qualification activities include those needed for establishing and preserving qualification of items important to safety. Such elements would include:

— Training specific to the job, task and procedure;

— Integration of qualification details in the hands-on maintenance training for each item type (e.g. maintenance personnel training on maintaining transmitters will cover applicable qualification related details, effective criteria to be used when inspecting for degradation);

— Description of related responsibilities and their scope.

2.42. The training programme should include an element for oversight of the training of both internal

and contract personnel involved in qualification activities.

3. DESIGN INPUTS

IDENTIFICATION OF ANTICIPATED SERVICE CONDITIONS

3.1. ~~Before the qualification begins, it is necessary to~~Qualification programme begins with establishing the range of conditions and events under which the items important to safety should be qualified. To establish this, every design basis event for the nuclear installation should be identified and its effects on the items important to safety should be quantified.

3.2. A set of anticipated service conditions for which qualification is to be established should be selected to provide confidence in equipment performance.

3.3. The set of anticipated service conditions should include normal operating conditions (e.g. resulting from mechanical conditions, electrical conditions, electromagnetic interference (EMI) ~~and radiofrequency interference (RFI)~~, process conditions e.g., voltage, current, temperature, pressure, ~~and~~ fluid conditions (including differential pressure, temperature, flow, fluid parameters, and chemical content) and environmental conditions resulting from plant states, internal and external events.

3.4. The operating conditions are generally defined by the conditions of the systems in which the items are installed.

3.5. The environmental conditions are generally defined by the ambient conditions associated with operational states within the areas (zones) of the nuclear installation where the items are installed.

3.6. Conservative, yet realistic, service conditions should be selected for the purposes of qualifying items important to safety.

3.7. The set of anticipated service conditions should bound normal operational states, accident conditions, internal and external events, as applicable.

3.8. Differences between these anticipated service conditions and actual conditions can be addressed through additional qualification of the items (e.g. establish exclusion zones to prevent adverse impact of EMI/RFI fields on the performance of important to safety items).

3.9. Qualification processes should provide confidence that safety functions will be accomplished for the set of anticipated service conditions.

Anticipated service conditions for operational states

3.10. Anticipated service conditions during operational states should be used to evaluate suitability of items to ensure adequate performance of the items.

3.11. Relevant environmental conditions typically include:

— Ambient temperature and pressure;

— Humidity/steam;

— Radiation;

— Submergence;

— Boric acid and other applicable chemical spray;

— Chemicals in the atmosphere (dust, salt mist, oil aerosols);

— Vibration from neighbouring equipment

— Electromagnetic compatibility.

3.12. Relevant operating conditions typically include:

— Power;

— Operating cycles (electrical and mechanical);

— Electrical loading parameters (e.g. voltage, frequency, current);

— Mechanical loads (e.g. self-induced flow, self induced vibration, thrust or torque, stress, displacement);

— Seasonal and climatic variations;

— Process fluid conditions (e.g. pressure, temperature, chemical composition, flow rate, water hammer);

— Chemical ~~loads~~composition;

— Loads and duty cycles;

— Self-heating;

— Submergence;

— Electromagnetic interferences (e.g. electromagnetic and radio frequency interference);

— Power surges.

3.13. Representative values should be identified for the purpose of evaluating whether the items important to safety have an ageing effect under the conditions identified for the operational states.

3.14. Service conditions should generally cover those conditions occurring at the individual item location. General area ambient environmental conditions of nuclear installation may not be representative of the actual conditions where the item is installed. Ventilation variations and local heat sources are typical effects that can change environmental conditions.

3.15. When items are installed inside other devices or behind panels, the local environment may differ from the general area conditions. Self-heating due to energization of electrical equipment and elevated process temperatures should be identified and considered.

3.16. Voltage variations can cause significant differences in the temperature rise due to self-heating for most electrical equipment and therefore should also be considered.

3.17. Evaluation of the performance of items important to safety for operational states generally involves demonstrating the item's functional capability when experiencing a combination of service condition extremes ~~(e.g. maximum operating temperature, full load horsepower, rated current capacity)~~.

Electromagnetic interference

3.18. Electromagnetic interference can affect electrical and I&C systems and components. Electromagnetic qualification addresses the combination of system and component design to minimize the coupling of electromagnetic disturbances to electrical and I&C components.

3.19. Electromagnetic interference includes radiofrequency interference, electrical surges (e.g. voltage spikes resulting from switching transients, lightning), and electrostatic discharge.

3.20. Detailed requirements and acceptance criteria for electromagnetic interference (EMI) and radiofrequency interference (/RFI) qualification should be determined for safety systems and components in accordance with international standards or alternatively on the basis of individual system requirements.

3.21. A site survey of EMI/RFI should be performed during normal operations to include the effects of operating and maintenance activities to verify and establish a basis for qualification criteria.

3.22. Periodic measurements of the electromagnetic environment are recommended to be performed to verify and trace the electromagnetic environment since EMI/RFI characteristics are different in time and locations.

Service conditions resulting from postulated accidents

3.23. The postulated initiating events resulting in harsh environment conditions include loss of coolant accidents or high energy line breaks. These conditions are characterized by changes or increases of temperature, pressure, humidity, radiation, environmental submergence or by changes in process fluid conditions or chemical composition.~~the simultaneous changes or increases of temperature, pressure, humidity, radiation, submergence, or process or environmental chemical composition~~.

3.24. The bounding thermodynamic profiles and chemical effects associated with each of the postulated initiating events should be derived from design basis and the safety analysis of the nuclear installation.

3.25. Other postulated initiating events might need to be addressed by qualification if they are more severe than loss of coolant accidents and high energy line breaks conditions.

3.26. Items important to safety should be qualified for the mission time of the safety functions corresponding to its performance requirements for the applicable accident conditions.

Internal and external events

3.27. The design basis and the safety analysis of the nuclear installation identify internal and external events, such as fire, flooding and seismic events that the installation is required to withstand and for

which protection or qualification of items important to safety is necessary.

3.28. Fire testing of cables for flame self-extinguishing capabilities has been included in certain standards providing guidance on the relative fire resistance of various cable constructions. Therefore, demonstrating cable performance under postulated fire conditions in the nuclear installation is not required as part of the qualification.

3.29. Guidance on protection ~~or qualification~~ of items important to safety against internal and external events such as fire and~~,~~ flooding ~~and seismic events~~ that the installation is required to withstand is provided in other IAEA safety standards and therefore excluded from this Safety Guide.

3.30. Items important to safety should be protected against the effects of fire and explosion in accordance with the recommendations of IAEA Safety Standards Series No. NS-G-1.7, Protection against Internal Fires and Explosions in the Design of Nuclear Power Plants [14].

3.31. Items important to safety should be protected against the effects of other internal hazards in accordance with the recommendations of IAEA Safety Standards Series No. NS-G-1.11, Protection against Internal Hazards other than Fires and Explosions in the Design of Nuclear Power Plants [15].

3.32. Items important to safety should be designed and qualified to withstand seismic hazards in accordance with the recommendations of IAEA Safety Standards Series No. NS-G-1.6, Seismic Design and Qualification for Nuclear Power Plants [4].

