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review**

**Soliciting comments by Member
States**

Equipment Qualification for Nuclear Installations

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DRAFT SAFETY GUIDE

New Safety Guide

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CONTENTS

1. INTRODUCTION	6
Background.....	6
Objective.....	7
Scope.....	7
Structure.....	8
2. QUALIFICATION CONCEPT AND PROCESS	8
Basic concept.....	8
Qualification process	10
Quality assurance.....	11
Documentation.....	12
Training.....	13
3. DESIGN INPUTS.....	13
Identification of anticipated service conditions	13
Identification of intended safety functions	16
Identification of items and criteria for qualification	17
4. ESTABLISHING QUALIFICATION.....	19
Qualification practices for different service conditions.....	19
Assessment of initial qualification status.....	22
Qualification by type testing.....	22
Qualification by analysis	28
Extrapolation of qualification	28
Qualification by operating experience.....	28
Demonstration of production items	29
Combined methods	29
5. PRESERVING QUALIFICATION.....	29
General.....	29
Ageing effects and qualified life.....	31
Elements of qualification preservation	31
Measurement of Environmental conditions monitoring	32
Condition monitoring.....	33
Periodic surveillance.....	34
Maintenance.....	34
Protective barriers	34
Supply chain, procurement and warehousing	35
Reassessment of qualification.....	35
6. EVALUATION OF THE EFFECTIVENESS OF QUALIFICATION PROGRAMME.....	36
Purpose and scope.....	36
Periodic reviews and audits	36
7. PROGRAMATIC INTERFACES AND INTEGRATION OF QUALIFICATION IN SAFETY PROGRAMMES AND PROCESSES	38
Programatic interfaces	38
Safety analysis report.....	39

Modifications..... 39

REFERENCES 41

ANNEX 43

DEFINITIONS..... 48

CONTRIBUTORS TO DRAFTING AND REVIEW 49

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1. INTRODUCTION

BACKGROUND

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

1.2. Requirements for the design and operation of nuclear power plants are established in IAEA Safety Standards Series Nos SSR-2/1 (Rev. 1), Safety of Nuclear Power Plants: Design [1], and SSR-2/2 (Rev. 1), Safety of Nuclear Power Plants: Commissioning and Operation [2]. Requirements for other types of nuclear installations are established in IAEA Safety Standards Series Nos SSR-3, Safety of Research Reactors [3], and SSR-4, Safety of Nuclear Fuel Cycle Facilities [4]. Additional requirements relevant to equipment qualification are established in IAEA Safety Standards Series No. GSR Part 4 (Rev. 1), Safety Assessment for Facilities and Activities [5].

1.3. IAEA Safety Standards Series No. SSG-30, Safety Classification of Structures, Systems and Components in Nuclear Power Plants [6] provides recommendations on how to classify systems and components and other items of equipment 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 equipment qualification.

1.4. IAEA Safety Standards Series No. NS-G-1.6, Seismic Design and Qualification for Nuclear Power Plants [7] provides recommendations on equipment qualification specific to seismic design for nuclear power plants.

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

1.6. Additional guidance on equipment qualification is available from individual States and from international organizations that develop nuclear and industrial codes and standards. This includes publications that provide specific implementation details and methodologies for qualification of items important to safety (see Annex).

OBJECTIVE

1.7. The objective of this Safety Guide is to provide a structured approach and guidance on the establishment and preservation of equipment in nuclear installations.

1.8. This Safety Guide provides recommendations on the equipment qualification for nuclear installations to meet specific requirements established in SSR-2/1 (Rev. 1) [1] and SSR-2/2 (Rev. 1) [2] for nuclear power plants, in SSR-3 [3] for research reactors, in SSR-4, [4] for nuclear fuel cycle facilities, and in GSR Part 4 (Rev. 1) [5] for all facilities and activities.

1.9. This Safety Guide is intended for use by entities responsible for aspects of equipment qualification for nuclear installations. This Safety Guide is also intended for use by regulatory bodies to support their licensing and inspection activities related to equipment qualification.

