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Guidelines for New Technology Qualification

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CHAPTER 1 GENERAL

Section 1 General

101. General

1. This Guideline provides qualification activities for new technologies to confirm their ability to perform intended functions in accordance with defined performance requirements.
2. This Guideline introduces a systems engineering approach to qualification that allows for systematic and consistent evaluation of new technologies as it matures from a concept through confirmation of operational integrity in its intended application. The approach is divided into a multi-stage process that is aligned with the typical product development phases of a new technology. The qualification activities within each stage employ risk assessments and engineering evaluations that build upon each other in order to determine if the new technology provides acceptable levels of safety in line with current marine industry practice. The qualification efforts by all stakeholders including the vendor, system integrator and end-user at each stage are recognized and captured within a new technology qualification plan(NTQP). Completion of qualification activities as identified within each stage of the NTQP results in a Statement of Qualification for each stage being issued attesting to the maturity level of the new technology.
3. The process is also compatible with approaches(e.g. ISO 16290) based on technology readiness levels(TRLs) and the different level of qualification methods can be tailored to projects.
4. When a certification or classification is intended in conjunction with the New Technology Qualification process, the application of relevant regulations may be required in addition to the requirements of this Guideline.
5. Technology qualification through the NTQ process is based on the data submitted by the applicant, and the Society only verifies the level of technology being applied for.
6. The applicant is responsible for any damage to life and property that may occur at each stage of the NTQ process(e.g. system integration stage, operational stage).

102. Application

1. This Guideline is in general applicable to all new technologies for offshore units and marine vessels that are not normally subject to Rules, Guidance, or industry standards. This Guideline provides guidance to parties seeking recognition of the maturity level of a proposed new technology.
2. A new technology for the purpose of this Guideline is defined as any design (material, component, equipment or system), process or procedure which does not have prior in-service experience, and/or any classification rules, statutory regulations or industry standards that are directly applicable. It is possible to categorize the type of "novelty" in one of four categories:
   (1) Improved technology in existing applications (offshore units, ships, etc.)
   (2) Existing technologies in new or novel applications
   (3) New or novel technologies in existing applications.
   (4) New or novel technologies in new or novel applications
3. The New Technology Qualification(NTQ) process could be applicable in the following cases:
   (1) To qualify new technology that may need to be classed or certified at a later date
   (2) To simultaneously qualify new technology identified while seeking class approval for a novel concept
   (3) To qualify a new technology related to operation of ships other than the above
4. If the proposed new technology is intended for incorporation on an asset to be classed by the Society, then it is recommended that the new technology complete up to and including the System Integration Stage of the NTQ process. In other cases, the level of maturity to which the new technology may be qualified depends on the client's request. New technology qualification could be requested from the Society at any level of indenture as desired such as component, sub-system or system level.

103. New Technology Qualification Process

1. The NTQ process confirms the ability of a new technology to perform its intended functions in accordance with defined performance requirements. The process starts with a comprehensive description of the technology to be qualified, followed by a screening of the technology to reveal the new or novel features that the qualification should focus on.

2. The process is divided into four sequential stages that progressively qualify the technology from feasible to operational stages as requested. The four qualification stages are:
   (1) Feasibility and Concept Verification Stage
   (2) Prototype Validation Stage
   (3) System Integration Stage
   (4) Operational Stage

3. Upon completion of each of the four stages, a Statement of Qualification for each stage will be issued to the vendor(s) and the technology can progress to the next stage of maturity.

4. Figure 1 provides a basic overview of the process along with the Statements of Qualification for each stage issued. Further guidance on each topic and deliverables that are to be submitted for review can be found in later Sections.

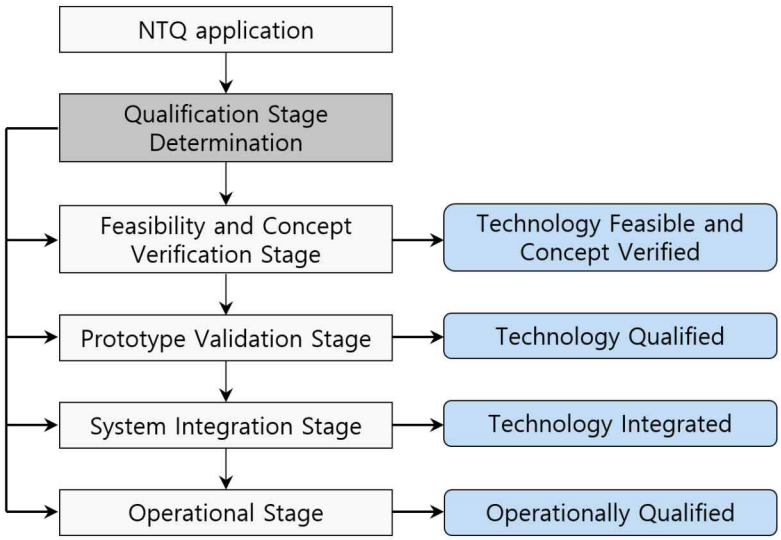

Fig 1 New Technology Qualification Process

104. Type Approval

1. If the new technology that has completed the technology verification or technology integration stage of the NTQ process can be consistently manufactured with the same design and specifications, type approval can be applied in accordance with the **Guidance for Approval of Manufacturing Process and Type Approval, etc.** of the Society. However, if necessary, the statement of qualification for the operational stage may be requested.

105. Definitions

1. **As Low As Reasonably Practicable(ALARP)** means refers to a level of risk that is neither negligibly low nor intolerably high, for which further investment of resources for risk reduction is not justifiable. Risk should be reduced to ALARP level considering the cost effectiveness of the risk control options.

2. **Approval** means confirmation that the plans, reports or documents submitted to the Society have been reviewed for compliance with one or more of the required Rules, Guides, standards or other criteria acceptable to the Society.

3. **Availability** means ability of an item to be in a state to perform a required function under given conditions at a given instant of time or over a given time interval, assuming that the required ex-

ternal resources are provided (ISO 14224).

4. **Boundary** means interface between an item and its surroundings (ISO 14224).

5. **Consequence** means the measure of the outcome of an event occurrence in terms of people affected, property damaged, outage time, dollars lost or any other chosen parameter usually expressed in terms of consequence per event or consequence amount per unit of time, typically per year.

6. **Engineering Evaluations** means various engineering analysis tools and testing that may be used to support new technology qualification activities. Typical examples include but not limited to the following: Finite Element Analysis(FEA), Computational Fluid Dynamics(CFD), Functional and Performance Testing, Model Testing, System Integration Testing, etc.

7. **Failure** means the loss of the ability to perform the intended function.

8. **Failure Causes** means circumstances associated with design, manufacture, installation, use and maintenance that have led to a failure (ISO 14224).