3.33. Items important to safety should be protected against or designed and qualified, to withstand other external hazards in accordance with the recommendations of IAEA Safety Standards Series No. NS-G-1.5, External Events Excluding Earthquakes in the Design of Nuclear Power Plants [16].

IDENTIFICATION OF REQUIRED SAFETY FUNCTIONS

3.34. The safety functions (active and passive) required to prevent or mitigate identified events and accidents should be specified.

3.35. The process of specifying those events includes an evaluation of the events and accidents.~~quantifying those events includes an evaluation of the events and accidents~~. This is usually achieved by modelling to determine the ambient effects of the conditions resulting from the event at the location of items important to safety.

3.36. Items important to safety required to achieve the intended safety functions necessary for prevention or mitigation of the events should be identified.

3.37. The design requirements for the items to be qualified should include the identification of safety functions, performance requirements, and service conditions (see Section 3 for information regarding the identification of service conditions).

3.38. Performance requirements and service conditions should be quantified and documented as ranges

of parameters valid throughout applicable operational states, accident conditions, internal and external events.

3.39. Items important to safety required to function during accident conditions should meet the performance requirements during the specified mission time.

3.40. Performance requirements typically include measurement accuracy, upper/lower limits of functional physical parameters, functional characteristics and response time.

3.41. Performance requirements should be derived from the design requirements and functional acceptance criteria and should also address environmental conditions anticipated for operational states, accident conditions, and external events during which the function of the items is required.

3.42. Safety design documentation, safety analyses, systems analyses, and the master list of items of a nuclear installation should be used to develop a list items important to safety requiring qualification.

3.43. Other information sources (drawings, specifications and inspections) are necessary to identify equipment interfaces and other auxiliary circuit devices requiring qualification.

3.44. The equipment specification of items important to safety subject to qualification should include:

- Equipment type, manufacturer, model number and variants of it, current manufacturing status;
- Hardware/software versions of firmware and application software;
- Dimensions, ranges of rated parameters (mechanical and/or electrical);
- Mechanical, ~~and~~ electrical, process and I&C interfaces of the equipment;
- Operational manual and maintenance, installation and test procedures;
- Certificates and test documentation with respect to industrial standards.

IDENTIFICATION OF ITEMS AND REQUIREMENTS FOR QUALIFICATION

3.45. Requirements for qualification should be derived from the safety design and accident analysis of the nuclear installation, normal and emergency procedures, and supplemental design documents of items important to safety. These include:

- Classification system of the nuclear installation;
- General requirements for mechanical systems and components;
- General requirements for the electrical safety systems and components;
- General requirements for the safety automation system (I&C system) and components;
- Requirements of environmental, seismic and EMC qualification based on applicable codes and standards.

3.46. Design inputs necessary for qualification of items important to safety should be established and documented in a requirements specification. The requirements specification generally includes:

— Description of the required safety function;

— Description of anticipated environmental and operational conditions expected during operational states, accident conditions and external events;

— Definition of postulated accidents and external events, and the corresponding mission time for which each item important to safety is required to function;

— Definition of the safety class of the equipment and the corresponding supplemental classifications e.g. seismic classification or quality classification;

— Definition of acceptance criteria.

3.47. Environmental and operational conditions during operational states, accident conditions and external events considered in design inputs should be defined in terms of:

— Thermodynamic parameters (characterized by temperature, pressure, humidity);

— Radiation parameters (characterized by radiation energy, type of radiation, fluence, total integrated dose, and dose rate for operational states and accident conditions);

— Induced vibration parameters (characterized by spectra of excitations, response spectra of excitation, response spectra of displacement or acceleration, time history of displacement or acceleration power density spectrum);

— Submergence and flooding;

— Electromagnetic and radiofrequency field parameters for operational states and accident conditions (characterized by frequency range, kind of potential couplings, field strength);

— Fluid condition inside the primary or secondary circuits or containment (characterized chemical composition, fluid level, potential jets, pH-values, temperature, water hammer, flow, differential pressure across valves);

— I&C system parameters (e.g. characterized by processing time);

— Electrical system parameters (e.g. characterized by short circuits current, delay of circuit breakers, ranges of system voltages, trip characteristics of motor control centres);

— Mechanical system parameters (e.g. characterized by load cycles, required torques and forces, mode of operation – continuous or intermittent, type and size of ~~type of~~ valve, pump or flap).

4. ESTABLISHING QUALIFICATION

4.1. Qualification of items important to safety should be based on a selection of ~~one or more of~~ the

following methods:

— Use of engineering and manufacturing processes in compliance with recognized standards;

— Evaluation of past operating experience in similar applications;

— Type tests;

— Analysis;

— Extrapolation of test results or operating experience under relevant conditions;

— Evaluation of equipment material vulnerability to ageing or environmental degradation mechanisms;

— Evaluation of the design and manufacturing process.

4.2. The specific combination of methods selected will depend upon the equipment assembly or component under consideration. For example, in the qualification of pre-existing items, more emphasis might be placed on past operating experience and analysis. In addition, the qualification for some types of items important to safety (such as functional qualification of power-operated valves) should be based on testing or test-based analysis.

4.3. The method or combination of methods, theories, analysis and assumptions used for equipment qualification should be justified. Type testing is the preferred method.

QUALIFICATION PRACTICES FOR DIFFERENT SERVICE CONDITIONS

4.4. Modelling or simulation of postulated service conditions should be used to derive the parameters needed as inputs for qualification process. Discussion regarding specific methods for conducting this modelling or simulation is outside of the scope of this Safety Guide.

4.5. The qualification parameters for items important to safety located in areas which are ~~always considered mild conditions~~ less severe than harsh conditions should be derived from the performance conditions associated with the heating, ventilation and air conditioning for those areas. When estimating these parameters, a margin should be included to account for occasional variations or malfunctions of heating, ventilation and air conditioning performance.

Environmental qualification or assessment

4.6. In this Safety Guide, ‘environmental qualification’ means the part of qualification that focuses on qualification of items important to safety for anticipated service conditions caused by operational states and accident conditions.

4.7. Operating, maintenance and testing conditions which have an impact on qualification status of items should be identified and included in requirement specifications. Examples include operating cycles: switching on/off, pressure changes, plugging/unplugging connectors, electronic cards extraction/insertion, terminal box cover openings/closings.

Items exposed only to mild environments

4.8. Mild environment areas are locations within a nuclear installation that would at no time be significantly more severe than the environment that would occur during operational states of the installation. It should be recognized that while mild environment areas are defined as those areas where the environmental conditions do not significantly change during accident conditions, those "mild" areas may be subject to severe environmental conditions for which the items in those areas need to be capable of performing their safety functions.

4.9. Qualification of items important to safety located in mild environments should be achieved by:

— Clearly specifying the functional and performance requirements;

— Clearly specifying the applicable mild environment service conditions;

— Evaluating vendor performance specifications and/or certifications from suppliers to verify that the items will perform their required safety functions under the stated environmental conditions;

— Documenting the basis for concluding that the qualification status of the items is acceptable.