SCOPE

1.10. This Safety Guide addresses the process for establishing and preserving equipment qualification in nuclear installations¹, to ensure reliable performance of the safety functions within anticipated service conditions during the entire lifetime of the nuclear installation.

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

1.12. Equipment within the scope of this Safety Guide includes 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). Non-active items important to safety that safety function is demonstrated according to applicable codes (e.g. piping and metallic components) are outside the scope of this Safety Guide.

1.13. The main topical areas for which this Safety Guide provides recommendations are the following:

- (a) Identification of design inputs necessary for equipment qualification;
- (b) Qualification methods and practices for establishing and preserving the equipment qualification to provide reliable confirmation that equipment is capable to perform its safety function for operational states and for accident conditions throughout the lifetime of a nuclear installation;
- (c) Integration of qualification processes within the design, installation, commissioning, operation and maintenance of nuclear installations throughout their lifetime.

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

¹ In the context of this Safety Guide, nuclear installations comprise nuclear power plants, research reactors and nuclear fuel cycle facilities.

- (a) Development and review of the safety analysis report;
- (b) Modification processes;
- (c) Other processes that affect qualification (e.g. supply chain, procurement, storage, maintenance, corrective action programme);
- (d) Operational experience feedback (e.g. internal, external).

1.15. This Safety Guide does not specify seismic qualification methods and processes in detail. Recommendations on seismic qualification (for nuclear power plants) are provided in NS-G-1.6 [7].

1.16. This Safety Guide does not specify software verification and validation methods and processes in detail. Recommendations on these topics are provided in SSG-39 [12].

STRUCTURE

1.17. 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 recommendations on establishing qualification. Section 5 provides recommendations for preserving qualification. Section 6 provides recommendations on the evaluation of the effectiveness of the equipment qualification programme. Section 7 provides recommendations on programmatic interfaces and integration of qualification within other safety programmes and processes.

1.18. The Annex provides a list of international nuclear and industrial standards that can be used for equipment qualification, 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. Qualification should demonstrate that items will be capable of performing their intended safety function(s) under the full range of service conditions anticipated for the nuclear installation in operational states and accident conditions, and during internal and external events.

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

2.5. Equipment qualification is a necessary condition for prevention 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 equipment is designed, manufactured, installed, commissioned, operated, and maintained such that the equipment is capable of performing its required safety functions, when necessary, and in the specified service conditions, throughout its qualified life, with due account taken of plant conditions during maintenance and testing.

2.7. Within the context of qualification, items should be considered as 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 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 their 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 performing the 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 all plant states and during 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. Equipment qualification should be considered as an essential programme throughout the whole lifetime of a nuclear installation.

QUALIFICATION PROCESS

2.13. The equipment qualification process 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 Sections 3, 4 and 5 of this Safety Guide.

Qualified life

2.15. The qualified life should be established for items important to safety that are subject to significant ageing degradation mechanisms and are expected to function within a harsh environment. Such mechanisms can degrade the functional capabilities of items to perform safety functions during anticipated service conditions.

2.16. The parameters and any modelling of anticipated environmental conditions used to establish the qualified life should be specified.

2.17. The qualified life should ensure that the items important to safety are capable of functioning within acceptance criteria during specific operating conditions while retaining the ability to perform their safety functions in a design basis accident.

2.18. Items important to safety that are not in a harsh environment and are not subject to significant aging degradation mechanisms are typically accessible and therefore compliance with the design specification and adherence to the maintenance program is considered adequate.

2.19. Items important to safety that are located in a harsh environment should be maintained within their qualified life while installed in service or in while in storage prior to installation. The qualified life of an item might not necessarily cover the lifetime of the nuclear installation, as it might need to be periodically replaced.

Qualification methods

2.20. Appropriate qualification methods should be applied in accordance with the different equipment types, for example as listed below:

- Pressure boundary active components with non-metallic parts;
- Other mechanical equipment with non-metallic parts;
- Electrical, instrumentation and control equipment.

2.21. The qualification methods should ensure traceability of as-built conditions to tested or analysed

equipment and to tested or analysed configurations.

