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Space systems — Qualification assessment

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Contents

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

International Standard ISO 15865 was prepared by Technical Committee ISO/TC 20, *Aircraft and space vehicles*, Subcommittee SC 14, *Space systems and operations*.

Annex A is informative and annex B is normative

Space systems — Qualification assessment

1 Scope

This International Standard establishes common rules for assessing the qualification of space systems and products used in space systems against their technical specifications. It establishes a basis for determining system or product readiness for any stage of the life cycle. This includes, for example, readiness for development, manufacture, test, operation, modification, or disposal.

It applies to systems and products used in flight or for ground support, and to products at all levels in a product tree. It applies to systems and products consisting of hardware, software, facilities, materials, methods, processes, or procedures, or any combination of these.

It establishes common:

a) rules for assessment of item readiness;

b) approaches to qualification.

This International Standard is intended for use as the basis for a Design Justification Plan. It is intended to be used either in establishing an agreement for such a plan, between a customer and a supplier, or as the basis for a supplier's internal qualification practices.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 14300 -1 Space systems – Programme management – Part 1: Management

ISO 14300 -2 Space systems – Programme management – Part 2: Product assurance

ISO 9000:2000 Quality management systems – Fundamentals and vocabulary

3 Terms, definitions and abbreviations

This standard uses the following terms, definitions and abbreviations:

DJF Design Justification File

DJDF Design Justification Data File

DJP Design Justification Plan

QS Quality System

EEE Electrical, Electronic, and Electromechanical

GTP Ground Test Plan

MS Mathematics Software

RAP Reliability Assurance Program

RMP Reliability and Maintainability Plan

SAP Safety Assurance Program

SS Space System

ST Space Technology

TS Technical Specification

NOTE 1 The results of the qualification activity (verification process) are compiled in the DJF.

NOTE 2 The qualification activity covers all the verification process depending on the level of the product in the product tree (component, equipment, sub-system and system).

4 Objectives and principles

4.1 Linkage to other International Standards

This Standard should be used in addition to the provisions of International Standards ISO-9001, 14300-1 and 14300-2, which relate to qualification assessment of SS items against the customer's technical requirements.

4.2 General requirements and recommendations

A supplier can develop a space system item either in fulfillment of a customer–supplier contract, or independently in the prospect of later sales after development is complete. In either case, a supplier acts as a customer towards its own suppliers.

When this International Standard is made part of a contractual agreement between a customer and supplier, the agreement shall establish the customer and supplier responsibilities and authorities, as appropriate, concerning the qualification processes and item acceptance. This agreement shall define the stages of qualification, qualification results, and justifications that are required for customer acceptance at each specified stage. Other considerations that should be considered for inclusion in the agreement are:

a) specific development items that are subject to the qualification process;

b) designation of responsibility, and processes to be used for:

1) approval of items to be used for qualification assessment,

2) deviations from use of approved items;

3) other deviations and waiver's that are required for corrective actions due to problems that potentially impact cost, schedule, or quality of the program;

c) customer approvals required for supplier implementation of the DJP;

d) content and scheduling of status, progress, or completion reports from the supplier to the customer;

e) participation of the customer in reviews.

To achieve the qualification goals:

a) The supplier, when in the role of a customer, should analyse the past performance of potential suppliers and use this performance as an element of supplier selection criteria and should issue TS.

b) The supplier shall be responsible for qualification of its product, whether the development is done in fulfillment of a customer-supplier contract, or as an independent development.

When this International Standard is applied in a contractual situation, the supplier shall ensure that the supplier's product definition is valid with respect to the customers TS.

When this International Standard is used as a basis for qualification of a product that is developed independently by a supplier (outside of a customer–supplier contract), the supplier shall perform an internal qualification to ensure that the product meets the design input data requirements. At each order, the supplier should justify the ability of the product to satisfy the requirements expressed in the customer's supply specification.

The supplier shall determine when the item is qualified, based on the theoretical and experimental justification established by the supplier and the results of qualification testing. In a contractual situation, this determination shall be in accord with contract provisions.

In a contractual situation, the customer shall have final responsibility for endorsing the qualification and declaring that the product meets its design requirements, and can be manufactured. This endorsement and declaration shall be based on the contractually agreed upon conditions.