9. **Failure Mechanism** means a physical or chemical process resulting in a form of damage which will ultimately lead to failure.

10. **Failure Mode** means the specific manner of failure that the failure mechanism produces.

11. **Functional Specification** means document that describes the features, characteristics, process conditions, boundaries and exclusions defining the performance and use requirements of the product, process or service (ISO 13880).

12. **Frequency** means the occurrence of a potential event per unit of time, typically expressed as events per year.

13. **Global Effects** means total effect an identified failure has on the operation, function or status of the installation or vessel and end effects on safety and the environment.

14. **Hazards** means conditions that exist which may potentially lead to an undesirable event.

15. **Indenture Level** means the level of subdivision of an item from the point of view of maintenance action (ISO 14224).

16. **Item** means any part, component, device, subsystem, functional unit, equipment or system that can be individually considered (ISO 14224).

17. **Local Effects** means impacts that an identified failure mode has on the operation or function of the item under consideration or adjacent systems.

18. **Maintainability** means ability of an item under given conditions of use, to be retained in, or restored to, a state in which it can perform a required function, when maintenance is performed under given conditions and using stated procedures and resources (ISO 14224).

19. **Manufacturing Plan** means document setting out the specific manufacturing practices, technical resources and sequences of activities relevant to the production of a particular product including any specified acceptance criteria at each stage (ISO 13880).

20. **Quality Assurance and Quality Control** means typical quality plans and related processes for controlling quality during production.

21. **Qualification** means the process of confirming, by examination and provision of evidence, that equipment meets specified requirements for the intended use (API RP 17N).

22. **Qualification Activities** means usually in the form of risk assessments, engineering evaluations, and testing that is required to be performed in order to mature the new technology to the next stage.

23. **Qualification Plan** means a document containing the qualification activities listed to mature the new technology to the next qualification stage. This is submitted as a New Technology Qualification Plan(NTQP) report.

24. **Redundancy** means existence of more than one means for performing a required function of an item (ISO 14224).

25. **Reliability** means ability of an item to perform a required function under given conditions for a given time interval (ISO 14224).

26. **Risk** means the product of the frequency with which an event is anticipated to occur and the consequence of the event's outcome.

27. **Validation** means the process of evaluating a production unit(or full scale prototype) to determine whether it meets the expectations of the customer and other stakeholders as shown through performance of a test, analysis, inspection, or demonstration.

28. **Verification** means the process of evaluating a system to determine whether the product of a given development stage satisfy the approved requirements and can be performed at different stages in the product life cycle by test, analysis, demonstration, or inspection.

29. **Risk assessment** means an integrated array of analytical techniques, e.g. reliability, availability and maintainability engineering, statistics, decision theory, systems engineering, human behaviour, etc. that can successfully integrate diverse aspects of design and operation in order to assess risk.

106. Abbreviations

1. **ALARP:** As Low As Reasonably Practicable
2. **CFD:** Computational Fluid Dynamics
3. **FEA:** Finite Element Analysis
4. **FMECA:** Failure Mode Effects and Criticality Analysis
5. **FTA:** Fault Tree Analysis
6. **HAZOP:** Hazard and Operability
7. **HAZID:** Hazard Identification
8. **ITP:** Inspection Test Plan
9. **MTBF:** Mean Time Between Failure
10. **NTQ:** New Technology Qualification
11. **NTQP:** New Technology Qualification Plan
12. **PFD:** Process Flow Diagram
13. **P&ID:** Piping and Instrumentation Diagram
14. **QA:** Quality Assurance
15. **QC:** Quality Control
16. **RAM:** Reliability, Availability and Maintainability
17. **RBD:** Reliability Block Diagram
18. **TDD:** Technical Description Document
19. **SIT:** Systems Integration Test ⚓

CHAPTER 2 NEW TECHNOLOGY QUALIFICATION APPLICATION

Section 1 General

101. General

1. The process begins when a customer requests technical qualification using this guideline.
2. The client presents to the Society a brief overview of their proposed technology along with their expectations, any ongoing qualification activities (if initiated) and project timelines.
3. The client presents to the Society the data corresponding to 202. for the new technology for which qualification is requested.
4. The Society will advise the client if new technology qualification is the most appropriate path for proceeding and recommend next steps.

Section 2 Submission of Documents

201. New Technology Qualification Plan(NTQP)

1. The New Technology Qualification Plan
   (1) NTQP should be established by agreement between the customer and the Society.
   (2) NTQP should be a high level document that tracks the maturity level and status of qualification activities. These activities help verify and validate the new technology's ability to qualify all desired NTQ stages.
   (3) The NTQP is to be updated throughout qualification process.
   (4) Recommended template items for NTQP
      (A) General
         (a) Summarize the project objectives.
         (b) Provide an overview of the new technology and its application.
         (c) Describe current status of design and qualification activities.
         (d) Provide key points of contact.
      (B) New Technology Stage Determination
         (a) Summarize defined system goals, functional and performance requirements (with reference to appropriate TDD document).
         (b) Summarize the results of the new technology stage determination process.
      (C) New Technology Qualification Activities
         (a) For each new technology item being qualified, list all qualification activities including the following details for each activity
            (i) Summarize the qualification activity (scope, objective and method)
            (ii) Performance Requirement and its source.
            (iii) Identify the stage in which this qualification activity was determined.
            (iv) Provide reference to appropriate engineering evaluation report or risk assessment report from which this activity was determined.
            (v) Scheduled Timelines (start/finish).
            (vi) Provide reference to appropriate engineering evaluation or risk assessment reports that documents the results of the qualification activity.

202. Technical Description Document(TDD)

1. General
   (1) Properly defining a new technology is a critical aspect of NTQ. For this purpose, a technical description document(TDD) should be developed for the new technology and maintained throughout the NTQ process.
   (2) TDD defines and sets the baseline requirements for the new technology and may be derived from functional and technical specifications. The requirements will be defined for each level

within the system hierarchy as applicable.

(3) As the design matures through development and more knowledge is gained through qualification, these requirements may be subject to change. The TDD will need to be updated accordingly.

2. Defining System Requirements

(1) Goals

(A) The goals defined for the new technology should identify the high-level scope, objectives, or requirements that the new technology needs to meet. Goals may be derived from client's needs, mission, measures of effectiveness, environmental or application constraints, program/policy decisions and/or requirements derived from tailored specifications or standards.

(2) Functional Requirements

(A) Functional requirements define each function that the system is required to perform. The functional requirements should be mapped to specific items that will perform the function and typically includes a description of the function to be performed, the environment within which the function should be performed, the conditions under which the system should start the function and the conditions under which the system should terminate the function.