2.22. Internationally recognized methods for qualification are: type testing, analysis, use of operating experience or a 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 equipment qualification. The specific methods of qualification for any particular type of item might include the application of more than one method of qualification (for example seismic, environmental, and periodic functional testing).

Preservation of qualified status

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

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

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

2.26. A review of qualified status should also be conducted due to other reasons; for example, equipment design or installation changes, changes in the licensing basis of the nuclear installation, parts changes, component material changes, component failures, uncontrolled maintenance, life extension review.

2.27. 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

2.28. A quality assurance programme for equipment being qualified includes a variety of elements, 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.

2.29. Qualification activities should be conducted in accordance with a management system that meets the requirements established in GSR Part 2 [8].

2.30. Qualification activities should be performed in accordance with approved procedures and controls.

2.31. Data acquisition tools used during type testing should be calibrated against traceable criteria and documentation supporting such calibrations should be provided.

2.32. Traceability should be established between the testing documentation, the 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.

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

DOCUMENTATION

2.34. Documentation on qualification includes the qualification specification and 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 evaluations), qualified life evaluations, plant field testing and analytical evaluations, equipment modifications and changeouts, and surveillance and maintenance records.

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

2.35. The qualification status of items should be properly documented and maintained in an auditable form while the item is in service or in storage while awaiting installation.

2.36. The initial qualification status of items 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.

2.37. 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, chemical composition of certain components could be of paramount importance to its safety functions and safety margins.

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

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

2.40. 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 specific application of the installation and safety functions to be implemented.

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

TRAINING

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

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

2.44. Key training elements for personnel implementing qualification activities include those needed for establishing and preserving equipment qualification. Such elements include the following:

- (a) Training specific to the job, task and procedure;
- (b) Integration of qualification details into 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);
- (c) A description of related responsibilities and their scope.

2.45. The training programme should include an element for oversight of the training of both internal staff and any contractor's personnel involved in qualification activities.

3. DESIGN INPUTS

IDENTIFICATION OF ANTICIPATED SERVICE CONDITIONS

3.1. The equipment qualification programme begins with establishing the range of conditions and events under which the items should be qualified. To establish this, every design basis event for the nuclear installation should be identified and its effects on 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, in order 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), process conditions (e.g. voltage, current, temperature, pressure), fluid conditions (e.g. differential pressure, temperature, flow, fluid parameters, and chemical content) and environmental conditions in all plant states, and during internal events 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 plant 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. by establishing exclusion zones to prevent adverse impact of electromagnetic or radiofrequency fields on the equipment performance).

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 the suitability of items to perform adequately.

3.11. Relevant environmental conditions typically include the following:

- Ambient temperature and pressure;
- Humidity/steam;
- Radiation;
- Submergence;
- Boric acid and other applicable chemical sprays;
- Chemicals in the atmosphere (dust, salt mist, oil aerosols);
- Vibration from neighbouring equipment;
- Electromagnetic compatibility.

3.12. Relevant operating conditions typically include the following:

- 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 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 experience 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. The general ambient environmental conditions in a nuclear installation may not be representative of the actual conditions where the item is installed. Ventilation variations and local heat sources are typical factors 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 the operation of electrical equipment or 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. The evaluation of equipment performance for operational states generally involves demonstrating the functional capability of an item when experiencing a combination of service condition extremes.

Electromagnetic interference

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

3.19. Electromagnetic interference can affect electrical and instrumentation and control systems and components. Electromagnetic qualification addresses the combination of system and component design to minimize the coupling of electromagnetic disturbances to electrical and instrumentation and control components.

3.20. Detailed requirements and acceptance criteria for electromagnetic interference 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 electromagnetic interference should be performed during normal operations and should include the effects of operating and maintenance activities to verify and establish a basis for qualification criteria.

3.22. Electromagnetic fields can vary in time and in space, and periodic measurements of electromagnetic fields should be performed to identify and quantify sources of electromagnetic interference.

Service conditions resulting from postulated accidents

3.23. 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, submergence or by changes in process fluid conditions or chemical composition.