A preparatory process of internal qualification may be carried out by the supplier for its own purposes in advance of the contractually agreed upon qualification process.

4.3 Objectives

The qualification plans and methods should ensure achieving the following objectives:

a) assuring that the product meets specified requirements;

b) assuring that the product matches production drawings;

c) confirming product operability after tests, verifications, flight, and landing;

d) assuring the human and environmental safety of SS products.

e) protecting SS customers against poor quality;

f) assisting customers in selection of proper SS products and services on a competitive base;

g) creating terms and conditions favourable for SS insurance.

4.4 Principles

SS qualification assessment should be based on the following principles:

a) proper definition of the requirements used during qualification assessment;

b) use of only approved items for qualification assessment with deviations justified and agreed upon by customer and supplier in accordance with contractual provisions;

c) use of all appropriate information obtained in all phases of the program;

d) sequential analysis of the results obtained during all phases and levels of the program, taking into account the results obtained in the previous phase and other levels as appropriate;

e) lowering the uncertainty of the assessment as the additional information becomes available, particularly when the development transitions from one phase to the next, or proceeds to the next level;

f) proper planning of the qualification assessment;

g) early detection of problems potentially capable of impacting cost, schedule, or quality of the program or human lor environmental safety (or any combination of these) and implementation of corrective action with customer approval of deviation permits and waivers as provided for in contractual provisions.

h) tailoring of execution of qualification assessment and its precision during the item life cyclle

4.5 Levels

Qualification Assessment should be implemented sequentially at different levels of the product tree as defined in the TS. Typical qualification levels are the following:

a) part (for example, an EEE part)

b) component;

c) subsystem;

d) system.

Items to be qualified at any level can include any of the following types: hardware, software, facility, material, processes, methods, and procedures.

4.6 Design Justification Data File (DJDF).

The DJDF is aimed at integration of all information obtained for confirmation of an item's conformance to specified requirements. It provides a record of the values of specified technical characteristics that are subject to qualification. It includes data from all qualification assessments obtained during all phases of the qualification process. It is developed under the supplier’s responsibility and authority during design, production, qualification, operation, and disposal. The DJDF integrates information from qualification process documents and is based on technical characteristics that are subject to qualification.

Each characteristic recorded in the DJDF is periodically assessed to detect trends. All measurement results are maintained in the DJDF. For characteristics displaying uncertainties or deviations, their values are entered into the DJDF prior to and after corrective measures are taken.

NOTE The purpose of trend detection is to enable early application of corrective actions that are necessary to control a characteristic and maintain its value within a specified range.

5 Qualification Assessment Approach

5.1 General

5.1.1 General features

Qualification assessment of a SS item depends on first achieving a specified level of precision in the estimated or measured values of the specified technical characteristics. The qualification decision is based on comparing these values with the specified values for these characteristics.

Qualification assessment is based on the DJP. Before each new phase, the results of the previous phase should be used to prepare revisions to the DJP.

The qualification strategy should take the form of a reasonable compromise between cost, schedule, risk, and effectiveness.

5.1.2 Specific Features

Qualification assessment for SS is characterised by unique features (i.e., features not present in the qualification assessment of other products), such as:

a) sparseness of data and (generally) an insufficient quantity of data for the use of statistical methods ;

b) limited access to the product during space operation;

c) a limited number of like products available for assessment;

d) requirements for high reliability, and safety;

e) a significant number of new technical problems due to lack of similarity to previous items;

f) Insufficient knowledge of environmental conditions and their impact on SS;

g) inability to reproduce some space environmental conditions on the ground;

h) the necessity to solve complicated scientific and technical problems in a short fixed time due to external factors (e.g., to enable launch on a fixed date or during a short launch window).

The SS qualification process utilises documentation and other results of activities performed during phases 0, A, B, C, D, E, and F, that are specified in ISO 14300-1, 4.4.2. In the general case these results include:

a) issue and co-ordination of the TS;

b) design;

c) working documentation;

d) production set-up and prototype manufacturing results;

e) ground test results;

f) flight-test results;

g) results of full-scale production and operation.

