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Guidance Document for Organizations in Aviation, Aerospace and Defence

Appendix-6

- How to proceed with design and development that incorporate risk management -

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1. Objectives

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- **In the design and development of the products for Aviation, Aerospace and Defense, the verification test of the product performance before going for the mass production is often required and certification by the customer and the regulatory authorities is needed. These processes are conducted at the final stage of designing and become the critical gates of mass production for success of the desired business. For up to the final stage of design, non-compliance with laws, regulations and customer requirements have been overlooked, as a result, there is a case that has lost the trust of the customer.**
- **This is mainly because failing to take appropriate actions in product design and development incorporated with new technology in particular at the stage of designing and development with anticipating of risks in advance.**
- **This guidance document intends to provide the guidelines for the process and the reviewing method that the division of design and development should take to avoid the risks risen by failing to comply with the laws and the regulations, and customer requirements in the stages immediately before switchover to the manufacturing phase (QTs, initial tests, etc.), and the guidelines for methods of reviewing those processes. The risk management (AS/EN/JIS Q9100 7.1.1) in Project Management view point is not included in this document.**

2. Scope

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- **This guidance is applied to design and development of the new products by the manufacturer authorized for designing of assemblies, devices, modules, body parts and materials in Aviation, Aerospace and Defense areas.**

- **This guidance materials are valid with respect to the following kinds of cases within the above scope.**
  - To avoid of delaying of the project planning as much as possible when the unexpected risk arises at the final stage of design and development.
  - To avoid failing to achieve the expected results due to mere formality of design review
  - To avoid troubles as much as possible, such as manufacturing failure at the mass production stage.
  - To avoid operational troubles as much as possible after delivery to the customer.

3. Terms and abbreviations

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- **Configuration Control Board (CCB)**
  The group of specialists in the technology and management fields to make decisions on the configuration and on its management by being given authority and responsibility.
  This is also called the Change Control Board in some other cases.
- **As Designed Configuration (ADC)**
  The configuration at each final design stage of hardware and software related to the systems or the components.
- **As Built Configuration (ABC)**
  The configuration of the hardware and software related to the systems or the components after completion of manufacturing and tests.
- **QT (Qualification Test)**
  The tests implemented in order to demonstrate technically that the target product has the ability to meet the requirements based on the prescribed criteria.
- **PQR (Post Qualification test Review)**
  The review after the qualification test.
- **Dependability**
  The item's ability to execute the required function during the given period under the given conditions. Reliability and maintainability added.
- **Technology Readiness Level (TRL) of the product**
  This is an indicator used to evaluate the readiness level of a new technology before introducing that technology into systems and sub-systems.

4. How to proceed with design and development that incorporate risk management

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In this document we classify how to proceed with design and development into the following items and describe the matters that should be taken into account from the perspective of risk reduction.

4.1 Design and Development Planning

(refer to JIS Q9100 Section 7.3.1)

4.2 Design and Development Review

(refer to JIS Q9100 Section 7.3.4)

4.3 Design and Development Verification

(refer to JIS Q9100 Section 7.3.5)

4.4 Design and Development Validation

(refer to JIS Q9100 Section 7.3.6)

4.5 Control of Design and Development Changes

(refer to JIS Q9100 Section 7.3.7)

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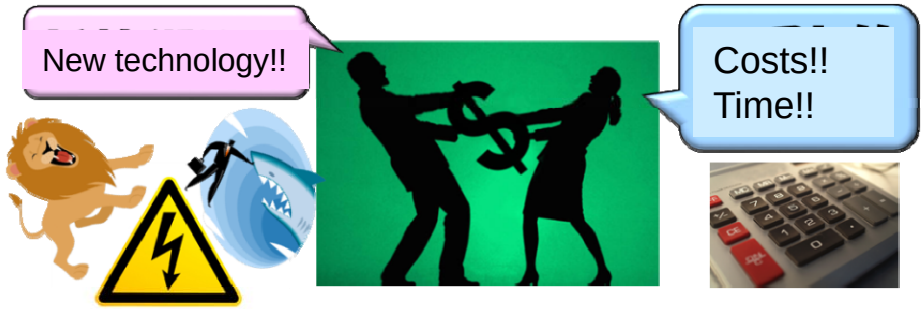
4.1 Design and Development Planning

(1) What is the design and development planning?