Items exposed to harsh environments

4.10. Harsh environment areas are locations within nuclear installation with significant changes of ambient environmental conditions as a result of a postulated initiating event (i.e. loss of coolant accident, high energy line break, and main steam line break).

4.11. Qualification of items important to safety located in harsh environments should demonstrate that the item is, at the end of its qualified life, capable of performing its safety functions under the ambient environmental conditions as a result of a postulated initiating event and to show that the required functionality (e.g. number of load cycles) is maintained to enable the item to continue performing its required safety functions.

4.12. The demonstration that an item can function as required at the end of its qualified life should account for significant ageing effects resulting from operational states which can cause degradation in performance of the item (e.g. due to absorbed energy from radiation, thermal ageing, valve friction coefficient increases, or valve actuator output degradation).

4.13. The qualified life of an item is dependent on individual components (e.g. gaskets, sealings) within the assembly, or is based upon the performance of the entire assembly. The individual components which have a qualified life that is shorter than the expected in-service requirements should be replaced at predetermined intervals consistent with their qualified lifeservice life shorter than the qualified life of the assembly, should be replaced at predetermined intervals.

4.14. When protective barriers, enclosures, shields or sealing devices are provided for protecting the item from possible environmental effects, they should be included in a qualification programme.

Items exposed to severe accidents

4.15. Paragraph 5.29, item (b) of SSR-2/1 (Rev. 1) [1] states:

> "…the features that are designed for use in, or that are capable of preventing or mitigating, events considered in the design extension conditions shall be capable of performing in the environmental conditions pertaining to the design extension conditions, including design extension conditions in severe accidents, where appropriate."

4.16. A basic assumption is that items that have already been qualified to postulated accident conditions, have a higher probability of performing its intended safety function under severe accident conditions.

4.17. Qualified items may have the capability to maintain their intended safety functions for time required under severe accident conditions as appropriate.

4.18. The mission time for each item used for mitigation or monitoring functions during a severe accident should be derived from the analyses of the various stages of the severe accident progression.

4.19. The specific function of the item to be accomplished at each phase of a severe accident should be defined, as well as the severe accident parameters associated with each accident phase.

4.20. The capability of the item to perform reliably under the severe accident conditions should be assessed.

4.21. When assessing design capabilities of the items during various stages of the severe accident progression, the following factors should be considered:

— Mission time;

— Safety functions during a severe accident;

— Specific service conditions at installed locations (e.g. severe accident environmental profiles);

— Availability, accessibility and functionality;

— Uncertainty in the estimation of loading parameters for the item performance;

— Suitability of item locations;

— Adequacy of protective barriers or shielding;

— Acceptability of degraded performance of the item under severe accident conditions.

4.22. Type testing should be used as far as possible to support the prediction of behaviour of the item under simulated severe accident loads.

4.23. Ref. [18] provides information regarding the identification of items relied upon to support the accomplishment of mitigating strategies and actions under severe accident conditions. It also provides examples of severe accident condition profiles and examples for demonstrating the reliable performance

of items under severe accident conditions.

ASSESSMENT OF INITIAL QUALIFICATION STATUS

4.24. The selection of the items should be performed by means of a preliminary suitability assessment, showing that the selected items is generally capable of meeting the functional and performance requirements while operating within anticipated service conditions.

4.25. To assess the initial qualification status, the following information is necessary:

— Qualification criteria;

— Regulatory and industry requirements and notifications associated with the item;

— Design and performance requirements derived from the safety design of the nuclear installation;

— Description of the items used to achieve required safety functions;

— Installation and maintenance requirements for the item;

— Clear description of anticipated service conditions at the specific installation location of the item.

4.26. The preliminary suitability assessment should consider at minimum functional characteristics, resistance to all anticipated service conditions~~adverse environmental conditions~~, and other aspects, such as electrical safety performance, conformity with respective product standards, and requirements for testability and maintainability.

4.27. If the preliminary suitability assessment reveals deficiencies between the available documented qualification status and the design requirements for given service conditions, supplemental qualification steps are needed. The selection of supplemental qualification steps should be described and justified.

QUALIFICATION BY TYPE TESTING

General

4.28. Qualification by type testing refers to a test or a series of tests demonstrating that the items important to safety meet or exceed the performance requirements with suitable margin under the anticipated service conditions.

4.29. If it is necessary to test separately for different environmental parameters (e.g. separate tests for radiation effects and temperature effects), the sequence in which these tests are conducted should be justified as one that ~~appropriately~~ conservatively simulates the degradation due to ageing during service life followed by exposure to the accident conditions. Synergistic effects of multiple parameters, such as application of appropriate radiation dose rates and temperatures, should be accounted for when preparing the test plan.

4.30. Qualification results obtained by type testing in accordance with nuclear industrial product standards should be used to demonstrate that the item meets the performance requirements and

associated safety functions under anticipated service conditions. The basis for concluding that the qualification under nuclear industrial product standards is acceptable should be documented.

Test Specification

4.31. Type testing should be performed in accordance with a well-defined test specification.

4.32. The test specification is a document derived from the qualification programme, covering individual tests or test sequences with respect to one or more testing areas (e.g. environmental, seismic, electromagnetic interference).

4.33. The test specification should provide information to execute qualification tests.

4.34. The test specification should include:

— The item unique identification (one-to-one relationship);

— Internal dimensions of critical parts that might impact functional performance of the item (such as internal clearances and edge radii of valves);

— The ~~basis of~~ quality assurance to be applied;

— Scope of activities covered by the qualification;

— Applicable regulatory codes and standards;

— Physical description of the item;

— Special requirements based on the test method of qualification;

— The test parameters to be monitored with diagnostic equipment and required accuracy;

— A description of the required test parameters to be monitored, the required diagnostic equipment, and the required accuracy;

— The need for any witness or hold points among the test steps (e.g. by independent expert organisation, if applicable);

— Requirements for the test assembly, measurement devices, mounting and interfaces;

— Identification of the type of test facility to be used;

— Maintenance activities and/or replacements during the tests (e.g. replacement of gaskets after the ageing);

— Type of documentation to be prepared by the laboratory;

— The need for auxiliary equipment to be included in the test specifications (e.g. test connections, measurement cables or power supplies);

— Actions to be taken in the event of deviations and/or failures.

4.35. The test specifications should outline anticipated service conditions to be simulated, along with the applied margins for each test step. For example, the functional qualification of valves needs to include the pressure, temperature, differential pressure, flow, and other fluid conditions of the valve design.

4.36. The test specifications should include the following design and performance requirements:

— Test conditions and margins to be applied;

— The safety function(s) of the item to be demonstrated throughout the tests;

— The test sequence(s) and/or the test steps, including the performance characteristics to be tested;

— The acceptance criteria for each test step demonstrating the performance requirements have been achieved (e.g. opening and closing times, response time, accuracy);

— Normal operating condition of the equipment (energized / de-energized);

— Ranges in performance requirements of each test step demonstrating the safety function under different plant states (e.g. operational states and design basis accidents);

— Qualification boundaries and interfaces between the items which are subject to qualification. The interfaces should be defined based on the mechanical and/or electrical design criteria;

— Data recording and test equipment accuracy, diagnostic data for valve operating requirements and valve actuator output;

— Applicable mission times;

— Specified qualified life;

— The need for taking measurements (e.g. continuous recording, accuracy of the items used to perform recording of data);

— Quality assurance requirements.