(3) Performance Requirements

(A) The performance requirements define how well each functional requirement should be accomplished, and the set of performance metrics including identification of critical performance parameters. The performance requirements can be defined qualitatively at early design stages and progressively more quantitatively during subsequent stages of technology maturation. In case where performance requirements are not defined because of the novelty of the technology, the requirements should be extrapolated from existing Rules, Guides, and/or other industry standards. Any relevant requirements from regulatory agencies or Flag Administration should be also considered. The performance criteria is the acceptance criteria against which the results of each qualification activity is evaluated.

(4) Design Conditions

(A) The system design conditions describe all applicable loading requirements under the environmental and operating conditions. This should include, but not be limited to, the natural environment (e.g., temperature and chemical exposure), the induced environment (e.g., vibration and noise), electromagnetic signal environment, and threats. Typical loading and design conditions to be considered include, but are not limited to, the following:

(a) Pressure and temperature induced loads and fluctuations
(b) Static and dynamic loads
(c) Fatigue and fracture effects
(d) Wear and vibration effects
(e) Material degradation and associated loss from damage mechanisms
(f) Accidental loads (as applicable)

(5) System Interface Requirements

(A) The system interface requirements define all internal and external physical and functional interfaces (e.g., mechanical, electrical, etc.) relevant to the new technology. Interfaces among system elements should also include interfaces with the human element. The system interface definition confirms that various elements of the system can functionally and physically interact with each other and with all external systems they connect to or communicate with. A graphic description of the interfaces can be used when appropriate for clarity.

(6) Human System Integration Requirements

(A) During the design process, specific areas, stations, or equipment arrangement that would require concentrated human engineering attention should be defined. Any special requirements, such as constraints on allocation of functions to personnel and communications and personnel/equipment interactions, should be specified.

(7) Maintainability

(A) Specify the quantitative maintainability requirements that apply to maintenance in the planned maintenance and support environment. Examples are as follows (ISO 29148):

(a) Time (e.g., mean and maximum downtime, reaction time, turnaround time, mean and maximum times to repair, mean time between maintenance actions)
(b) Rate (e.g., maintenance staff hours per specific maintenance action, operational ready rate, maintenance time per operating hour, frequency of preventative maintenance)
(c) Maintenance complexity (e.g., number of people and skill levels, variety of support equipment, removing/replacing/repairing components)
(d) Maintenance action indices (e.g., maintenance costs per operating hour, staff hours per

overhaul)
(e) Accessibility to components within systems and to parts within components

(8) Reliability
(A) Reliability is the ability of a system or component to function under stated conditions for a specified period of time, and determines the robustness, consequences, and redundancy of the system through risk assessment or a means of verifying reliability(e.g., mean time between failures(MTBF)).

3. System Description

(1) The TDD is also to include a detailed technology description. This involves additional documentation that could help provide evidence or demonstrate the ability of the technology to meet defined system requirements. The description of the technology typically includes the following:
(A) Equipment list
(B) Comparison with existing similar technologies
(C) Lessons learned from similar technologies
(D) Possible applicable standards, codes, or industry practices
(E) Relevant engineering documents as applicable:
(a) Piping and Instrumentation Diagrams (P&IDs)
(b) Heat and material balances
(c) Block diagrams (including system interface)
(d) Design schematics
(e) General arrangements
(f) Material specifications including material properties
(g) Design analysis methodology and related reports
(h) Installation analysis
(i) Test reports
(F) Control and safety system details
(G) Operational, maintenance, and inspection strategies
(H) New or unproven manufacturing, assembly, transit, storage, installation, hook-up, testing, commissioning, and decommissioning details
(I) Quality, health, safety, and environmental philosophies

(2) The TDD needs to be submitted for review. The TDD is not intended to be a single consolidated document but a design review package that compiles the relevant documents.

(3) It is recognized that the requirements definition and the supporting description documentation is developed throughout the NTQ process. The submittal only needs to include the information available based on the design maturity of the new technology.

Section 3 New Technology Qualification Plan and Activities

301. General

1. The NTQP defines a roadmap for progressing the new technology through the appropriate qualification stages. The objective of the NTQP is to provide a summary of qualification activities that need to be performed at each stage in order to demonstrate the ability of the new technology to meet the requirements specified in the TDD.

2. The NTQP for each subsequent stage is updated based on the findings from the previous stage activities and discussions between the client and the Society.

3. Qualification within each stage is comprised of a set of iterative activities that include engineering evaluations and risk assessments to verify new technology design. Results of these activities could lead to design improvements or modifications to the requirements specified in the TDD. All design improvements and/or modifications should be documented in the NTQP with necessary technical justification. Figure 2 summarizes the iterative NTQP activities.