- **To clarify for designing of products and services in accordance with the business plan while successfully dealing with the risks imposed on realization of the products meeting the customer's needs and requirements by using the limited resources of personnel, time and money to the maximum.**
- **Identifying the actions needed before starting of to start designing and development in order to avoid the risks in realization of the product as much as possible. The actions to take should be selected depending on of the novelty of the product and designing (inexperience, high level requirement and frequency of the risks which arise with new technology) with the level of impact when the risks events occur.**

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4.1 Design and Development Planning

(2) Content incorporated into the design and development plan

- **Design and Development Planning should incorporate the following items at least.**

(i) Clarification of the product specifications (Including applications and background of development)
(ii) Cost targets
(iii) Inputs and outputs
(iv) Restrictions
(v) Realization policies and standards
(vi) Responsibility and structures
(vii) Stages of development and sched
(viii) Method of design review
(ix) Method of verification
(x) Method of validation
(xi) Method of configuration managemer
(xii) Method of sharing the road to commercialization with the project and line organization*

The items in blue are effective for controlling risks

Effective use of (v) ~ (xii) to realize risk reduction.

*How to clarify the personnel competence needed (e.g. the Plan applying the special process) and the facility capacity for commercialization, and how to share those among the entire project (i.e. the organization).

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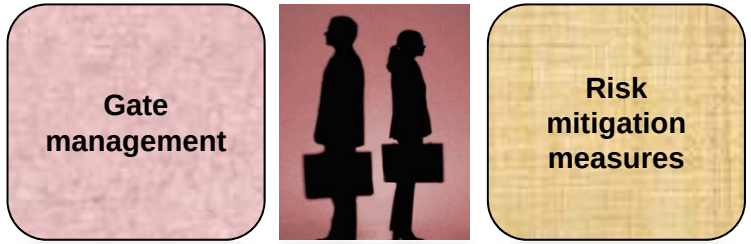
4.2 Design and Development Review (Design Review)

(1) What is design review?



- **This is the gate management process to judge if the phase can be moved to the next by evaluating whether the results of designing and development satisfy the requirements, or clarifying the problems and deciding the necessary actions, etc.**
- **On the other hand, Design review is the Risk reducing measures to solve the problems that the design and development staff are facing while the reviewers assess those problems and support the measure with the reviewers' abilities and experiences. It is part of Risk management as well.**

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4.2 Design and Development Review (Design Review)

(1) What's design review? (continued)

- **There are the customer's review and the in-house review. The organization conducts the design review internally regardless of whether there is the customer's review or not. (In this document, the in-house review is described)**

*** The design review held before the screening meeting of the customer could review only the materials given for the meeting in lack of the whole view. It should be held with the clear purpose of reviewing.**

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4.2 Design and Development Review (Design Review)

(2) Topics to discuss and review points

■ **The topics to discuss for Design Review are as follows:**

A. Needs of customers	B. Product specifications	C. Product manufacturing (for commercialization)	D. Design, development processes and risks
• Comparison of the Customer's requirements, needs, and mission requirement with the technical specifications • Performance under the unforeseeable environmental conditions • Unintended use and incorrect use • Compatibility of safety and environment • Laws and regulations • Comparison with the competing design and product	• Dependability/service requirements • Tolerance • Acceptance criteria of product • Easy to install and delivery • Alleviation of Malfunctioning impact & Fail-safety • FMEA & FTA • Diagnosis of problems & response capacity • Requirements and the instruction manuals for labels, warnings, identification, and traceability • Assessment of and specifications for standards /parts requiring authorization • Drawing and the process specs • Software requirements • Quality assurance level of the electrical and electronic parts(components), etc.	• Product manufacturing capacity that should be prepared (key personnel competences, manufacturing technology, equipment, and area environment which include for special processes) • Manufacturability and foolproof (mechanization/automation, etc.), the process capacity • Inspection and testing ability(including the special inspection and testing) • Procurement capacity • Materials /component /subassembly specifications (including goods purchased /subcontractors) • Packaging, handling, storage methods /storage deadline requirements (in particular safety) • Costs	• Status of achievement / prospects for the compliance matrix • Design and Development planning & its status of achievement • Compliance status of the upper level plan (business plan) • Design verification processes (plan/results) • Validity confirmation processes (plan/results) • Evaluation of risks until product realization and risk mitigation measures (novelty and similar designs) • Risk assessment and the reducing measures for product realization • Technology Readiness Level (TRL) of the product

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4.2 Design and Development Review (Design Review)

(2) Topics to discuss and review points(continued)

- **The followings should be clarified;**
  ***The risk level of design and development(the novelty of products or the designing technology and their level of impact)**
  ***What to be reviewed at each designing stage or the policy for planning in section 4.1**

(Examples 5.2 and 5.3)
(Example 5.4)

- **On the other hand, from the view point of the gate management, it should be clarified to define the transfer standards specifically for passing the gate in planning in section 4.1 beforehand.**

For a Good example: ・The required performance for the YY feature of A module is being expected to be attained.・The specification for the items to be procured for the long lead time is being fixed.
Bad example: • Have been reached to the level of the detailed design phase.