Test specimens

4.37. The test specimens, their assembly and mounting should be representative of the type or type series of the item to be qualified, in terms of electrical or mechanical attributes, geometrical dimensions, installed configuration and electrical and mechanical interfaces.

4.38. The test specimen description should provide sufficiently detailed information to ensure the unambiguous ~~assignment~~ association of the specimen to the type or type series of the item in accordance with the design specification.

4.39. The same test specimens should be subject to ageing prior to postulated initiating events testing.

4.40. A description of the test setup should provide detailed information to conduct the test and/or test steps. This should include information related to assembling, mounting, and functional testing.

4.41. Scale models may be used to simulate the actual configuration of the equipment. Scale models should be representative of the configuration and material properties of the item to be qualified and the effects of scaling should not adversely impact the qualification results should be addressed.

4.42. Test specimens of assemblies may be split into individual modules which are tested separately. The interfaces between the modules should be properly identifiable and comprehensively described, and the individual modules should be tested with overlapping interfaces.

4.43. Individual modules or components may be tested separately, but for certain tests, such as EMI/RFI, the tests of the whole assembly (e.g. I&C cabinet, electrical switchgear) should be performed to measure the possible interactions.

Demonstration of safety functions during type tests

4.44. Functional tests should be used to demonstrate the ability of items to perform the required safety functions over the full range of their operating and accident conditions.

4.45. While the complete qualification process should cover all of the required safety functions, a single functional test may be used to simulate only a portion of the required safety function.

4.46. The safety function ~~should~~ may also be demonstrated by using indirect tests methods. For example, testing of ~~a construction~~environmental seal material (e.g. gasket compression set) using functional related acceptance criteria may apply to this test category.

Anticipated service conditions under operational states and accident conditions relevant for type testing

4.47. The test conditions to be considered for type testing should include parameters associated with anticipated service conditions.

4.48. If needed, other specific parameters (e.g. boric acid/steam spray, salt spray, dust) should also be considered.

4.49. Anticipated service conditions should be simulated using appropriately justified or accepted methods or models. These methods or models should be explained and justified.

Ageing effect simulation (pre-ageing)

4.50. Significant ageing effects should be simulated during the qualification. Ageing of items expected during operational states (energized, loaded) should be simulated by accelerated ageing (e.g. radiation, humidity, thermal) to determine the qualified life of the item.

4.51. The sequence of equipment ageing should consider sequential, simultaneous, and synergistic effects to simulate the most representative state of ageing degradation.

Accelerated thermal ageing

4.52. Thermal ageing effects should be simulated by exposing equipment samples to higher

temperatures for a specified duration (accelerated thermal ageing). The rate of thermal aging acceleration should be documented and justified.

4.53. The Arrhenius methodology (isothermal ageing at elevated temperature) is considered an acceptable method for performing accelerated thermal ageing. Alternative methods can be used.

4.54. The test temperature used during accelerated thermal ageing should be below the threshold value causing significant rapid changes in physical and chemical properties of the item.

4.55. The parameters used during the accelerated ageing process should be documented and justified. For example, the material activation energy, the temperature applied during the tests, and duration of the test should be documented and justified when using the Arrhenius method.

Accelerated rRadiation ageing

4.56. Total integrated dose during operational states and accident condition dose should be simulated.

4.57. Applied dose rate should be high enough to cause homogeneous changes simulate the expected total integrated dose, but low enough to and prevent the effects caused by oxidation and gaseous diffusion.

4.58. Unless otherwise stated (e.g. national requirements), the irradiation ageing simulation is performed under ambient temperature.

Simulation of other stressors

4.59. Other stressors (e.g. wear, operational cycles, temperature cycles, mechanical) causing age-related degradation should be considered.

Non-seismic vibration and mechanical shocks

4.60. Non-seismic vibration and shocks originated from self-vibration, vibration from pipes, pumps, running motors or vibrations as hydrodynamic loading, which produce significant degradation (e.g. fatigue, wear) during normal and abnormal use, should be considered where applicable.

4.61. Such non-seismic vibration should be included in the age conditioning sequence prior to the seismic tests.

Seismic event

4.62. Seismic effects should be simulated on pre-agedoperationally aged samples prior to accident testing, if required.

4.63. Details on seismic testing are provided in Ref. [4].

Simulation of postulated initiating event conditions

4.64. Tested equipment should be subjected to environmental conditions resulting from postulated initiating events specified in the design basis of the nuclear installation.

4.65. The simulation of such environmental conditions by performing sequential tests is acceptable (e.g. accident radiation, thermodynamic loads appropriate to mission time of the item).

4.66. The total radiation dose resulting from normal operational exposure and postulated initiating events should be applied in one step or in sequence.

4.67. The conditions resulting from postulated initiating events should be defined in terms of thermodynamic profiles and chemical effects to be simulated. These conditions include, for example, temperature, pressure, humidity, submergence, chemical composition for the required mission time.

4.68. Tested items should be powered and loaded in a manner accurately representing the installed configuration.

4.69. Successful performance of the safety functions during the simulation of the postulated initiating events for the required mission time, should be verified and documented.

Margins for test profiles

4.70. Margins should be applied during the qualification process to account for test instrument inaccuracies, production variations and modelling uncertainties.

4.71. Qualification by type testing should include margins that apply to calculated design basis accident profiles. Suitable margins for conducting the qualification type tests are provided in Ref. [17].

4.72. Margins are not required to be applied for age conditioning.

4.73. Qualification type test should include provisions to verify that an adequate qualification margin exists.

4.74. Increasing the number of test cycles or the test durations are acceptable methods of adding margin in testing.

QUALIFICATION BY ANALYSIS

4.75. Qualification by analysis may be used to extrapolate existing qualification results to address changes in equipment, material design, performance requirements, installations, and reassessing qualified life.

4.76. Qualification by analysis can be used to extend the results of qualification testing to represent an entire equipment type family, provided it can be shown that the tested items are representative of other items in the same family (e.g. cables, type series of motors, different sizes of flow meters). However, qualification by analysis alone might not be appropriate for certain items without supplemental qualification testing to support the qualification.

4.77. Analysis that is part of the evidence of qualification should include a justification of the methods and assumptions.

4.78. The validity of the mathematical models used for qualification might be justified on the basis of experimental data, test data or operating experience.

4.78 a. Qualification by analysis alone is only recommended for analysis of the structural capability of the item (not functionality).

4.78 b. Qualification by similarity analysis may be used to demonstrate that an item is qualified based on a similar item which has been qualified to equivalent or more stringent conditions.

EXTRAPOLATION OF QUALIFICATION

4.78 c. Extrapolation of the qualification of an item important to safety to another size or a different application of the same item should be justified.

4.78. d. Extrapolation of a qualified design of a pump or valve should be justified by testing and analysis.

QUALIFICATION BY OPERATING EXPERIENCE

4.79. Qualification by operating experience should be used as supplemental information demonstrating the reliability of the item to perform safety functions. However, qualification by operating experience alone might not be appropriate for certain items without supplemental qualification testing to support the qualification.