3.24. The bounding thermodynamic profiles and chemical effects associated with each of the postulated initiating events should be derived from the 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 their performance requirements for the applicable accident conditions.

Internal events and external events

3.27. The design basis and the safety analysis of the nuclear installation identify internal events 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 fire protection standards providing guidance on the relative fire resistance of various cable constructions. In such cases, demonstrating cable performance under postulated fire conditions in the nuclear installation is not necessary as part of the qualification.

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

3.30. Items important to safety should be designed and qualified to withstand seismic hazards in accordance with the recommendations provided in NS-G-1.6 [5]. 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 INTENDED SAFETY FUNCTIONS

3.31. The safety functions needed to prevent or mitigate the consequences of identified events and accident conditions should be specified.

3.32. The process of specifying those identified events includes an evaluation of the events and

accidents. This is usually achieved by modelling to determine the effects at the location of the items important to safety of the conditions resulting from the event.

3.33. Items important to safety that are necessary to fulfil the intended safety functions that are needed for prevention or mitigation of the events should be identified.

3.34. The design requirements for the items to be qualified should include the identification of safety functions, performance requirements, and service conditions (see paras 3.1–3.30 for recommendations on the identification of service conditions).

3.35. Performance requirements and service conditions should be quantified and documented as ranges of parameters that are valid throughout applicable operational states, accident conditions, internal and external events.

3.36. Items important to safety that are needed to function during accident conditions should meet the performance requirements during the specified mission time.

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

3.38. 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 needed.

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

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

3.41. The equipment specification of items subject to qualification should include the following:

- Equipment type, manufacturer, model number (and variants), current manufacturing status;
- Versions of firmware and application software;
- Dimensions, ranges of rated parameters (mechanical and electrical);
- Mechanical, electrical, process and instrumentation and control interfaces of the equipment;
- Operating manual and maintenance, installation and test procedures;
- Certificates and test documentation with respect to industrial standards.

IDENTIFICATION OF ITEMS AND CRITERIA FOR QUALIFICATION

3.42. Criteria for qualification should be derived from the safety design and the accident analysis of the nuclear installation, as well as from normal and emergency procedures and supplemental design

documents. These criteria include:

- Classification system of the nuclear installation;
- General qualification criteria for mechanical systems and components;
- General qualification criteria for the electrical safety systems and components;
- General qualification criteria for the safety automation system (instrumentation and control system) and components;
- Criteria for environmental, seismic and electromagnetic interference qualification, based on applicable codes and standards.

3.43. The design inputs that are necessary for qualification of items important to safety should be established and documented in a specification that includes the following:

- A description of the required safety function;
- A description of the 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 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.

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

- Thermodynamic parameters (characterized by temperature, pressure, humidity);
- Radiation parameters (characterized by radiation energy, type of radiation, fluence, total 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);
- Instrumentation and control 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 valve, pump or flap).

4. ESTABLISHING QUALIFICATION

4.1. Equipment qualification should be based on a selection 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 the qualification process. The specific methods for conducting this modelling or simulation are outside of the scope of this Safety Guide.

4.5. The qualification parameters for items important to safety located in areas in which conditions are less severe, 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 that have an impact on the qualification status of items should be identified and included in the qualification specifications. Examples include operating cycles, such as switching on and off, pressure changes, plugging and unplugging connectors, electronic cards extraction and insertion, terminal box cover opening and closing.

Items exposed only to mild environments

4.8. Mild environment areas are locations within a nuclear installation in which conditions would at no time be significantly more severe than those 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, such areas could be subject to 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 that are located in mild environment should be achieved by the following:

- 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 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 that are 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 environmental conditions resulting from a postulated initiating event, and should show that the required functionality (e.g. number of load cycles) is maintained to enable the item to continue

performing its safety functions.

4.12. The demonstration that an item can function as needed at the end of its qualified life should take account of any significant ageing effects resulting from operational states that 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. Individual components that have a qualified life that is shorter than the expected in-service life should be replaced at predetermined intervals consistent with their qualified life.