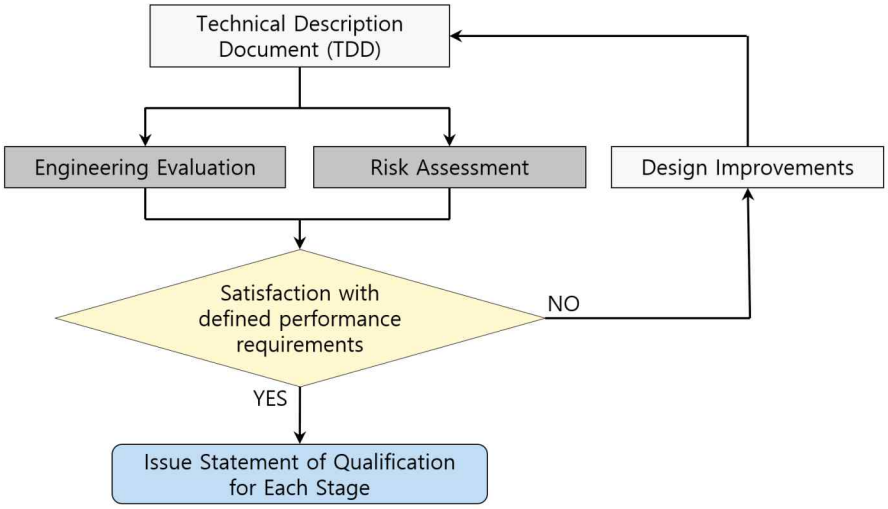

Fig 2 New Technology Qualification Stage Iterative Process

302. Risk Assessment

1. A risk assessment is to be prepared and submitted for review.
2. For a new technology requesting qualification through the NTQ process, a risk assessment is to be performed/updated at each stage as applicable. The risk assessment within the NTQ process will vary from qualitative to quantitative depending on the maturity level and information available at that stage. The primary objective of the risk assessment is to identify technical risks and uncertainties associated with the proposed design and document all foreseeable hazards, their causes, consequences, and potential risk control measures considering the new technology in its proposed application and operating environment. All possible interfaces, and known integrations are to be evaluated as part of this assessment.
3. All risk assessments performed must consider the following areas:
   (1) Personnel safety
   (2) Asset protection
   (3) Environmental protection
4. It is recommended that the risk assessment be carried out by a multidisciplinary team that includes the design team(vendor) and the end-user.
5. Prior to performing the risk assessment, a risk assessment plan should be prepared and submitted for review. The risk assessment plan should include the following information:
   (1) Scope of the Assessment
      (A) Description of the proposed new technology including physical and operational boundaries
      (B) Intended service application of the new technology
   (2) Assessment Team
      (A) Subject matter experts/participants/risk analysts
   (3) Assessment Preparation
      (A) All available new technology information (e.g., design basis, drawings, procedures, etc.)
      (B) Proposed risk assessment method (e.g., FMECA)
      (C) Proposed risk assessment criteria for evaluation (e.g., risk matrix)
6. After the risk assessment has been completed, a report that includes the following information should be submitted for review:
   (1) Scope
      (A) Description of the proposed new technology including physical and operational boundaries
      (B) Intended service application of the new technology
   (2) Risk Assumptions and Data References
   (3) Supporting Engineering Documents
      (A) Technical drawings
   (4) Risk Assessment Worksheets that
      (A) Identifies hazards associated with the new technology in its current boundary conditions (ap-

plication and operating environment)
(B) Identifies scenarios associated with each identified hazard
(C) Identifies causes of the hazardous scenario
(D) Identifies consequences of the hazardous scenario
(E) Identifies existing risk control measures for each hazardous scenario
(F) Estimates the likelihood (frequency) and the severity of the consequence
(G) Evaluates the risk of the hazardous scenario by measuring it against the acceptable risk criteria agreed
(H) Identifies and evaluates the need for any recommendations to lower the risk to acceptable levels (design improvements through risk control measures)

(5) Conclusions and Recommendations
(A) Action items and/or recommendations

7. It is recognized that each new technology may be unique in terms of design, operating environment, and application, therefore it is difficult to provide precise guidance on which risk assessment techniques should be used in a given situation. Therefore the selection of risk assessment methodology should be considered on a case-by-case basis and discussed with the Society prior to performing a risk assessment.

303. Engineering Evaluation

1. Engineering evaluations are used to verify and validate that the new technology is capable of performing acceptably with respect to intent and overall safety according to the requirements of each stage. This is achieved gradually for each qualification stage through specific qualification activities as the technology matures and can be found in the NTQP. The types of activities for engineering evaluation are:

(1) Review Engineering Design Requirements: As the technology matures, and more detailed design information becomes available, the functional and performance requirements are reviewed/updated as needed.
(2) Technical Analyses and Simulations: Engineering design analyses and simulations are used to verify the technology at the earlier qualification stages.
(3) Validation Testing: Functional, model testing, and prototype testing are used to verify that the new technology satisfies all the specified functional and performance requirements.
(4) Interface Analyses: Interface analyses of the technology with existing systems are required and system integration testing is needed in order to fully understand all interactions between the new technology and surrounding systems, including people and the environment.
(5) Verification of Operability: Operational testing and the collection of test data are required to verify the new technology satisfy the operational requirements.
(6) Verification of Inspectability and Maintainability: The various components of the new technology must be reviewed to confirm that they can be monitored, inspected and maintained in a manner consistent with existing practice.
(7) Quality Assurance and Quality Control(QA/QC) Program: Establish and maintain an effective quality control procedure(s) and quality acceptance criteria at each stage in accordance with recognized industry standard.

304. Design Improvements

1. Based on the results of the engineering evaluation and risk assessment activities, design improvements may be necessary to enhance reliability and safety of the design. The opportunities to improve safety could be through changes or modifications that make the design inherently safer or implementation of appropriate risk control measures. Example design changes include, material changes, reconfiguration, redundancy, and loading requirements.

2. Any design improvements that are identified and determined necessary as part of further refinement of the new technology is to be re-evaluated against the functional and performance requirements outlined in TDD. The updated qualification activities should aim to meet these new requirements. Design improvements should be tracked in the NTQP.

3. An inherently safe design approach to design improvements is recommended in order to eliminate design elements that are limiting the new technology from meeting defined functional and performance criteria. This philosophy should shift focus on improving design by implementing elimination,

substitution, or engineering risk control measures.

4. A new technology qualification applicant shall establish an appropriate design change management process to review, evaluate, and document design improvements during the design and development of the technology. ⚓

CHAPTER 3 NEW TECHNOLOGY QUALIFICATION STAGES

Section 1 Feasibility and Concept Verification Stage

101. General

1. The first stage of the NTQ process is the Feasibility and Concept Verification Stage. In this stage, a design analysis is performed to verify the concept in the intended application and that the overall proposed level of safety is comparable to those established in Rules, Guides, other recognized industry standards and recommended practices. The new technology is verified as performing its functions in accordance with defined performance requirements. This is accomplished by performing more detailed engineering studies and physical or model testing. Reliability testing of select items may be performed.
2. The production strategy is developed in the form of a preliminary manufacturing plan. A design risk assessment is carried out to identify technical risks related to design failures.

102. Qualification Plan Activities

1. Engineering Evaluation

(1) Engineering Design Review

(A) At the Feasibility and Concept Verification Stage, the concept is confirmed and the engineering design is performed to verify that the functionality and performance of the new technology can be satisfied. The subsystem and component level requirements following the systems engineering approach should be defined. The objective is to define complete and consistent requirements that an item should have and confirm that the design correctly and completely captures each specification in the system requirements.

(B) The performance requirements should state how the technology will perform its function and how the system requirements will be met. The performance requirements are to be established and should be detailed enough that the technology can be evaluated against the expected performance criteria. In addition, the requirements for the integration of subsystems and components into system prototypes should be defined. The overall configuration of the system should be provided and a preliminary interface analysis should be performed to verify the interfaces between configurations.

(C) Design constraints should be identified and incorporated into the system requirements and design documentation. At this stage, the system requirements should be stated in quantitative measures that can be verified by subsequent numerical or analytical models and model tests. The overall system requirements defined at the Feasibility Stage should be reviewed to confirm continued relevance. Any change should be reviewed and documented with technical justification.

(D) A preliminary manufacturing plan should be developed and should include the manufacturing methods and processes, the facilities, the production schedule, and the quality assurance requirements. The materials used in the system should be determined and reviewed during the qualification process. The technology design documentation is to be submitted for review.

(2) Functional and Model Testing

(A) Tests are an essential part of the NTQ process and they can demonstrate the performance of the new technology. The types of tests required depend on the novelty of technology itself and preexisting experience with similar concepts.

(B) Functional and model tests are used to verify the functionality of the system and its ability to meet the defined functional requirements. Testing is to be performed in the technologies anticipated environment and operating conditions. The objectives of the functional testing are to verify that the system meets the performance and reliability requirements, as well as to verify the results obtained from the analytical models. The functional testing should consider and address the critical failure modes identified during the risk assessments.