4.80. Qualification by operating experience alone should be limited to items that perform safety functions in mild environment where similarity of the item to previously qualified items can be justified.

4.81. For an item that needs to perform safety functions in a harsh environment, evidence of qualification on the basis of operating experience alone is insufficient because operating experience generally do not include capability to withstand design bases environment. Therefore, operating experience information should be combined with at least limited type testing and with evaluation of the production processes and quality measures applied during manufacturing.

4.82. Qualification by operating experience should be based on representative data and technically justifiable conditions.

4.83. The operating experience data should be comparable to the service conditions and performance requirements of items that are equivalent to, or more severe, than the items to be qualified.

DEMONSTRATION OF PRODUCTION ITEMS

4.83. a. The functional performance of production items from a qualified design should be justified.

4.83. b. Demonstration of the performance of production pumps and valves from a qualified design should be justified by testing and analysis.

COMBINED METHODS

4.84. Items can be qualified by combinations of type test, operating experience, and analysis. For example, where type testing of a complete assembly is not possible, component testing supplemented by analysis ~~should~~ may be used. For example, in some cases the overall qualification of the item, is dependent on the qualification of the most limiting individual component within that item.

4.85. If individual components within the item are not subject to degradation from the effects of anticipated service conditions, it is possible to demonstrate that the item is environmentally qualified through a material analysis.

4.86. The specific combination of methods selected will depend upon the system or component under consideration. For example, in the qualification of already installed items, operating experience and analysis can compensate for a lack of completely documented verification and validation during engineering and manufacturing.

4.87. The method or combination of methods used for qualification of the items should be justified and documented.

5. PRESERVING QUALIFICATION

GENERAL

5.1. Requirement 13 of SSR-2/2 (Rev. 1) [2] states:

> "The operating organization shall ensure that a systematic assessment is carried out to provide reliable confirmation that safety related items are capable of the required performance for all operational states and for accident conditions."

5.2. Furthermore, paragraph 4.48 of SSR-2/2 (Rev. 1) [2] states:

> "…. A programme to establish, to confirm and to maintain required equipment qualification shall be launched from the initial phases of design, supply and installation of the equipment. The effectiveness of equipment qualification programmes shall be periodically reviewed."

5.3. To meet the above requirements, qualified items important to safety should be designed, procured, stored, installed, commissioned, inspected, operated, maintained and replaced or modified in a manner, which ensures that the qualified status is maintained for the lifetime of the item and components.

5.4. Requirement 10 of SSR-2/2 (Rev. 1) [2] states:

> "The operating organization shall establish and implement a system for plant configuration management to ensure consistency between design requirements, physical configuration and plant documentation."

5.5. In order to meet the above requirements, configuration management (change control) should

provide a systematic process to ensure that qualification implications are appropriately considered whenever changes occur to the plant, equipment or operating/maintenance/replacement activities.

5.6. Preservation of qualification is an ongoing process that begins from manufacturing, during installation and commissioning of the item and continues throughout the service life of the item within the nuclear installation.

5.7. Factors that impact the qualification status of items important to safety include changes in design basis, accident analysis, service conditions, operating experience, plant modifications, maintenance, training, procurement activities and material control.

5.8. The qualified life of an item should be reassessed during its lifetime, taking into account progress in the knowledge and understanding of degradation mechanisms and the actual operating environment of the item. If the qualified life is to be extended, a thorough evaluation supported by adequate basis for the extension should be provided

5.8. a. If the item important to safety relies on programmable logic or software to perform its required safety actions, the control of access to such software shall be protected, and the software should be periodically verified as correct to retain the item's qualified status.

5.9. The qualification status of each item should be properly documented and maintained throughout the lifetime of the installation. The documentation relating to qualification, which is typically part of the equipment qualification programme, includes:

— A master list of items subject to qualification;

— Procurement technical specification;

— Manufacturer data in support of qualification;

— Installation specification;

— Results of environmental monitoring, when relevant;

— The summary report of the qualification;

— Test reports relating to qualification;

— Results of maintenance activities;

— Non-conformity reports from vendors and operating organizations;

— Relevant operating experience;

— Reports of time limited ageing analyses relating to qualification (e.g. for evaluation for long term operation) or reports of another suitable equivalent analysis.

5.10. Programmatic interfaces and procedural control of prescribed activities should be established to

provide assurance that activities essential to preserving the qualified status of the items are correctly performed and properly integrated into plant processes and work practices.

5.11. Operating experience feedback from internal and external industry sources should be used for identifying unanticipated ageing mechanisms, or changes in items performance.

5.12. The process of preservation of the qualified status of each item important to safety should be accomplished in an all-inclusive manner. All elements of the equipment qualification programme work together and should be evaluated when assessing the qualification status for each item requiring qualification. ~~An effort to achieve high compliance with each of the qualification elements can help to make up for weaknesses in one or more of the other elements.~~

AGEING EFFECTS AND QUALIFIED LIFE

5.13. Paragraph 5.51 of SSR-2/1 (Rev. 1) [1] states:

> "The design for a nuclear power plant shall take due account of ageing and wear out effects in all operational states for which a component is credited, including testing, maintenance, maintenance outages, plant states during a postulated initiating event and plant states following a postulated initiating event."

5.14. Assessing the actual effects of ageing on the equipment operation is an essential part of the qualification. This assessment includes a determination of the significance of each ageing effects.

5.15. When significant new ageing mechanisms or increases in the effects of previously known ageing mechanisms are identified, the ageing portion of the qualification programme should be re-evaluated to determine whether changes in the qualified life or maintenance of the item is needed.

PRESERVATION ELEMENTS

5.16. Factors that can adversely impact the established qualification include:

— Deviations from appropriate installation and maintenance practices;

— Changes to the design basis or safety analysis;

— Changes in regulations and plant licensing activities;

— Modification of nuclear installation;

— Deviation in service conditions from those accounted for in the qualification;

— Feedback on adverse operating and maintenance experiences;

— Unavailability of qualified spare parts;

— Storage conditions of the qualified items and spare parts ;

— Obsolescence of the item or spare parts;

— New information developed from recent qualification tests or research tests that challenge or modify original assumptions or test/analysis results.

5.17. Periodic preventive maintenance, predictive maintenance, equipment calibration, surveillance, testing, condition monitoring, corrective action, failure trending and operating experience reviews are acceptable methods to detect and mitigate unanticipated age-related degradation that was not accounted for when establishing the qualified life of an item.

5.18. Results of processes that identify age-related failures or significant material degradation of qualified items should be used to assess the need to revise the qualification related maintenance, surveillance and replacement requirements. These revisions should also be reflected in the applicable qualification support documentation.

ENVIRONMENTAL MONITORING

5.19. A preliminary analysis should be carried out to determine where environmental monitoring should be implemented based on environmental zones, rooms and items. This analysis should take in account different factors, such as identification of the stressors acting upon the items (e.g. service temperature, radiation, submergence, local vibration, electromagnetic interference, radio frequency interference, toxic chemical exposure) to confirm whether environmental conditions are more severe than assumed.