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 (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 ... [s]hall 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 their intended safety function under severe accident conditions.

4.17. Qualified items should have the capability, as appropriate, to fulfil their intended safety functions for the time necessary under severe accident conditions.

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 items should be performed by means of a preliminary suitability assessment, showing that the selected item 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 needed:

- 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 functional characteristics, resistance to all anticipated service 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 for temperature effects), the sequence in which these tests are conducted should be justified as one that conservatively simulates the degradation due to ageing during service life followed by exposure to the accident conditions. The synergistic effects of multiple parameters, such as application of appropriate radiation dose rates and temperatures, should be taken into account 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), and should provide information on conducting the qualification tests.

4.33. The test specification should include the following:

- (a) The item unique identification (one-to-one relationship);
- (b) Internal dimensions of critical parts that might impact functional performance of the item (such as internal clearances and edge radii of valves);
- (c) The quality assurance to be applied;
- (d) Scope of activities covered by the qualification;
- (e) Applicable regulatory codes and standards;
- (f) Physical description of the item;
- (g) Special requirements based on the test method of qualification;
- (h) The test parameters to be monitored with diagnostic equipment and required accuracy;
- (i) A description of the required test parameters to be monitored, the required diagnostic equipment, and the required accuracy;
- (j) The need for any witness or hold points among the test steps (e.g. by independent expert organisation, if applicable);

- (k) Requirements for the test assembly, measurement devices, mounting and interfaces;
- (l) Identification of the type of test facility to be used;
- (m) Maintenance activities and/or replacements during the tests (e.g. replacement of gaskets after the ageing);
- (n) Type of documentation to be prepared by the laboratory;
- (o) The need for auxiliary equipment to be included in the test specifications (e.g. test connections, measurement cables or power supplies);
- (p) Actions to be taken in the event of deviations and/or failures.

4.34. The test specifications should outline the 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.

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

- (a) Test conditions and margins to be applied;
- (b) The safety function(s) of the item to be demonstrated throughout the tests;
- (c) The test sequence(s) and/or the test steps, including the performance characteristics to be tested;
- (d) The acceptance criteria for each test step demonstrating the performance requirements have been achieved (e.g. opening and closing times, response time, accuracy);
- (e) Normal operating condition of the equipment (energized or de-energized);
- (f) Ranges in performance requirements of each test step, demonstrating the safety function under different plant states (e.g. operational states and design basis accidents);
- (g) Qualification boundaries and interfaces between the items subject to qualification. The interfaces should be defined based on the mechanical and electrical design criteria, as appropriate;
- (h) Data recording and test equipment accuracy, diagnostic data for valve operating requirements and valve actuator output;
- (i) Applicable mission times;
- (j) Specified qualified life;
- (k) The need for taking measurements (e.g. continuous recording, accuracy of the items used to perform recording of data);
- (l) Quality assurance requirements.

Test specimens

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

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

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

4.39. 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.

4.40. 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.

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

4.42. Individual modules or components may be tested separately, but for certain tests, such as for electromagnetic interference, the tests of the whole assembly (e.g. instrumentation and control cabinet, electrical switchgear) should be performed to measure the possible interactions.

Demonstration of safety functions during type tests

4.43. Functional tests should be used to demonstrate the ability of items to perform the required safety functions over the full range of their anticipated service conditions.

4.44. 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.

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

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

4.46. The test conditions to be considered for type testing should include parameters associated with anticipated service conditions. If needed, other parameters (e.g. boric acid or steam spray, salt spray, dust) should also be considered.

4.47. 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)

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

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

Accelerated thermal ageing

4.50. Thermal ageing effects should be simulated by exposing equipment samples to higher temperatures for a specified duration (accelerated thermal ageing). The rate of accelerated thermal ageing should be documented and justified.

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

4.52. The higher 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.

4.53. 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.

Radiation ageing

4.54. The total dose that might be received during operational states and accident condition dose should be simulated.

4.55. The applied dose rate should be high enough to cause homogeneous changes and prevent the effects caused by oxidation and gaseous diffusion.