5.1.3 Criteria

The following criteria shall be verified during qualification assessment of the SS or SS item.

a) The system is completed and its documentation is approved.

b) Requirements traceability is established.

c) All operational constraints and environment load limitations are specified.

d) All the assumptions inherent in the design of the system are defined.

e) The range of all technical characteristics (parameters) subject to qualification assessment is defined.

f) Assessment tolerances are established to allow for uncertainties of the applied qualification assessment method.

g) The applied method provides both nominal values and worst cases values of technical characteristics.

5.1.4 Design Justification Plan (DJP)

The supplier develops the DJP. Depending on contractual arrangement the customer reviews and co-ordinates the Plan, submitted by supplier, and accepts the reports.

The DJP contains:

a) defined values of the technical characteristics to be assessed at each phase of the product lifecycle and each level of the product tree as defined in TS;

b) acceptable deviations from these values;

c) list of tests and verifications, their purpose, description, composition of the item under test, together with justification of any deviations from the nominal configuration (if applicable);

d) the characteristics of assessment methods, assessment sequence, equipment used and their parameters, models, software, measurements, and the methods for processing results;

e) acceptance criteria;

f) sequence of actions when a negative result is obtained;

g) means and periodicity of equipment calibration, operator training plan and the periodicity of operator qualification examination;

h) list of the reporting documentation for each phase and level;

i) the reporting order;

j) traceability arrangement.

The SS qualification assessment matrix may include SS quality assessment for the development and production phases and SS item inspection during the production and operation phases.

Implementation of the DJP should be aligned with the Program Implementation Schedule.

5.2 Arrangement of Work

5.2.1 Principles for selection of an organisation or a group of specialists for qualification reviews

The following principles should be followed when selecting any organisation or group of specialists for qualification assessment review.

a) Selectees should not be administratively or materially dependent on the assessment results;

b) Selectees should have competence, which can be estimated by the frequency of expert assessments accomplished, practical confirmation of their assessments and the extent to which their assessment recommendations were followed.

The following are examples of sources of suitable personnel for performing qualification assessment review (in order of increasing level of independence):

a) for an internal review, any part of the suppliers organisation;

b) any part of the customer organisation;

c) specially established commissions comprised of skilled experts from the customer's organisation, who are not responsible for the SS item program or project;

d) other industrial organisations (research and development institutes or laboratories are advisable).

5.2.2 Objectivity and Sufficiency of Results

The unbiased confirmation of SS qualification with respect to the specified requirements is supported by the following factors:

a) traceability of DJP implementation;

b) completeness and sufficiency of procedures for qualification assessment;

c) completeness and sufficiency of test and control programs;

d) capability of the applied methods used (as defined in 5.2.3).

The following actions also support the unbiased conformation of SS qualification:

a) implementing preliminary (local) reviews performed by the organisations taking part in SS development, production, or operation;

b) accounting for all of the factors impacting SS item quality, reliability, and safety in the process of SS development, testing, manufacturing, and operation;

c) ensuring that test equipment (test control equipment) and measuring equipment meet the necessary technical levels.

d) ensuring the competence of the laboratories (centres) by periodic verifications.

5.2.3 Applied Methods

Table 1 lists the recognised applied methods.

Table 1 — Descriptions of applied methods

ID	Name of method	Description
1	Analysis	Determination of essential qualities, performance, and limitations of an item by cognitive or computational methods.
2	Acceptance tests	Tests and verifications performed during product acceptance, including waiver and input control.
3	Estimation tests	Tests for detailed estimation of item capabilities.
4	Qualification tests	Tests for confirmation of meeting TS requirements, including safety factors.
5	Delta-qualification method	Specific tests of a part of an item in a limited area in which the loads and environment have changed (due to modification, use, etc.).
6	Qualification by similarity	Method of qualification of a new item based on the qualification of similar items in the past.
7	Quality system certification	A determination that the supplier’s production process can reliably produce an item within specified quality limits.
8	Inspection	customer’s planned or unplanned verification of the work performed by the supplier.
9	Review	Systematic examination of items for the purpose of assessing the results obtained at a given time in the project; conducted by persons not themselves responsible for the project.