5.20. Trends in the service conditions should be assessed to determine the impact on the qualified status of the items and identify corrective actions if required.

5.21. The analysis and monitoring of actual ambient environmental conditions support the identification of any hot spots and worst-case conditions.

5.22. Ambient environmental monitoring of the nuclear installation under operational states should ensure that:

— The assumptions in the qualification meet the installation ambient conditions;

— The design limits of the equipment are not exceeded;

— The initial qualified status remains valid.

5.23. Additionally, ambient environmental monitoring should be used to support evaluation of remaining qualified life by determining if an item is suitable for continued service because it has aged more slowly than expected. Environmental monitoring can also lead to reduced qualified life if the measured environment was more adverse than what was originally assumed in the qualification.

CONDITION MONITORING

5.24. Condition monitoring refers to activities performed to assess the item functional capability by measuring and tracking suitable condition indicators. Condition monitoring supports the identification

of optimal maintenance activities for the preservation of the qualified status.

5.25. Periodic condition monitoring should be implemented to determine if actual ageing is occurring at a higher rate, which would indicate that possible corrective actions are necessary to ensure qualification is preserved. Periodic condition monitoring should be performed throughout the service life of the items.

5.26. Condition monitoring provides information relative to ageing degradation of the qualified items. Condition monitoring measures variables that indicate the physical state of the item and assess its ability to perform its intended function under anticipated service conditions.

5.27. Condition monitoring should be used to preserve qualified status if any of the following occur:

— Service conditions are suspected to be more severe than previously assumed;

— Ageing evaluations contain uncertainties in the initial assumptions;

— Known ageing mechanisms cannot be fully evaluated or simulated when qualification was established.

5.28. When unexpected degradation is observed during execution of periodic surveillance or visual inspection, the impact of degradation should be identified and evaluated, tracked and trended to ensure reliable operation of items important to safety.

5.29. Premature failures, degradations, or performance anomalies of items important to safety should be identified and documented. These deficiencies should be addressed through corrective action programme.

5.30. Appropriate condition indicators for a given equipment type should be selected to detect changes caused by significant ageing mechanisms. For example, gaskets and sealing materials should be monitored for their ability to retain their compression properties.

5.31. Condition indicators should be measurable, linked to the functional degradation of the qualified item, and should be selected to indicate a consistent observable trend.

5.32. As the qualified item approaches the end of its established qualified life, periodic condition monitoring should be implemented to determine if actual ageing is occurring at a slower rate, which would indicate that it is possible to extend the qualified life of the item.

5.33. The combination of condition monitoring and environment monitoring should be used to support the re-assessment of qualified life of the item. This should ensure that the nuclear installation is continually operated within its design basis.

PERIODIC SURVEILLANCE

5.34. Surveillance activities should be performed to ensure that:

— Operation and maintenance activities do not compromise the qualified status of the items by changing the qualified in-plant configuration, mounting orientation (horizontal or vertical supports), or electrical, pneumatic, and hydraulic interfaces;

— Systems and components continue to meet their performance requirements;

— Configuration abnormalities are detected, and their corrective actions are completed in a timely manner to preserve the qualified status of the items.

MAINTENANCE

5.35. Qualification-related maintenance should be performed to preserve the qualified status.

5.36. Qualification-related maintenance should be performed in accordance with the procedures identified in paragraph 5.9.

5.37. To preserve the qualified status, the maintenance programme should address the following:

— The control of maintenance documentation (e.g. maintenance manuals, procedures) to include qualification requirements and to describe a method by which qualification is maintained;

— The establishment of a preventive maintenance schedule, as appropriate. Maintenance intervals are set to ensure the qualified life of the item is maintained;

— The need for any trending of condition indicators associated with qualified items and the detection of any precursors indicating that the item is degrading;

— A means to identify to plant personnel that the item is qualified.

5.38. Monitoring and oversight should be performed on all maintenance work on qualified items to ensure that qualified replacement parts are used, that the appropriate maintenance procedures are followed and that other preservation requirements are met.

PROTECTIVE BARRIERS

5.39. When qualification is dependent on the use of barriers, enclosures or shielding which reduce or eliminate the environmental stressors, controls should be implemented to ensure that these barriers remain effective and in their proper configuration for the lifetime of the installation.

5.40. Any protective barriers that can be removed should be clearly identified as being an element of the equipment qualification programme.

SUPPLY CHAIN, PROCUREMENT AND WAREHOUSING

5.41. Qualified equipment and components should be procured in accordance with procurement requirements specified in the applicable qualification report. An explanation of the purpose of this report, its contents, and use in the procurement process can be found in section 2.37 of this safety guide.

5.42. Replacement purchased equipment should be identical or equivalent to the original qualified item. If the replacement is not identical, the ~~equivalency~~ evaluation should determine if the substituted item is acceptable.

5.43. Qualification documentation should be updated as necessary to reflect any substitutions that alter the basis for qualification, configuration, maintenance or procurement requirements.

5.44. The acceptance of the vendors and manufacturers supplying qualified items should be in accordance with the Member State requirements for quality assurance. Procurement documentation should explicitly reflect the identification and traceability requirements of the applicable standard.

5.45. Qualified equipment and components should be procured, be evaluated in a receipt inspection, and stored in a controlled manner to ensure that the qualified status is maintained.

5.46. Procurement documentation should contain criteria for addressing the need to demonstrate that the substituted item is acceptable.

5.47. Qualified items and components (including subassemblies, spare parts and materials) stocked in the warehouse for future use in qualified applications, should be identified as qualified.

5.48. Qualified items subject to storage life considerations should be controlled to ensure that upon installation, the qualified status of the items is maintained. A reliable means should be established to ensure that storage life expiration dates are not exceeded.

REASSESSMENT OF QUALIFICATION

5.49. The qualified life of items should be reassessed during the lifetime to account for changes in the actual service conditions, such as temperature and radiation, and development in the knowledge and understanding of degradation mechanisms.

5.50. If the qualified life of the item is to be extended, ~~a thorough safety demonstration~~the technical bases should be provided.

5.51. The technical bases of any conclusions regarding qualified status should be revaluated to support the re-assessment of initial qualified life of the item to account for any changes in performance requirements or installation conditions.

5.52. The technical basis should be evaluated to determine whether any changes in documented material composition and parameters, assumed actual environmental conditions, load cycles and other parameters are needed to support this evaluation. This includes, for example, new information regarding the appropriate activation energy levels associated with materials of replacement items.

5.53. Methods such as revaluation of conservativism used in original assumptions, type test of the naturally aged items with additional ageing ~~at the installation, performing type test~~ for qualified life extension, item replacement and refurbishment, should be used for reassessing qualified life.

5.54. Reduction in exposure to the stressor intensity (e.g. lower~~ing~~ temperature, radiation) with proper justification, can be used to extend the qualified life.

5.55. The method chosen should be justified and documented.

6. EVALUATION OF THE EFFECTIVENESS OF QUALIFICATION PROGRAMME

PURPOSE AND SCOPE

6.1. An assessment of the effectiveness of the qualification programme should be made in accordance with Requirement 13 of SSR-2/2 (Rev. 1) [2]. A typical scope of the review includes:

— Compliance with the governing framework documents;

— Programmatic or technical adequacy of qualification documentation;

— Effectiveness of programmatic interfaces;

— Effectiveness of training related to qualification;

— Corrective actions effectiveness reviews.