4.56. Unless otherwise stated (e.g. national requirements), the irradiation ageing simulation should be performed under ambient temperature conditions.

Simulation of other stressors

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

Non-seismic vibration and mechanical shocks

4.58. Non-seismic vibration and shocks originating 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.

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

Simulation of seismic events

4.60. Seismic effects should be simulated on aged samples, simulating operating conditions to which the sample is subjected to, prior to accident testing, if required.

4.61. Details on seismic testing are provided in NS-G-.16 [7].

Simulation of postulated initiating event conditions

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

4.63. The total radiation dose resulting from operational states and postulated initiating events should be applied in either a single exposure or in a series of exposures.

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

4.65. Tested items should be powered and subjected to loads in a manner that accurately represents the installed configuration.

4.66. The 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

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

4.68. 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].

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

4.70. Qualification type tests should include provisions to verify that an adequate qualification margin exists.

4.71. Increasing the number of test cycles or the test durations are acceptable methods of adding margins in testing.

QUALIFICATION BY ANALYSIS

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

4.73. Qualification by analysis can be used to extend the results of qualification testing to represent an entire family of equipment of the same or similar type, if it can be shown that the tested items are representative of other items in the same family (e.g. cables, series of motors of the same type, 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.

4.74. Qualification by analysis that forms part of the evidence of qualification should include a justification of the methods and assumptions used. The validity of the mathematical models used for qualification might be justified on the basis of experimental data, test data or operating experience.

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

4.76. 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

4.77. Extrapolation of the qualification of an item to another size of item or to a different application of the same item should be justified.

4.78. 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 to demonstrate the reliability of the item to perform safety functions. Qualification by operating experience alone will not be appropriate for certain items without additional qualification testing to support the qualification.

4.80. Qualification by operating experience alone should be limited to items that perform safety functions in mild environments, and when the 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 does not include evidence of the capability to withstand the environments associated with design basis accidents. Therefore, operating experience information should at least be combined with 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 data from operating experience should be based on conditions that are 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

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

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

COMBINED METHODS

4.86. Items can be qualified by a combination of type testing, operating experience, and analysis. For example, where type testing of a complete assembly is not possible, component testing supplemented by analysis could be used. In some cases the overall qualification of the item, is dependent on the qualification of the most limiting individual component within that item.

4.87. 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.

4.88. 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.

4.89. 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 equipment 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, or 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 equipment qualification status 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.

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

5.10. 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) A master list of items subject to qualification;
- (b) Procurement technical specification;
- (c) Manufacturer data in support of qualification;
- (d) Installation specification;
- (e) Results of environmental monitoring, when relevant;

- (f) The summary report of the qualification;
- (g) Test reports relating to qualification;
- (h) Results of maintenance activities;
- (i) Non-conformity reports from vendors and operating organizations;
- (j) Relevant operating experience;
- (k) Reports of time limited ageing analyses relating to qualification (e.g. for evaluation for long term operation) or reports of another suitable equivalent analysis.

5.11. Programmatic interfaces should be identified, 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.

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

5.13. 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.

AGEING EFFECTS AND QUALIFIED LIFE

5.14. 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.”

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

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

ELEMENTS OF QUALIFICATION PRESERVATION

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

- (a) Deviations from appropriate installation and maintenance practices;
- (b) Changes to the design basis or safety analysis;

- (c) Changes in regulations and plant licensing activities;
- (d) Modification of nuclear installation;
- (e) Deviation in service conditions from those accounted for in the qualification;
- (f) Feedback on adverse operating and maintenance experiences;
- (g) Unavailability of qualified spare parts;
- (h) Storage conditions of the qualified items and spare parts;
- (i) Obsolescence of the item or spare parts;
- (j) New information developed from recent qualification tests or research tests that challenge or modify original assumptions or test or analysis results.

5.18. 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.

5.19. 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.

MEASUREMENT OF ENVIRONMENTAL CONDITIONS MONITORING

5.20. A preliminary analysis should be carried out to determine where measurements of environmental conditions 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.