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4.2 Design and Development Review (Design Review)

(3) Implementation method

- **Identify a person with authority for approving progression to the next stage and condition if necessary, and approve progression to the next stage.**

- **It is recommended to decide the best way of implementing design review method based on the products and the risk level of designing and development(the novelty of products or the designing technology and their level of impact), the organizational condition, the personnel condition and at each designing stage. That should be clarified in planning of design and development of the Section 4.1.**

(Example 5.5)

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4.2 Design and Development Review (Design Review)

(3) Implementation method (continued)

- **The organizer (secretariat), who holds the design review, and the reporter, who is a main presenter there ,should not be the same to reduce the burden on the reporter, to control of implementation as planned, and to allow pointing out the problems of the design review and accumulate know-how on the problems, except the mini design review separately held by the staff and the specialists.**

Reporter

Secretariat

Control of implementation as planned

Reducing the burden of the reporter

Accumulation of know-how

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4. 2 Design and Development Review (Design Review)

(4) Reviewer

■ **The following should be considered for selecting the reviewer.**

- **Include the person who represents the division of design and development.**
- **Nominate the competent personnel based on the items to review in (2), and the reviewing method in (3).**

- **Add a division in relation to the project. (Confirm the road to commercialization)**
- **Clarify the scope of review the review and the responsibilities.**
- **The representative from the certification division should be included if the new materials and new parts are to be certified.**

- **Selection should be clearly notified at the plan of design and development of Section 4.1.**
- **It is recommended to qualify certify the reviewers as necessary and make a list of them.**
- **In the case of conducting a risk evaluation, it is best to include third party knowledgeable persons.**

*****
When participating in reviewing, not only the reviewer him/herself but also supporters (subordinates, etc.) may conduct preliminary surveys, etc.

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4.2 Design and Development Review (Design Review)

(5) Deciding transition to the next phase

- **Clarify who decides transition to the next phase.**

- **Clarify the measures if there are any conditions for the actions to transit.**
  In particular, in preparation for the action that can not be completed until proceeding to the next stage, clarify the method to transfer it to the next stage.

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4.2 Design and Development Review (Design Review)

(6) Records of design review

- **Record and maintain the Design Review results for the ground to take the necessary actions, supports and for the briefing for the customer.**

- **The followings are the list of items to be record or the design review.**

  - **Date and time held**
  - **Participants**
  - **Agenda**
  - **Action items**
  - **Decisions**

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4.3 Design and Development Verification

(1) What is verification of design and development?

- **Confirming that the design results meet the requirements by presenting the objective proofs.**
- **It is recommended to clarify which stage and what method to take for verification (*1) or the policy to incorporate in the design and development plan in section 4.1 according to the risk level of designing and development(the novelty of products or the designing technology and their level of impact).**

(Example 5.6)

*1) For example, demonstration and testing for of the high risk items in addition to confirming by the documents. (Example 5.1)

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4.3 Design and Development Verification

(2) Types of Design and Development Verification

- **Types of Design and Development Verification are as follows:**

  - **Experiments, tests, simulation**
  - **Mockup**
  - **Checklist**
  - **Calculation using a different method**
  - **Comparison with similar proven design**
  - **Confirmation of document (drawing, parts lists, etc.), other**

- **Record and maintain the verification results and the necessary actions to take. Draft the testing plan with examinations for verification, perform the planned testing and document the results on a report.**

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4.4 Design and Development Validation

(1) What is confirmation of the validity of the Design and Development Validation?

- **Design and Development validation is to confirm that the final product is manufactured in accordance with the design meeting the needs and requirements by the customer.**
- **Implement the tests based on the plan (the testing draft) determined in advance.**
- **If the customer requirements are introduced in the design document, the manufacturer uses product tests, etc. to confirm the fact that the requirements has been reflected in the product.**
- **The confirmation results and the necessary actions (if it exists) shall be recorded.**

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4.5 Control of Design and Development Changes

It is recommended to plan the configuration management for identification and management of changes in the design and development as follows.