6.2. This section provides guidance for conducting periodic audits and reviews and ongoing/routine surveillance and inspection activities intended to assess the effectiveness of an equipment qualification programme and to identify areas for improvement.

6.3. The primary responsibility for conducting periodic audits and ongoing surveillance of equipment qualification programme activities rests with the operating organization. However, the regulatory body also performs, as appropriate, periodic audits of selected equipment qualification programme elements as part of its safety verification activities.

PERIODIC REVIEWS AND AUDITS

6.4. Evaluation of the effectiveness of equipment qualification programme should include evaluation of activities performed by the following organizations:

— Operating organizations;

— Suppliers of qualified items;

— Third party commercial and/or nuclear qualification services;

— Qualification testing facilities (e.g. accredited laboratories).

6.5. Evaluation of the effectiveness of equipment qualification programme should be an active and on-going process that provides insights into:

— Whether the qualification master list is available and up to date;

— Whether the methods and criteria utilized in the equipment qualification programme reflect required licensing and design basis;

— Whether the original safety, operability and performance assumptions were reasonable and remain valid;

— Whether the qualification documentation is available in an auditable and traceable form providing evidence of qualification for each item comprised in the equipment qualification master list, including a system for locating required supporting documentation;

— Whether the supporting documentation is traceable; it includes test and analysis documentation, evaluation of operating experience and information from feedback programmes, procurement documents, production quality assurance, storage, transportation and installation requirements, and surveillance and maintenance requirements;

— Whether there is evidence through inspection that:

(a) Technical basis and assumptions for modelling of qualified life (e.g. activation energy levels, material compositions, assumed actual environmental conditions, and other parameters supporting the qualified life modelling) remain valid;

(b) Installed equipment matches the qualified equipment;

(c) The equipment is installed correctly (e.g. mounting, connections and conduit seals comply with the qualified configuration documentation, actuators and hydraulic/pneumatic lines are connected and arranged per design requirements);

(d) The equipment and any protective barriers, if required, are appropriately maintained;

(e) Corrective actions identified and performed in timely manner;

(f) Personnel is capable of identifying characteristics of ageing degradation effects.

— Whether the measures required to preserve qualification during installed lifetime of the item are documented in appropriate plant procedures or instructions (e.g. storage and handling of qualified spare parts, installation, surveillance, maintenance and component replacement requirements) and are implemented;

— Whether the relevant personnel are appropriately trained and qualified to establish and preserve qualification;

— Whether the surveillance programme including testing, inspection, equipment condition, and environmental monitoring activities has been established to ensure that ageing degradation and functional capability of the items remain acceptable, and a feedback process is in place to address unanticipated degradation identified during surveillance or maintenance.

— Whether a programme is in place to analyse premature degradation or failures of qualified items, and to implement appropriate corrective actions, including revisions of qualification conclusions.

— Whether an operating experience programme is in place to collect and review information relevant to the status of qualified items. Such information includes nuclear installation operating experience, generic operating experience from other nuclear installations, significant event reports, supplier or manufacturer feedback, research and development results, and regulatory notices and advisories;

— Whether the above elements reflect current design information, including any recent plant and equipment modifications;

— Whether there is adequate evidence that programmatic controls (e.g. corrective actions, problem identification, configuration management) are effective.

7. PROGRAMATIC INTERFACES AND INTEGRATION OF QUALIFICATION IN SAFETY PROGRAMMES AND PROCESSES

PROGRAMATIC INTERFACES

7.1. The equipment qualification programme interfaces with other organizations, programmes, and processes to ensure continued sustainability of the status of qualification of items important to safety.

7.2. These interfaces should be clearly defined and typically include:

— Configuration management;
— Operating and industry experience;
— Ageing management;
— Maintenance;
— Radiation protection;
— Chemistry;
— Corrective action;
— Quality assurance programme audit and self-assessment;
— Procurement and storage of qualified items;
— Training for qualification group personnel.

7.3. Examples of organizations that interface with the qualification programme include:

— Licensing;
— Operations;
— Outage, planning, and scheduling;
— Electrical, instrumentation and controls;
— Maintenance for calibrations, preventative maintenance;

— Procurement and warehouse;

— Training;

— Engineering – replacement parts engineering or design engineering;

— Work management for task and work execution planning;

— Ageing management organization or personnel;

— Quality assurance (including vendor surveillance).

7.4. The qualification of items important to safety is an essential part of programmes of a nuclear installation, together with maintenance, in-service inspection and testing, surveillance and ageing management. The coordination of qualification activities between the relevant interfacing units such as maintenance, operations, parts engineering or design engineering should be ensured.

7.5. Paragraphs 4.23 to 4.31 of SSG-48 [13] provide guidance on how qualification is integrated and reviewed within the framework of ageing management programme.

7.6. Certain equipment qualification programme elements are integrated within existing maintenance, surveillance, event analysis, feedback of operating experiences and engineering programmes of the nuclear installation. The sections below outline the programmatic interfaces associated with qualification.

SAFETY ANALYSIS REPORT

7.7. Qualification considerations presented in the safety analysis report should include:

— Information regarding the scope of items and their applications subject to qualification;

— The assumptions regarding the choice of environmental zones and anticipated service conditions;

— The variations of environmental conditions expected in operational states and postulated accident conditions (e.g. vibration, temperature, pressure, electromagnetic interference, irradiation, humidity);

— Any unusual environmental conditions that can reasonably be anticipated or arise from specific operational states, such as in periodic testing of the containment leak rate;

— Principles of qualification of items important to safety.

7.8. Changes to the qualified status of items important to safety should be documented in updates to the safety analysis report.

7.9. Recommendations on the format and content of the safety analysis report are provided in IAEA Safety Standards Series No. GS-G-4.1, Format and Content of the Safety Analysis Report for Nuclear Power Plants [19].

MODIFICATIONS

7.10. The plant modification process should include provisions to ensure that qualification documentation is updated to reflect all design changes.

7.11. Any modification involving qualified items should be incorporated into plant controls before the modification is implemented. This includes:

— All the documentation affected by the plant modification, such as the safety analysis report, operational limits and conditions, drawings, operating and emergency procedures, periodic maintenance and testing procedures, and equipment indexes have been updated and are available. Documents should not be released for use until the modification has been completed;

— The as-built configuration of modified systems has been verified and the design basis document has been updated;

— Personnel have been trained on the modifications;

— Records for design, manufacturing, commissioning, quality assurance, testing and installation have been reviewed for completeness and accuracy.

7.12. Modifications that involve only items not important to safety may affect the qualified status of items important to safety due to interactions and should therefore also be evaluated for possible impact on affected qualified items.

7.13. Recommendations on controlling activities relating to modifications to nuclear power plants are provided in IAEA Safety Standards Series No. NS-G-2.3, Modifications to Nuclear Power Plants [20].