(C) For the new materials or those that can have a significant effect on the performance of the system, destructive or non-destructive testing should be used to identify the relevant failure modes and mechanisms or to explore the critical parameters and their effects. The same raw materials or components stated in the material specification for the actual product should

be used in the tests. For materials that will degrade over time, materials degradation testing should be performed. Accelerated testing methods may be used to test the lifetime performance of the materials in a shorter time. Additionally, reliability testing for select items may be required.

(D) Before performing any testing, a test plan should be developed and submitted to the Society. The test plan should document the test setup and strategy that will be used to verify that a product meets its design specifications and other requirements. The specific test plans should include the assumptions and constraints, input data, test procedures, expected test results, the parameters to be measured, instrumentation system specifications, and the acceptance criteria for evaluating results. For certain tests, it may be required for an Surveyor to witness the testing activities to verify that it meets performance requirements and confirm the presence of an effective quality control program.

2. Risk Assessment

(1) The objective of the risk assessment in this stage is to identify technical risks associated with the new technology design to the lowest level of indenture as practicable. The concept level design engineering documentation and the additional engineering documents developed in this stage serve as input to the risk assessment. This design risk assessment should take into account the following:

(A) Any design modifications from the Feasibility Stage

(B) Updated functional and performance requirements

(C) Updated configurations

(D) Possible interfaces and integrations

(E) All potential failure modes, failure causes and failure mechanisms in all expected operational modes and life cycle stages

(F) The effectiveness of existing risk control measures and the need for any additional or more reliable measures

(G) Closing out any action items(qualification activities) as agreed in the Feasibility Stage

(2) Based on the findings of this risk assessment, additional qualification activities in the form of risk assessments or engineering evaluation may be required to further assist in identifying and assessing the full potential ranges of failure causes, failure mechanisms, consequences and any related uncertainties. These additional studies may be coarse, detailed, or a combination depending on the objective of the study. The results of the risk assessment should be documented and tracked in a hazard register for assessment and implementation in future qualification stages. The resulting qualification activities should be documented within the NTQP. A risk assessment report including the hazard register should be prepared. The risk assessment report and the NTQP should be submitted for review.

(3) A risk assessment technique that is appropriate for reviewing the new technology design should be selected and submitted as part of the risk assessment plan. Potential design related failure events in all anticipated operational modes should be evaluated. Typically, for hardware or mechanical systems, a Failure Mode Effects and Criticality Analysis(FMECA) is recommended. The FMECA performed can help evaluate failure modes and corresponding failure causes, failure mechanisms, and the local and global effects of failure. It also includes a criticality analysis which is used to estimate the probability of failure and the severity of the associated consequence. The probability can be qualitative if lacking historical quantifiable data, but quantitative probabilities are preferred. The method of assigning criticality should be included within the risk assessment plan and agreed by the Society prior to the study. Results from the FMECA should be relayed back to the design process of the new technology to facilitate any design improvements or FMEA verification activities.

(4) The following risk assessments verifying all technical risks are to be performed and submitted for review.

(A) Design risk assessment(e.g., FMECA) as described above.

(B) Update Feasibility Stage risk assessments as needed based on updated design documentation.

(C) Perform any additional risk assessments identified while verifying the design and/or updating

previous risk assessments.

(5) If reliability, availability and maintainability(RAM) targets are defined as part of the functional requirements then a preliminary system RAM analysis should be carried out in this stage. System modeling techniques such as reliability block diagrams(RBD), fault tree analysis(FTA), Markov state diagrams or other established methods should be used to demonstrate the ability of the system to meet the defined performance requirements. The FMECA serves as input to the system reliability models along with the other engineering documentation developed at this stage. A RAM analysis should be prepared and submitted for review. The data sources used, their applicability and any related assumptions should be documented within this report.

103. Summary of Submittals

The following qualification activities along with future activities to be addressed in the Prototype Validation Stage should be highlighted in the NTQP and submitted for review:

1. Engineering Evaluation

(1) TDD

(A) Design basis, functional specification and/or technical specification of the new technology

(B) System and function architecture details such as functional flow block diagram

(C) Design details such as basic engineering drawings and engineering principles associated with further development

(D) Design analysis methodology and any available preliminary results

(E) Details regarding physical and functional interface requirements(mechanical, hydraulic, electronic, optical, software, human, etc.)

(F) Applicable design references, codes, standards and guidelines, and technical justification for any proposed deviations(may be identified independently or during the new technology screening process)

(G) Lessons learned, references and examples of comparable designs

(H) Documents that describe the concept verification design requirements

(I) Design documents that include but not limited to the configuration, drawings, PFD/P&ID, analytical models, etc.

(J) Functional and model test plans, test data(as requested), and test results

(2) Preliminary manufacturing plan

2. Risk Assessment

(1) Risk assessment plan in accordance with Ch 2, 402.

(2) The appropriate risk assessment report identified in 102.

(3) Risk assessment worksheets complete with an action tracking system

(4) Updated Hazard Register with updated action items closed out

(5) Preliminary design risk assessment(e.g., FMECA) report

(6) Preliminary system RAM analysis report(as applicable)

104. Feasibility and Concept Verification Stage Completion: Technology Feasible and Concept Verified

Once the TDD of 103. has provided and all specified performance requirements have been verified and the checklist in Table 1 has completed, then a Statement of Qualification for Each Stage will be issued stating that the feasibility and concept has been verified. The technology is now ready to proceed to the Prototype Validation Stage. However, the items in Table 1 may be considered as, but not limited to, a general checklist for system integration stage.

Table 1 Checklist for feasibility and concept verification stage

No.	Item	Yes/No/NA	Evidence
1	The concept of new technology is clearly explained in terms of new technology elements and differences specially.		
2	It defines what special conditions are required for the development of new technologies such as environment, stability, materiala, arrangement, safety device, fire-fighting equipment, maintenance manual, working environment, etc.		
3	Check whether potential human and material resources are in place or planned to take care an identified supplementary and action items through the review with comments.		
4	Present the target performance of the technology developed and establish a verification plan for durability.		
5	It has internal guidelines for R&D and engineering procedures for new technology development.		
6	Improvements are identified and documented from similar technology and performance data.		
7	Conducted concept/basic design, determined/established and performed necessary analysis and/or calculation methods.		
8	Identifies systems to be verified for reliability and has plans to conduct conformity assessment.		
9	Technical documents (specifications, application regulations, design, modeling, analysis, test results, procedures, risk assessment reports, similar approval records, etc.) required for new technology feasibility verification are submitted and durability is reviewed.		
10	Conduct risk assessment (HAZID, HAZOP, FMECA, etc.) based on the basic design and prepare a report on the results.		
11	It is necessary to make sure that a model or prototype of the new technology object has been manufactured and the necessary test items have been identified.		
12	If necessary, RAM study has been conducted and supplementary items were identified.		
13	Document quality assurance plan through manufacturing/testing with specific business model.		
14	Responding to supplementary items (Safeguard, recommendations, etc.) identified in the risk assessment.		