Selection of the applied methods and their level of detail is determined by a number of factors including, for example: the qualification tasks to be accomplished, available prior information, project innovation, risk; product tree level; life cycle phase; item reliability, lot size, and supplier's experience. Methods resulting in quantitative estimates (e.g. statistical methods) are preferable for analysis.

5.3 Qualification Assessment Process

5.3.1 Qualification Assessment Process inputs

Input data for activities initiated at any life cycle phase or product tree level are the following:

a) list of requirements to be confirmed at the given phase or level, applied methods, assessment accuracy, and the qualification assessments specified by DJP;

b) list of work performed during the previous phase;

c) list of non-conformances obtained during the previous phase or level (if any) and recommendations for their elimination;

d) revised DJP in accordance with 5.1.1;

e) actions on detailed qualification assessment performed at different phases of the product life cycle:

1) alternative calculations;

2) comparison of a new design with a similar and already accepted design, if available;

3) tests and demonstrations;

f) reviews.

5.3.2 Activities on Product Definition during Phases O – C

During these phases the following actions should be performed:

a) analysis of:

1) The TS for a product and its components (including analysis of their conformance to the advanced requirements);

2) justification of redundancy and reserves;

3) contingency plans intended to overcome hazardous situations;

4) single-points-of-failure;

5) critical items and their reliability;

6) primary reliability problems requiring special attention during subsequent development and test;

b) assessment of:

1) technical decisions and their rationale from the viewpoint of the specified reliability and safety requirements of the product and its components ;

2) feasibility of advanced requirements for items, systems, and components;

3) the proper selection of components, including EEE;

4) the experience obtained during the development of similar products and prototypes (including foreign items);

5) the application of qualification by similarity ;

6) compliance with reliability and safety requirements;

7) the implementation of the recommendations that resulted from reliability analysis (summary data on failures and associated corrective actions);

8) the manner in which reliability and quality assurance requirements are satisfied during the manufacturing process (including problems of run time, increased loads and severe conditions of routine hot tests, and other tests requiring additional resources);

9) the completeness and sufficiency of assurance plans for

i) reliability,

ii) safety,

iii) ground testing, and

iv) qualification assessment.

5.3.3 Design Review

In accordance with ISO 14300-1, 4.4.2, design reviews are held at various points in the life cycle. At each of these a group of experts, representing all of the relevant disciplines should be formed to participate in the review.

NOTE Each review is a critical verification with the participation of competent specialists in the appropriate disciplines and under the leadership of a person whose activity is not directly connected with the organisation responsible for the project or the program. Information and justification on the activities completed are reviewed by the experts in such activities.

The experts' aim should be to facilitate:

a) making a decision on whether the technical elements meet the contractual requirements and the aims of the phase under review;

b) taking corrective and preventive actions, or both, in case of non-conformances or insufficiency;

c) making a decision on transition to the next phase.

5.3.4 Design Verification

Design verification should be performed to make sure that the output of a phase complies with the specified requirements. Design verification actions should be documented.

5.3.5 Qualification Assessment during Updating of Production Technologies.

At this phase of qualification assessment the following issues should be addressed:

a) general design and technological assessment of component characteristics (i.e., feasibility, conceptual technological solutions);

b) applied materials assessment (list of structural materials, including new materials and their basic physical, mechanical, chemical, and technological properties);

c) problems of supplying advanced materials to production enterprises;

d) decisions on occupational safety and health, fire-and-explosion safety, toxicity, environmental safety, and industrial sanitation in the processing of selected materials and their wastes under industrial conditions;

e) analysis of recommendations on utilisation of worn or failed items; industrial waste utilisation or elimination considering requirements for personnel health and environment protection;

f) new technological processes, including analysis of material sciences problems and solutions (i.e., list the problems of the new processes that require solution and verification);

g) technological, material sciences, and metrology problems (i.e., list the scientific, experimental, and technological work to be performed in the next phases of the item's manufacture);

h) analysis of product assembly and integration plan and interface diagrams;

i) assessment of available and required capacity of experimental, industrial, and test base as well as required list of equipment, stands, and structures, including newly created, updated, procured, or leased;

j) technical documentation analysis;

k) analysis of production preparation actions;

l) analysis of tests, verifications, and other actions related to the processes including:

1) critical processes;

2) processes using equipment, which have extremely complicated, large-sized, labour-consuming, or unique characteristics;

3) arrangement or layout of production facilities;

4) construction or modification of production and test facilities;

5) training of personnel for new kinds of activities.