(1) Configuration management planning

- **Compile the plan for configuration management into a configuration management written plan, etc. Generally it is good to record the following content in the configuration management written plan. Furthermore, clearly state the used change control procedures in the configuration management written plan.**
  - ◇ Introduction (objectives, scope, schedule)
  - ◇ Policies (implementation policies, selection standards of configuration commodities, reports to customers)
  - ◇ Related documents (change control procedures, etc.)
  - ◇ Identification of configuration
  - ◇ Change control
  - ◇ Report on the configuration status
  - ◇ Configuration audits

(2) Identification of the configuration

- **Define the configuration units (the unit units of the product by which configuration will be managed) and identify the number on them (parts number, serial number and lot number, drawing number, revision code, etc.). The ones items requiring traceability must be ensured to be able to distinguish the products manufactured by the same primary material/process. And if required, the parts and components of products/assemblies with defined traces can also be identified.**
- **Set the configuration baseline at the advanced stage. As necessary, make an agreement with the customer regarding to which stage the configuration base line to be set.**

(3) Change control

- **Define the procedures of management of changes and follow them to implement.**

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4.5 Control of Design and Development Changes(continued)

(3) Change control (continued)

- **Obtain approval for items requiring approval before implementation from the customer/the regulatory authorities prior to changing.**
  {Example: In a special adoption, deviations/waivers (approval for deviations, and exemptions) and applications of Engineering Change Proposal (ECP), etc. are included in approval from the customer.}
- **In the review of the change, set up a Configuration Control/Change Control Board (CCB) to review the validity of the change to check impact on other parts and the delivered products.**

- **It is recommended to include the following items in the items of CCB assessment.**
  - ◇ Technical validity of the change proposal (functions, performance, reliability, safety, maintainability, etc.)
  - ◇ Risks in changing (manufacturing process, scheduling with timing to apply,, the impact on quality, etc.)
  - ◇ Impact of the delivery time and the amount of money in contract..
  - ◇ Conformity of the specification of changes to the specification of the requirements of the related documents and the baseline document.
  - ◇ Compliance with legal and regulatory systems
  - ◇ Impact on interchangeability, the interface and the delivered goods
  - ◇ Manufacturing, tests, inspection method
  - ◇ Status of inventory and delivered products and treatment
  - ◇ Compliance of the change procedures with customer requirements
  - ◇ Whether a FAI/supply source survey is necessary or not (if necessary, the outline of the survey)
  - ◇ Records about the design review
  - ◇ The impact on software

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4.5 Control of Design and Development Changes(continued)

- **The organization should give the CCB the authority and responsibility for the configuration and its management. The CCB should be consist of specialists from the engineering division (projects, systems/sub-systems/components)and the management division (safety, reliability, quality control, quality assurance), and when necessary add specialists in sales, purchasing, manufacturing, etc. Note that in case there is such a requirement in the contract, obtain the consent of the customer regarding the membership of the CCB.**
- **Keep records of the results of reviews of the change and the actions to be taken, if necessary.**

(4) Reporting of the configuration status

- **The base line is set at the important timings of milestones and then the configurations are approved.**
  { It is often the case that As Design Configuration (ADC) is set for the detailed design review (CDR) at the final stage of designing and the Built Configuration (ABC) is set at the time of the Post Qualification Review (PQR) after the certifying test. *1)}

- **It is recommended to report including the baseline and the status of its change (the configuration units list and their configuration baseline, the current change history, the status related to changing and the special adoption, the parts traceability and information about the products changed, etc.).**

(5) Configuration audits

- **The configuration audit is conducted in order to judge whether or not the product is complying with its requirements and product configuration information. It should be implemented in accordance with the planned procedures. The timings of the configuration audit include design verification, validity confirmation, FAIs, monitoring and measuring of the products.**

Note *1): Timing of the baseline setting depends on the contract and the product.

5. Examples

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5.1 Examples of how to proceed with design and development that takes risk into consideration

(1) Define the tables in (i) and (ii) at in the design and development plan stage.

(i) Set the risk level (RL) of impact on the project based on the feature of novelty and when the feature of novelty is not realized, for the necessary parts and the unique technology elements to realize the desired product.

Risk level (RL)		Novelty		
		Small	Medium	Large
Degree of impact	Large	3	4	5
	Medium	2	3	4
	Small	1	2	3

(ii) Decide the guidelines for the risk mitigation measures to be taken according to the risk level (RL)