Section 2 Prototype Validation Stage

201. General

1. The second stage of the NTQ process is the Prototype Validation Stage. New technology that has matured to this stage has previously completed conceptual functional, performance, and reliability testing in nonspecific environments. The main objective in this stage is to validate with a prototype what was verified in the Concept Verification Stage.

2. During this stage, the technology is further developed to the point where a prototype or full scale production unit can be manufactured. All engineering studies and design risk assessments are completed and the design is refined to the detailed design. Engineering documents such as detailed drawings, product specifications, manufacturing plan and qualification test procedures are all fully developed. A preliminary system-of-systems interface analyses may be performed and system integration testing plan developed. Process risk assessments may be carried out(as needed) to evaluate relevant procedures and further refine them.

3. A prototype or full scale production unit is manufactured and all necessary qualification testing is carried out to validate the design. After completing this stage, the new technology has demonstrated that it can perform within the established performance requirements in a simulated or actual environment for an extended period of time.

202. Qualification Plan Activities

1. Engineering Evaluation

(1) Engineering Design Review

(A) At the Prototype Validation Stage, the engineering design is to confirm that the overall system, down to the lowest component level, has satisfied all system requirements. The performance requirements a technology must meet should be finalized and measurable. In addition, the requirements for system integration, installation, commissioning, operation, maintainability, and decommissioning should be established.

(B) At this point the system has reached the necessary level of maturity to start fabricating, integrating, and testing. Changes in the requirements defined for any items during the previous stages should be reviewed and documented with technical justification.

(C) At this stage, all design analyses and configuration definitions are completed and all design decisions that are outstanding are to be finalized. It is noted that there may be a need to revisit certain analytical and other relevant studies based on results of the prototype test. Detailed drawings including all dimensional requirements, process and instrument details, safety features and ancillary systems are completed as applicable. For load bearing components, all relevant loading and the uncertainty in that loading are analyzed. For process and electrical systems, all associated potential system failure/breakdowns and their associated failure frequencies(if applicable), as well as the consequence and impact on the system from each failure are identified.

(D) In addition, all information(e.g., drawing and data) required for the production of the system are to be finalized. The actual performance of the new technology should be evaluated during prototype testing and compared against existing designs if available. The aforementioned design engineering documents are to be submitted for review. A preliminary system-of-systems interface analyses and system integration testing plan may be developed at this stage.

(2) Prototype Testing

(A) Prototype testing is intended to prove that the interactions between the systems/subsystems/components under relevant loading and environmental operating conditions can perform reliably as intended. Prototype tests can identify potential failure modes and mechanisms as well as the critical parameters, especially when operational experience in relevant environments is limited or unknown.

(B) Prototype testing can be used to verify the analytical models and the assumptions made during the engineering design process. A test plan which details test techniques, test limits,

expected test data, quality assurance requirements should be developed and submitted to the Society for review before prototype testing. Calibration of measuring devices is to be current with manufacturer's quality management system. Calibrations should be traceable to a recognized national standard.

(C) For certain new technologies, it may be very difficult to perform prototype testing in the actual environment. In this case, virtual prototype testing in a simulated environment can be performed. However, the virtual prototype testing must be reviewed by the Society to assess that the simulated environments are commensurate with expected operational practices. Analysis tools, such as finite element analysis(FEA) and computation fluid dynamics(CFD), and other methods used should be qualified for application. The prototype testing documents should include inputs, assumptions, boundary conditions, the computational models and appropriately conditioned/reported test results. Prototype test results should be documented and analyzed to determine whether the prototype satisfies specified functional and performance requirements in its actual environment. A prototype test report is to be submitted for review.

(3) Manufacturing

(A) A manufacturing plan should be finalized that includes the manufacturing methods and processes, the facilities, the production schedule, and quality assurance requirements. Quality assurance of the manufacturing process should confirm that the product meets the required specifications. The manufacturing plan should be submitted for review.

(4) Survey

(A) Survey during the manufacturing process and prototype testing may be required. The vendor should submit an Inspection Test Plan(ITP) for review. The Surveyor should witness the manufacturing process and prototype testing to verify that proper manufacturing and prototype testing processes are followed and it meets the quality assurance requirements.

2. Risk Assessment

(1) The main objective of the risk assessments performed in the Prototype Validation Stage is to validate the final design of the new technology. The design risk assessment from the Concept Verification Stage should be reviewed and updated to evaluate changes made to the design and/or other aspects of the new technology description. Changes made to one part of the design or new technology design requirements could have the potential to introduce new technical risks to other previously evaluated parts. The results of other qualification activities in this stage may also serve as input to the updated design risk assessment. Follow-on qualification activities determined from the results of the updated design risk assessment should be included within the NTQP.

(2) For certain new technologies with high consequence severity levels upon failure, if not already addressed by other risk assessments, the Society may recommend that an additional process risk assessment(e.g., process FMECA or HAZOP) is performed. The objective of this risk assessment is to evaluate the potential failures that could occur during specific steps as listed within the procedures. This process risk assessment typically evaluates procedures related to manufacturing(as defined within the final manufacturing plan), testing(prototype and systems integration), installation/integration, commissioning, operations and decommissioning. A risk assessment technique that is appropriate for reviewing these procedures should be selected and submitted as part of the risk assessment plan for review. Typically, a process FMECA or HAZOP study is recommended. It is recognized that the scope of this risk assessment depends on the availability of relevant procedures. All interfaces should also be considered when performing this assessment.

(3) Based on the findings of the final design risk assessment and process risk assessment(if applicable), a reevaluation of all previous risk assessments should be considered. All previous risk assessments should be reviewed against any newly identified failure modes or hazards. Changes made to the design due to findings in these risk assessments should also be checked against the final functional and performance requirements.

(4) Finally, all identified technical risks from the Prototype Validation Stage and risk assessments

from previous stages should be appropriately managed through any necessary design improvements. All corresponding action items should be closed in order for the new technology to complete this stage of the NTQ process.

(5) The following final design level risk assessments verifying all technical risks are to be performed and submitted for review:
  (A) Final design risk assessment (e.g., design FMECA)
  (B) Final process risk assessment (e.g., process FMECA or HAZOP) if applicable
  (C) Update all previous risk assessments as needed based on updated final design level documentation
  (D) Final hazard register based on the final design with all actions items closed out

(6) If applicable, the preliminary RAM analysis should be re-evaluated and finalized. The final RAM analysis report should be submitted for review.