5.3.6 Qualification Assessment during Ground Tests

5.3.6.1 Anticipated activities

Required input data for initiation of activities are described in section 5.3.1.

During ground testing the following actions should be anticipated:

a) analysis of:

1) the extent to which GTP requirements have been met in item and component testing (or analogue and prototype testing in the case of qualification by similarity);

2) the status of GTP implementation for SS product and its elements;

3) the status of reliability program implementation for SS elements and components;

4) final test reports for SS items and components (submitted by developing subcontractors who conducted the tests).

5) independent assessments conducted by expert commissions at the customer's (Developer) request;

6) results of flight item acceptance tests conducted at the Production facility;

7) developer's reports on elimination of failures and non-conformances detected during tests;

b) assessment of:

1) ground test results;

2) implementation of the expert commission's recommendations;

3) the conformance of technical characteristics to the TS requirements based on test results;

4) acceptance inspection, run time, and modes of test items and their components designated for flight tests.

5.3.6.2 Development of Ground Test Plan (GTP) for SS Items and their Elements.

Input data include non-conformances detected during GTP implementation, in addition to those specified in 5.3.1.

The following actions should be performed in each phase:

a) assessment of:

1) compliance with the requirements provided by standards and technical specifications on development of GTP for SS items and its components at each phase or level;

2) completeness of the verification of technical characteristics as specified in the TS for the item and its components;

3) appropriateness of the GTP to the item (and its component);

4) adequacy of mock-ups for different kinds of ground tests;

5) fidelity of ground tests in duplicating actual operational conditions;

6) completeness of interface tests of integrated systems;

b) analysis of:

1) distribution of qualification assessment in the different phases and levels;

2) production readiness;

3) emergency test plans in case of accident and hazardous situations;

4) flight dynamics testing and dynamic characteristic correction programs;

5) extent to which flight test problems might be solved in ground tests;

6) plans for testing of safety margins (for reserve assessment) and tests of resources;

7) verification of implementation of recommendations set forth in review reports;

8) verification of qualification by similarity application and data obtained from analogue and prototype testing.

5.3.6.3 Test Assessment

All necessary and sufficient tests should be performed at each phase or level for the purpose of:

a) verification of specified technical characteristics of a product;

b) verification of a product's functional characteristics;

c) obtaining data for the DJF.

During the preparation for, and performance of tests, as well as when processing test results, the following documents should be prepared:

a) plans or technical task descriptions for separate types of tests or verifications, which contain:

1) the requirements to be verified;

2) tests (verification) goals;

3) registered parameters;

4) acceptance or waiver criteria;

b) processing procedures, which contain:

1) equipment to be used;

2) tests and verifications;

3) measurements;

4) measurement registration and processing methods;

c) reports on the progress and results of tests**;**

d) reports, combining the results of individual tests, for transfer to the next phase or level;

Test verifications should be performed:

a) prior to the tests in order to be sure that adequate resources, procedures, and materials are available;

b) after the tests in order to determine test conformance (non-conformance) to the test procedures;

A review of the results obtained should be documented.

5.3.7 Flight Tests.

The following analyses and assessments should be performed:

a) analysis of:

1) reports of developing organisations on final elimination of non-conformances detected during past flight tests, as appropriate;

2) reports of the developers on product and component modifications;

3) developers' reports on the effectiveness of corrective actions;

4) any changes in items and components;

5) the modified item ground testing;

6) additional documents on readiness of the next item for flight-tests including results and recommendations from previous ground and flight tests, as appropriate;

7) readiness of the next item for flight test, including its acceptance test results and the elimination of detected non-conformances;

8) expert commission and developing organisation review reports authorising the next item for flight test or reflight;

b) assessment of:

1) the implementation of recommendations of expert commissions for correction of failures detected during previous ground and flight tests;

2) TS requirements implementation.

The flight test qualification process is completed by:

c) a report issued by the organisation or commission responsible for flight tests after the tests are completed; and

d) by a decision to initiate phase E, utilisation.

Simultaneously, preparations are made to enter full-scale production of the item, as appropriate.