5.21. 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.

5.22. The measurement of actual ambient environmental conditions helps to identify worst-case conditions.

5.23. Measurement of the ambient environmental conditions in the nuclear installation under operational states should ensure that:

- The assumptions in the qualification are consistent with the ambient conditions in the installation;
- The design limits of the equipment are not exceeded;

— The initial qualified status remains valid.

5.24. Additionally, ambient environmental monitoring should be used to support the 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 a reduction of the equipment qualified life if the measured environment conditions are more adverse than what was originally assumed in the qualification.

CONDITION MONITORING

5.25. 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.

5.26. 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.

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

- (a) Service conditions are suspected to be more severe than previously assumed;
- (b) Ageing evaluations contain uncertainties in the initial assumptions;
- (c) Known ageing mechanisms cannot be fully evaluated or simulated when qualification was established.

5.28. When unexpected degradation is observed during periodic surveillance or visual inspection, the impact of this degradation should be identified and evaluated, 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 a 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 measurements of environment conditions should be used to support the re-assessment of qualified life of the item. This should ensure that the nuclear installation is operated within its design basis.

PERIODIC SURVEILLANCE

5.34. Surveillance activities should be performed to ensure that:

- (a) 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 or hydraulic interfaces;
- (b) Systems and components continue to meet their performance requirements;
- (c) Configuration abnormalities are detected, and 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 para. 5.10.

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

- (a) The control of maintenance documentation (e.g. maintenance manuals, procedures) to include qualification requirements and to describe a method by which qualification is maintained.
- (b) The establishment of an appropriate preventive maintenance schedule. Maintenance intervals should be set to ensure the qualified life of the item is maintained.
- (c) The need for any trending of condition indicators associated with qualified items and the detection of any precursors indicating that the item is degrading.
- (d) A means to identify to plant personnel that the item is qualified.

5.38. 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 qualification preservation criteria are met.

PROTECTIVE BARRIERS

5.39. When qualification is dependent on the use of barriers, enclosures or shielding which reduce or eliminate 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 criteria specified in the applicable qualification report.

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

5.43. Qualification documentation (see paras 2.34–2.41) 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 vendors and manufacturers supplying qualified items should be in accordance with the national 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 throughout the lifetime of the installation to account for changes in the actual service conditions, such as temperature and radiation levels, and development in the knowledge and understanding of degradation mechanisms.

5.50. If the qualified life of the item is to be extended, the technical basis should be provided. The technical basis of any conclusions regarding qualified status should be reevaluated to support the re-assessment of the initial qualified life of the item to take into account any changes in performance requirements or installation conditions.

5.51. The technical basis should be evaluated to determine whether any changes in documented material composition and parameters, or in assumed 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.

5.52. Methods such as revaluation of the conservatism used in original assumptions, type testing of naturally aged items with additional ageing for qualified life extension, item replacement and refurbishment, should be used for reassessing qualified life.

5.53. A reduction in the stressor intensity (e.g. lower temperature, radiation levels) can be used to extend the qualified life.

5.54. 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. The scope of this assessment typically includes the following:

- Compliance with the governing framework documents;
- Programmatic and technical adequacy of qualification documentation;
- Effectiveness of programmatic interfaces;
- Effectiveness of training related to qualification;
- Reviews of the effectiveness of corrective actions.

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

PERIODIC REVIEWS AND AUDITS

6.3. Evaluation of the effectiveness of the 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).

6.4. Evaluation of the effectiveness of equipment qualification programme should be an active and

ongoing process that provides insights into the following:

- (a) Whether the qualification master list is available and up to date.
- (b) Whether the methods and criteria used in the equipment qualification programme reflect required licensing and design basis.
- (c) Whether the original safety, operability and performance assumptions were reasonable and remain valid.
- (d) Whether the qualification documentation is available in an auditable and traceable form providing evidence of qualification for each item in the equipment qualification master list, including a system for locating required supporting documentation.
- (e) Whether the supporting documentation is traceable and 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.
- (f) Whether there is evidence of the following:
 - (i) The technical basis and assumptions used in 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;
 - (ii) The installed equipment matches the qualified equipment;
 - (iii) The equipment is installed correctly (e.g. mounting, connections and conduit seals comply with the qualified configuration documentation, actuators and hydraulic or pneumatic lines are connected and arranged in accordance with design requirements);
 - (iv) The equipment and any protective barriers, if required, are appropriately maintained;
 - (v) Corrective actions are identified and performed in timely manner;
 - (vi) Personnel are capable of identifying characteristics of ageing degradation effects.
- (g) Whether the measures required to preserve qualification during the 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.
- (h) Whether the relevant personnel are appropriately trained and qualified to establish and preserve the qualification of equipment.
- (i) Whether the surveillance programme (including testing, inspection of equipment condition, and measurement of environmental conditions) has been established to ensure that the ageing

degradation and functional capability of items remain acceptable, and a feedback process is in place to address unanticipated degradation identified during surveillance or maintenance.

- (j) 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.
- (k) 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, operating experience from other nuclear installations, significant event reports, supplier or manufacturer feedback, research and development results, and regulatory notices and advisories.
- (l) Whether the above elements reflect current design information, including any recent plant and equipment modifications.
- (m) 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 programmes and processes to ensure continued sustainability of the equipment qualified status. These interfaces should be clearly defined and typically include the following:

- 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.

7.2. Examples of processes that interface with the qualification programme include the following:

- Licensing;
- Operations;

- Outage, planning, and scheduling;
- Maintenance for calibrations, preventative maintenance;
- Procurement and warehousing;
- Training;
- Engineering (replacement parts engineering or design engineering);
- Work management for task and work execution planning;
- Ageing management;
- Quality assurance (including vendor surveillance).

7.3. Equipment qualification is an essential programme for 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.

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

SAFETY ANALYSIS REPORT

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

- (a) Information regarding the scope of the items and their applications that are subject to qualification;
- (b) The assumptions regarding the choice of environmental zones and anticipated service conditions;
- (c) The variations of environmental conditions expected in operational states and postulated accident conditions (e.g. vibration, temperature, pressure, electromagnetic interference, radiation levels, humidity);
- (d) 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;
- (e) Principles of qualification of items important to safety.

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

7.7. 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

7.8. The plant modification process should include provisions to ensure that qualification

documentation is updated to reflect all design changes.

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

- (a) 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, should have been updated and be available. Documents should not be released for use until the modification has been completed.
- (b) The as-built configuration of modified systems should have been verified and the design basis document updated.
- (c) Personnel should have been trained on the modifications.
- (d) Records for design, manufacturing, commissioning, quality assurance, testing and installation should have been reviewed for completeness and accuracy.

7.10. Modifications that involve only items not important to safety might 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.

7.11. 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 RELATED TO EQUIPMENT QUALIFICATION

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 represent good practice among IAEA Member States. Beyond the recommendations 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 such design standards.

A-3. Two standards development organizations are responsible for most of the internationally used standards for instrumentation and control systems in nuclear installations: 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 number of design 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.

A-4. This Annex is intended to explain the relationship between this Safety Guide and the IEC and IEEE standards. Table A-1 lists the IEC and IEEE standards that relate directly the recommendations of this Safety Guide. Table A-1 is not a complete list of either set of design 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. 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. The IEEE standards focus mostly on items important to safety and, therefore, apply to a smaller set of functions, systems and equipment than this Safety Guide. Nevertheless, the IEEE standards can be

applied to safety related items (items important to safety that are not safety systems) using a graded approach.

TABLE A–1 IEC AND IEEE STANDARDS WITH A DIRECT 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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DRAFT

DEFINITIONS

The following definitions are specific to this publication and are not 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 a structure, system or component with time or use (e.g. 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.
- condition monitoring:** Refers to activities performed to assess the functional capability of an item by measuring and tracking suitable condition indicators. Condition monitoring supports the identification of optimal maintenance activities for the preservation of the qualified status.
- 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 that 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 assumed for qualification.
- 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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