203. Summary of Submittals

The following qualification activities along with future activities for the System Integration Stage should be highlighted in the NTQP and submitted for review:

1. Engineering Evaluation

(1) TDD
  (A) Review engineering documents that describe the component requirements and the interaction between components, subsystems, and the overall system if applicable.
  (B) Detailed design documents including detailed drawings, product specifications, process and instrument details, detailed calculations, etc.
  (C) Prototype test plans, test data (as requested), and test results summarized in a report.
  (D) Additional qualification testing, data, and results identified in the design risk assessment(e.g., FMECA).

(2) Inspection Test Plan(ITP)

(3) Detailed manufacturing plan

2. Risk Assessment

(1) The final updated risk assessment reports from the Concept Verification Stage(as applicable).

(2) The final design risk assessment(e.g., FMECA) report.

(3) The process risk assessment(e.g., process FMECA) report(as applicable).

(4) The final system RAM analysis report(as applicable).

(5) Final hazard register with all action items closed out.

204. Prototype Stage Completion: Technology Qualified

Once the TDD of 203. has provided and all specified performance requirements have been verified and the checklist in Table 2 has completed, then a Statement of Qualification for Each Stage will be issued stating that the technology has been qualified. The technology is now ready to proceed to the System Integration Stage. However, the items in Table 2 may be considered as, but not limited to, a general checklist for system integration stage.

Table 2 Checklist for prototype validation stage

No.	Item	Yes/No/NA	Evidence
1	Have all items in the manufacturing of the technology been specified?		
2	Has the manufacturing and assembly process been accepted?		
3	Has a prototype or full scale production unit been manufactured?		
4	Has the manufacturing and assembly defects been removed by stress screening?		
5	Has the technology passed basic functionality testing of prototype(physical or virtual) or full scale product to demonstrate fitness and function capability in a simulated or actual operating environment?		
6	Has a performance data collection system been established and properly documented?		
7	Has the technology passed performance, durability, and accelerated life tests?		
8	Is the degradation of function/performance within expected acceptable limits?		
9	Has the technology passed system reliability analyses?		
10	Has the operating/destruct limits been established or confirmed?		
11	Has the degradation limits and rates been established or confirmed?		
12	Has the required in-service monitoring needs and means been identified?		
13	Has a process risk assessment(e.g., process FMECA) been performed and documented(if applicable)?		
14	Has the final design risk assessment(e.g., FMECA) been completed for all life cycle modes (including assembly, transit, storage, installation, hook-up, commissioning, operation, decommissioning) for all interface permutations and properly documented?		
15	Have the residual risk and uncertainty been estimated and properly documented?		
16	Has the reliability study been updated and properly documented?		

Section 3 Systems Integration Stage

301. General

1. The third stage of the NTQ process is the Systems Integration Stage. In this stage, discussions between the vendor and end-user are held to understand the compatibility of the technology with final operating system and operating environment. An interface analysis is performed to confirm the compatibility of the item. The technical risks during operations that have not been addressed during previous risk assessments are evaluated and relevant reports updated. All necessary risk control measures are implemented.
2. The "Technology Qualified" item is then integrated(by installation) with the final intended operating system. All functional and performance requirements of the integrated system as outlined in the TDD are validated through testing before(or during) commissioning. Plans for in-service survey, inspection, monitoring, sampling and testing(as applicable) are determined.

302. Qualification Plan Activities

1. Engineering Evaluation

(1) System Interface and Integration Requirement
- (A) At this stage the overall technology goals and requirements may remain unchanged. However, specific requirements for system-of-systems functionality and interfaces should be finalized.
- (B) In addition, the detailed operational performance parameters should be defined and operational procedures should be developed.
- (C) System interface and integration requirements are to be submitted for review.

(2) Interface Analysis
- (A) It should be analyzed that the addition or incorporation of the new technology does not negatively affect the integrity of the surrounding systems and components.
- (B) All necessary functional and physical interfaces(e.g., mechanical, electrical, environment, data, human, etc.) and other systems should be reviewed and verified that the new technology does not adversely affect those systems. At this stage, the interfaces should be specified in quantitative limiting values, such as interface loads, forcing functions, and dynamic conditions.
- (C) The use of tables, figures, or drawings is recommended as appropriate.
- (D) The vendor/end-user should provide detailed interface control methods or other engineering solutions so that the new technology is compatible with the integrated systems.
- (E) The complete interface analysis and necessary engineering solutions are to be submitted for review.

(3) System Integration Testing(SIT)
- (A) The operational prototype is built and integrated into the final system. Full interface and function test programs are performed in the intended (or closely simulated) environment.
- (B) The impact of the new technology on the performance and integrity of other systems as well as the impact of other systems on the new technology itself should be addressed.
- (C) An initial operational test and evaluation should be performed to assess the operational effectiveness and suitability in the intended environment.
- (D) The operational test must demonstrate that the operational aspects associated with placing the application in a marine or offshore environment are commensurate with typical operational practice for these facilities.
- (E) Changes to the technology design or operational procedures may be necessary to address any issues encountered during operational testing.
- (F) A test plan which details test techniques, test limits, expected test data, quality assurance requirements should be developed and submitted for review before the system integration testing.
- (G) All test procedures and test results are to be summarized in a report and submitted for review.

(4) Survey

(A) Survey during the system integration testing may be required as agreed upon in the system integration test plan. Surveyor will witness the system integration testing to verify that proper testing processes are followed and it meets the quality assurance requirements based on the witness points as agreed between the vendor/end-user and the Society.

(B) An In-Service Inspection Plan(ISIP) to address in-service survey, inspection, monitoring, sampling and testing (as applicable) during operations should be submitted for review.

2. Risk Assessment

(1) The main objective of the risk assessments performed in the System Integration Stage is to evaluate any technical risks resulting from system integration and operations that have not been previously evaluated as part of the design risk assessment, process risk assessments or other risk assessments in the previous stages. The end-user should manage any additional/residual risks identified through appropriate risk control measures.

(2) An appropriate risk assessment technique should be selected and submitted as part of the risk assessment plan for review. The use of a process FMECA, HAZOP or HAZID are recommended. The scope of this risk assessment typically includes installation, SIT, commissioning, operations and decommissioning. The assessment should consider all interfaces between the validated prototype and the connected system(system-of-systems). Follow on qualification activities may be determined from the results of the risk assessment such as engineering evaluation, testing, design improvements or procedure changes. These activities should be addressed within the NTQP. All risk control measures should be implemented and any outstanding action items from the risk assessment closed before proceeding with system integration testing and commissioning.

(3) The need for updates to any previously submitted risk assessments or RAM analysis should be evaluated and addressed as appropriate. Updated risk assessment reports including hazard registers, RAM analysis(if applicable) and the NTQP should be submitted for review.