NOTE. SS items can be space vehicles that are produced as "one of a kind." In these cases, a flight test can be conducted before entering the utilisation phase, but there would be production phase coincides with the ground test.

5.3.8 Production

At the start of this phase (phase D) the following tasks should be performed:

a) establishment of parameters to control the stability of technological processes;

b) establishment of a process to maintain traceability of product technical characteristics during acceptance inspection, acceptance tests, and operation;

c) analysis of detected failures and non-conformances and effectiveness of actions to eliminate them;

d) analysis of product modifications, including:

1) assessment of their impact on cost, schedule, and risk, and

2) on the need for re-qualification assessment;

e) analysis of the adequacy and effectiveness of modifications intended to increase reliability;

f) analysis of the supplier's documentation on the elimination of any non-conformance;

g) analysis of adequacy of the inspection process for critical items;

Performing the tasks listed above utilises:

a) technical review;

b) qualification assessments of specified technical characteristics;

c) sampling to assess the current technical characteristics;

d) analysis of the causes of failures and non-conformances;

e) analysis of the effectiveness of actions taken to eliminate the non-conformances.

5.3.9 Software qualification assessment

In the process of software qualification assessment, analysis of the following is performed:

a) optimisation of algorithms, data formats, and the command system configuration;

b) software algorithms;

c) description of the mathematical model of the system and modelling results;

d) list of software algorithm modules;

e) memory, processor, and data transfer requirements for execution of algorithms;

f) input language;

g) software operational documentation;

h) list of functional and service modules;

i) dialog tables and languages (for interactive systems);

j) input and output data array structure;

k) data support algorithms;

l) the software development process;

m) the library of test algorithms;

n) functional block-diagrams and timing diagrams of software operation in all operational modes.

5.3.10 Configuration Aspects

All design changes and modifications should be identified, documented, verified, and approved by authorised personnel before their implementation in accordance with ISO 14300-1, clause 4.6.

The supplementary provisions in this sub-clause relate to configuration management and any additional requirements for qualification of modified components. In implementing these, the applicability of analysis by similarity should be considered.

Measures should be taken by the supplier to guarantee, that:

a) up to date definitions of the product and any modifications introduced are available continuously;

b) modifications are subject to thorough and detailed study by all concerned in order to:

   1) verify that all aspects of the modifications are identified and analysed (i.e., aspects relating to definition, design, production, inspection, testing, qualification, implementation, logistic support);

   2) ensure that any necessary qualification re-assessment is performed;

c) all interested parties are informed of the approved modifications.

Only the modifications approved by the organisation responsible for that product (project) may be incorporated into the product and the documents.

5.3.11 Disposal Phase

As a part of the process of qualification assessment, the supplier should study problems associated with end-of-life, such as:

a) recovery and processing of SS fragments (launch vehicle stages, landed worn-out spacecraft, etc.);

b) elimination of SS products when their operation is completed (e.g., de-orbiting for sinking in special areas of the ocean, boosting to higher orbits, or recovery for reuse or disassembly).

5.4 Documents

The following documents should be prepared and made available to appropriate recipients in accord with contractual provisions or program plans. Typical recipients include organisational elements of the supplier, customer, and subcontractors.

a) matrix relating the SS, subsystem, and component qualification to the specified requirements and containing documentation for the acceptance of each assessed parameter.

b) project schedule and DJP and DJDF by life cycle phases and product tree levels.

5.5 Requirements.

5.5.1 The documents confirming SS product qualification with respect to the specified requirements shall be subject to qualification review. At the completion of this review, an expert commission, as defined by 5.2.1, issues a conclusion on SS product qualification with respect to the requirements provided by normative documents. If the qualification assessment has detected any non-conformance of the product to the requirements, in a contractual situation, the decision on further actions shall be made in accord with provisions of the contractual agreement defined in 4.2.

The results of implementation of each phase of qualification assessment should be documented in a report containing an assessment of results obtained during that phase and a comparison of these results with the results predicted for that phase.

5.5.2 In a contractual situation the report shall be presented to the customer, in accordance with provisions of the agreement defined in 4.2.