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ANNEX

BIBLIOGRAPHY OF INTERNATIONAL STANDARDS REALTED TO QUALIFICATION OF ITEMS IMPORTANT TO SAFEY

A–1. Requirement 9 of IAEA Safety Standards Series No. SSR-2/1 (Rev. 1), Safety of Nuclear Power Plants: Design [A–1] states:

> "Items important to safety for a nuclear power plant shall be designed in accordance with the relevant national and international codes and standards."

A–2. This Safety Guide provides high level recommendations that are widely accepted among IAEA Member States. Beyond the guidance provided by the IAEA, a large body of national and international standards exists that give more detailed recommendations about design methodologies and system characteristics that support compliance with SSR-2/1 (Rev. 1) [A–1]. It is expected that designers, operating organizations and regulatory bodies will take advantage of the information in these standards.

A–3. Two standards development organizations are responsible for most of the internationally used standards for instrumentation and control systems in nuclear power plants: the International Electrotechnical Commission (IEC) Subcommittee 45 and the Institute of Electrical and Electronic Engineers (IEEE) Nuclear Power Engineering Committee. Each organization has developed a large number of standards. Both organizations produce standards that respond to the common principles underlying the requirements of SSR-2/1 (Rev. 1) [A–1] and the recommendations of this Safety Guide. Consequently, either set of standards can be used to further interpret the recommendations of this Safety Guide.

A–4. This Annex is intended to help readers understand the relationship between this Safety Guide and the IEC and IEEE standards. Table A–1 lists the IEC and IEEE standards that have a strong relationship with the recommendations of this Safety Guide. Table A–1 is not a complete list of either set of standards, but it identifies the entry points into the sets of IEC and IEEE standards.

A–5. A concerted effort was made to avoid conflicts between the recommendations of this Safety Guide and the standards of IEEE and IEC. Members of both the IEC and the IEEE standards committees participated in the development of this Safety Guide and both standards organizations reviewed drafts to help identify and eliminate conflicts.

A–6. Nevertheless, users need to recognize and take account of the fact that there are important differences between the IEC and the IEEE standards. IEC standards take the IAEA Safety Requirements publications and Safety Guides as fundamental inputs for their development. As a result, the IEC standards deal with items important to safety and take the guidance on instrumentation and control systems provided by the IAEA as the source of general recommendations.

A–7. IEEE standards focus largely on items important to safety and, therefore, the IEEE guidance directly applies to a smaller set of functions, systems and equipment than this Safety Guide does. Nevertheless, the guidance of the IEEE can be applied to safety related items (items important to safety that are not safety systems) using a graded approach.

TABLE A–1 INTERNATIONAL STANDARDS WITH A STRONG RELATIONSHIP TO THIS SAFETY GUIDE

IEC 60515:2007 [A–2]	Nuclear power plants - Instrumentation Important to Safety - Radiation Detectors - Characteristics and Test Methods
IEC 60772:2018 [A–3]	Nuclear Power Plants - Instrumentation Systems Important to Safety - Electrical Penetration Assemblies in Containment Structures.
IEC 60980:1989 [A–4]	Recommended practices for seismic qualification of electrical equipment of the safety system for nuclear generating stations
IEC 61513:2011 [A–5]	Nuclear power plants – Instrumentation and control important to safety – General requirements for systems
IEC 62003:2009 [A–6]	Nuclear power plants - Instrumentation and control important to safety - Requirements for electromagnetic compatibility testing
IEC 62342:2007 [A–7]	Nuclear power plants - Instrumentation and control systems important to safety - Management of ageing
IEC/IEEE 60780-323:2016 [A–8]	Nuclear Facilities – Electrical Equipment Important to Safety – Qualification, IEC/IEEE 60780-323 std. (Edition 1.0)
IEEE 308-2012 [A–9]	Standard Criteria for Class 1E Power Systems for Nuclear Power Generating Stations
IEEE 334-2006 [A–10]	Standard for Qualifying Continuous Duty Class 1E Motors for Nuclear Power Generating Stations
IEEE 344-2013 [A–11]	Standard for Seismic Qualification of Equipment for Nuclear Power Generating Stations
IEEE 382-2006 [A–12]	Standard for Qualification of Safety-Related Actuators for Nuclear Power Generating Stations
IEEE 383-2015 [A–13]	Standard for Qualifying Electric Cables and Splices for Nuclear Facilities
IEEE 420-2013 [A–14]	Standard for the Design and Qualification of Class 1E Control Boards, Panels, and Racks Used in Nuclear Power Generating Stations

IEEE 535-2013 [A–15]	Standard for Qualification of Class 1E Vented Lead Acid Storage Batteries for Nuclear Power Generating Stations
IEEE 572-2006 [A–16]	Standard for Qualification of Class 1E Connection Assemblies for Nuclear Power Generating Stations
IEEE 603-2018 [A–17]	Standard Criteria for Safety Systems for Nuclear Power Generating Stations
IEEE 627-2010 [A–18]	Standard for Qualification of Equipment Used in Nuclear Facilities
IEEE 649-2006 [A–19]	Standard for Qualifying Class 1E Motor Control Centers for Nuclear Power Generating Stations
IEEE 1682-2011 [A–20]	Standard for Qualifying Fiber Optic Cables, Connections, and Optical Fiber Splices for Use in Safety Systems in Nuclear Power Generating Stations
ASME QME-1-2017 [A–21]	Qualification of Active Mechanical Equipment Used in Nuclear Facilities

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DEFINITIONS

The following definitions are specific to this publication and are either not provided in, or are different from, those provided in the IAEA Safety Glossary: Terminology Used in Nuclear Safety and Radiation Protection (2018 Edition)

accelerated ageing. Ageing in which the simulation of natural ageing approximates, in a short time, the ageing effects of longer term service conditions. Usually, the accelerated ageing attempts to simulate natural ageing effects by application of stressors representing plant preservice and service conditions, but perhaps different in intensity, duration and manner of application.

ageing mechanism. Specific process that gradually changes characteristics of an SSC with time or use (examples: curing, wear, fatigue, creep, erosion, microbiological fouling, corrosion, embrittlement or chemical decomposition).

Arrhenius ageing model. A simplified mathematical model, characterizing the kinetics of a chemical reaction (degradation process). It indicates a linear relationship between the logarithm of exposure time and the reciprocal of the absolute temperature. Its correct usage is restricted to such a relationship between a reaction rate constant (activation energy) and the thermodynamic temperature.

harsh environment. Environmental conditions in a location of nuclear installation which significantly change as a result of a postulated initiating event.

mild environment. Environment that would at no time be significantly more severe than the environment that would occur during operational states.

mission time. Time for which the equipment is required to perform (maintain) its intended function, under conditions of postulated accidents.

pre-existing item. An item which has already been already qualified in accordance with an industrial or nuclear standard for use in application different from what is required in the nuclear installation.

qualification margin. Difference between service conditions and the conditions used for qualification

traceability. The ability to verify the history, location, or application of an item by means of recorded identification.

type testing. A type test subjects a representative sample of equipment, including its interfaces, to a series of tests, simulating the effects of significant ageing mechanisms during normal operation. Equipment qualification testing shall be performed with equipment functioning in a state representative of its intended use in actual operation (including any software).

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