303. Summary of Submittals

The following qualification activities along with future activities for the Operational Stage should be highlighted in the NTQP and submitted for review:

1. Engineering Evaluation

(1) TDD

(A) All documents that describe requirements for system-of-systems functionality and interfaces.

(B) All documents that describe detailed operational procedures and performance parameters.

(C) System integration test plans, test data, and test results summarized in a report.

(D) Plans for in-service survey, inspection, monitoring, sampling and testing(as applicable) during operations or ISIP.

2. Risk Assessment

(1) Updated risk assessment reports from the previous stages(as applicable)

(2) Other applicable technical safety studies(e.g., RAM).

304. System Integration Stage Completion: Technology Integrated

Once the TDD of 303. has provided and all specified performance requirements have been verified and the checklist in Table 3 has completed, then a Statement of Qualification for Each Stage will be issued stating that the technology is integrated. The technology is now ready to proceed to the Operational Stage. However, the items in Table 3 may be considered as, but not limited to, a general checklist for system integration stage.

Table 3 Checklist for system integration stage

No.	Item	Yes/No/NA	Evidence
1	Has the design risk assessment(e.g., FMECA, HAZOP) considering full system interfaces been updated and properly documented?		
2	Have all other technical risks been identified/addressed and properly documented?		
3	Has the technology been deployed into a full prototype and fully integrated with the intended system?		
4	Has the function/performance when connected/integrated into a wider system been fully tested?		
5	Have all mechanical, hydraulic, optical, electronic, software, etc. and human interfaces been fully addressed and documented?		
6	Have all system integration requirements been confirmed?		
7	Has installation/hook-up/testing/commissioning with a wider system been completed as per specifications?		
8	Is there a data collection system in place to document performance and reliability?		
9	Has a detailed in-service inspection/monitoring/sampling plan been defined and properly documented?		
10	Can inspection/monitoring/sampling functionality be validated?		

Section 4 Operational Stage

401. General

1. The last stage of the new technology qualification process is the Operational Stage. New technology categorized as "Operationally Qualified" denotes that it has been integrated into the final system and has been operating successfully in service in the relevant operational environment.

2. Once the technology has been qualified at the Prototype Stage, it must be confirmed that the knowledge gained by the engineering and risk assessment tests and studies is fed into the operational stage, in order to monitor prior assumptions and predictions through in-service field verification. In other words, the first implementation of any new technology should be treated as a first time application to some extent. This Section will outline the necessary activities that must be completed and the information to be supplied to the Society during this stage. It is recommended that the qualification process involves members with operational background in this stage of the project. These members should become familiar with the results of all the previous qualification stages, if they had not participated from the start of the qualification process.

3. At this stage, the operational objectives, operating environment and the performance requirements established during design are reviewed and applied to define goals for in-service operation. Following successful operation and performance achievement of the goals in the actual operational environment, the technology can be granted a Statement of Qualification for Each Stage.

4. In case of verifying the operational stage by installing it onboard, the applicant or ship owner shall notify the flag state for the relevant information and, if necessary, obtain approval from the flag state.

5. The activities of the Operational Stage are as follows:
   (1) Implementation of in-service survey, inspection, monitoring, sampling and testing plans
   (2) Collection and analysis of reliability, availability, maintainability(RAM analysis) and other operational performance data as needed
   (3) Comparison of operational data above with previously specified performance requirements, goals and criteria
   (4) Performance of root cause analyses for any observed failure and using feedback to introduce modifications for improvement
   (5) Comparison of observed parameters with any critical assumptions made during the previous qualification stages and updating calculations as necessary

402. Qualification Plan Activities

1. The need and extent of special in-service qualification requirements are dependent upon the justifications and risk assessment results during the design and qualification process. System requirements have been started to be defined in the Feasibility Stage of qualification, and they have been updated in later stages as the design evolved. Such requirements have to be translated into specific and quantifiable performance requirements to be attained during operations. Additionally, any critical assumptions made in the risk assessment and engineering evaluations during the three previous qualification stages should be monitored to confirm that operational experience does not disprove them. Taking all the above into consideration, the vendor and/or end-user together with the Society should outline the necessary elements of in-service survey, inspection, monitoring, sampling and testing needed to gain confidence in the real world application of the new technology.

2. These special requirements can be integrated in the end-user's Asset Integrity Management program. Advanced inspection and maintenance approaches like Reliability Centered Maintenance(RCM) and Risk Based Inspection(RBI) are appropriate strategies to follow since they are based on reliability and risk goals. Data collection and management are very important activities to consider for the in-service qualification stage.

3. The amount of operational history that is sufficient to verify performance requirements during operations depends on several factors, including actual equipment run time, failure rate and exposure time to failure. Therefore, the time to reach the "Operationally Qualified" status for the proposed new technology will be determined on a case-by-case basis.

4. All records related to the inspection, monitoring, sampling and testing of the new technology as es-

tablished by the agreed-upon operational qualification plan or ISIP should be kept and made available for review upon request by the Society at any time. These records will be reviewed periodically to establish the scope and content of the required surveys that should be carried out by the Society.

403. Summary of Submittals

1. The output of this stage is a report reviewing the operational data collected, and demonstrating how the specified performance requirements and criteria have been met.
2. The following items are typical submittals that the Society would expect to receive annually in order to conduct an Operational Stage audit:
   (1) Summary report of results of the inspection, monitoring, sampling and qualification testing activities
   (2) Failure data analysis of critical components
   (3) Non-conformance reports and corrective actions taken.

404. Operational Stage Completion: Operationally Qualified

Once the TDD of 403. has provided and the operational experience of the new technology has proven to be successful and the checklist in Table 4 has completed, then a Statement of Qualification for Each Stage stating the operational qualification of the technology will be issued. However, the items in Table 4 may be considered as, but not limited to, a general checklist for operational stage.

Table 4 Checklist for operational stage

No.	Item	Yes/No/NA	Evidence
1	Has the technology demonstrated acceptable reliability and availability in the targeted operating environment?		
2	Has the in-field service monitoring, sampling, and inspection plan been successfully implemented?		
3	Has reliability and integrity performance data been properly collected, analyzed, and documented?		
4	Have any underperforming components of the technology been identified?		
5	If so, then has there been any reliability improvements for failed or underperforming components?		
6	Has there been any performance feedback from projects or suppliers?		
7	Have any unexpected aspects(e.g., interdependencies or influences on performance) or safety concerns been observed?		
8	Has the technology been reliable for at least one survey(or maintenance or planned replacement) cycle or agreed upon time period as indicated in the TDD or in-service inspection plan(ISIP)?		
9	Has the design risk assessment(e.g., FMECA) been updated with inservice performance data?		
10	Has the system reliability assessment been updated and properly documented?		

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