5.5.3. The customer should use the report, together with other provisions of the contractual agreement, as the basis for a decision either to continue work or to take other actions as provided for in the customer-supplier agreement. The decision should be distributed in accordance with any contractual provisions.

Annex A
(informative)
Use of DJF

A.1 Justification of Design

On completion of development, the theoretical and experimental justifications (study files, calculations, test reports**)** support a conclusion on whether or not the design of the product meets the requirements of the TS.

A.2 DJF

A2.1 General

The DJF is incrementally generated during the detailed design process in conformity with the Design Justification Plan (DJP). The DJF

a) facilitates access to required justification information,

b) provides a list of the required justifications, and

c) represents an important element in making a decision on the product Design qualification.

A2.2 Content and completion of the DJF

The supplier incrementally puts together the DJF concurrently and in parallel with the design and development of the product and of its Design Data File. The DJF thus provides, at all times, the status of the justification with respect to the requirements of the TS.

In the course of product development, studies and computations, as well as tests and simulations of any sort contribute to the collection of justification information identified in the DJP.

A2.3 Sequential status of the DJF

The following observations characterise the sequential and incremental development of the DJF.

a) The DJF changes and is improved steadily in parallel with the generation of the product design.

b) The DJF may have several pre-defined milestones, depending on the complexity of the product.

c) The first milestone applicable to the DJF is the Preliminary Design Review (PDR). At this point it contains the initial data elements, and is essentially a preliminary DJF.

d) The design and justification already contained in the DJF are used by the supplier as a basis for the decision to begin production of articles for qualification tests (or coding in the case of computer programs). This decision is made when the supplier judges that the design is sufficiently advanced. This is done within the framework of a design review (usually a Critical Design Review).

e) When submitting the Design for qualification, if this step is planned for in the DJP, the DJF ties together the justifications already obtained and those that remain to be obtained. The DJF ensures a reduction in

the risk of failure during qualification testing, particularly when failure has a high potential to affect program progress (increased cost, schedule delays, etc.).

f) The DJF enables an evaluation of the validity and the completeness of the justification and supports decisions on design qualification of the product of interest. It includes the results of qualification test analysis and assures that any product produced in conformity with the qualified design meets the needs of the customer expressed in the TS and that its design is feasible.

Annex
(normative)
Contents of DJF

The DJF shall have the organisation and contents specified in this Annex.

Part 1: Using an agreed-to format, facilitates access to information including:

a) the DJF reference;

b) the DJP reference;

c) a list of each requirement in the TS;

d) each requirement broken down into its identified characteristics;

e) those DJF components that facilitate the satisfaction of requirements at the negotiated visibility level.

f) the documents that support justification (study reports, calculation sheets, test reports, etc.), indicating their validity with respect to the TS and the DJF (or both);

g) an overview of the justification obtained for each requirement, including any significant findings.

Part 2: A summary of all justifications, including:

a) specified items and commitments which have not been honoured, along with proposed corrective actions and associated timetable;

b) significant problems;

c) justification remaining to be completed;

d) analysis of justification either not provided or insufficiently established and the associated risks;

e) margins with respect to required performance (if required for the justification);

f) means of resolution for unresolved critical items;

g) the status of justification, relative to the DJP.

The justification of a particular requirement may be needed after special sequential tasks are carried out. In such cases, an additional document should be called for in the DJP, and should be produced when needed. This document should compile all justification information on the relevant requirement.

NOTE This situation arises when the product design approaches the limits of requirements related to life cycle and associated environment conditions (high technical risk).

The following information should be included in the DJF for all characteristics, and should be presented in the form of a matrix (known as the qualification matrix):

a) name of characteristic;

b) specified quantitative or qualitative value(s) of the characteristic;

c) conditions under which the characteristic values or behaviour are required;

d) the characteristic value or behaviour obtained during qualification;

e) summary of the means used to obtain the values or behaviour measured;

f) anomalies encountered during any qualification assessment and how they might affect the interpretation of results;

g) assessment of the qualification results, specifically, conformance to the values in b) and c), above;

h) results of analysis of registered deviations or discrepancies;

i) correction and preventive actions (if necessary);

j) complete reference information for documents or data supporting the justification and other information contained in the DJF.

Sources of data for the DJF should include data created during all phases of the program.