Guidelines to risk mitigation measures

Risk level (RL)	Resources	Design review	Verification	Validity confirmation	Confirmation of the road to commercialization
5	a	a	a	a	a
4	b	b	b	a	b
3	b	c	b	b	c
2	b	c	c	b	d
1	b	c	c	c	d

a, b, c

Types of risk mitigation measures

Resources	a	Reviewing of the specialized team / utilization of outsourcing.
	b	Actions within the ordinary organization.
Design review	a	Discuss the risks in the design review.
	b	Discuss the risks in the mini design review.
	c	Control the risks within the ordinary organization.
Verification	a	Confirm the reviewed items in documentation and calculation by demonstration. Discuss them in the design review.
	b	Discuss in the design review.
	c	Implement verification activities within the ordinary organization.
Validity confirmation	a	Deliberate in the design review.
	b	Implement confirming within the ordinary organization.
	c	Not include in validation.
Confirmation of product manufacturing	a	Form the specialized teams across organizations (collocations, etc.) . List in the project management items and watch.
	b	Actions within the ordinary organization. List in the project management items and watch.
	c	Actions within the ordinary organization. Discuss in the design review.
	d	Implement confirmation activities within the ordinary organization.

(2) In each design stage, set the risk level (RL) referring to (1) (i) for the parts and the unique technology element, and implement the design review, the verification method, and validity confirmation in accordance with the guidelines in (1) (ii).

5. Examples

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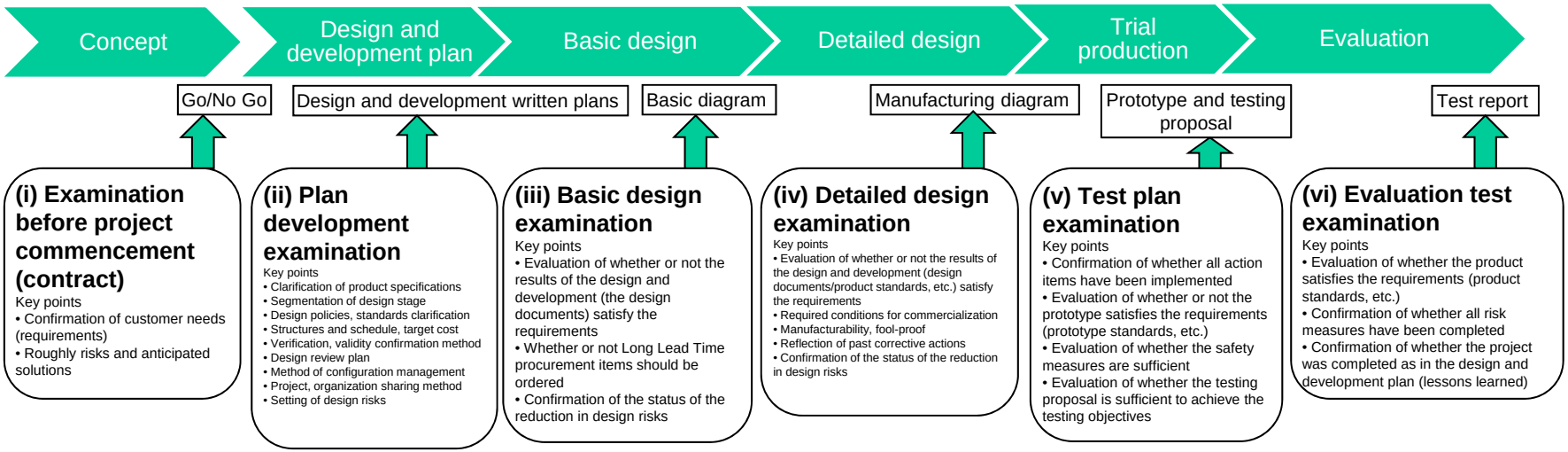
5.2 An example of the reviewing items and the review points at each design stage



Classification	Content	Examination before project commencement (contract)	Design development plan examination	Basic design examination	Detailed design examination	Test plan examination	Evaluation test examination
Needs of customers	Confirmation of customers, laws and regulations, in-house requirements Confirmation of potential required performance	■	■				
Specifications of product Specifications of manufacturing processes (Confirmation of outputs)	Confirmation of process (confirmation of verification results)			■	■		
	Confirmation of results			■	■		
	Review of validity confirmation test results				■	■	■
	Status of handling based on past non-compliance information				■	■	■
	Review of manufacturability				■	■	■
	Compliance matrix			■	■	■	■
Design processes and risk management	Design plan		■	■	■		
	Status of achievement of design plan and amendments when necessary			■	■	■	■
	Risks for achieving the requirements (Severity and novelty)	■	■	■			
	Formulation of risk reduction measures for achieving the requirements and the acceptability of the residual risks		■	■			
	The implementation status of the risk reduction measures for achieving the requirements and confirmation of the residual risks			■	■	■	■
	Whether or not there are any newly emerging risks and whether or not it is necessary to take countermeasures for those risks				■	■	■
	Reflection on the design development processes and lessons learned						■

5. Examples

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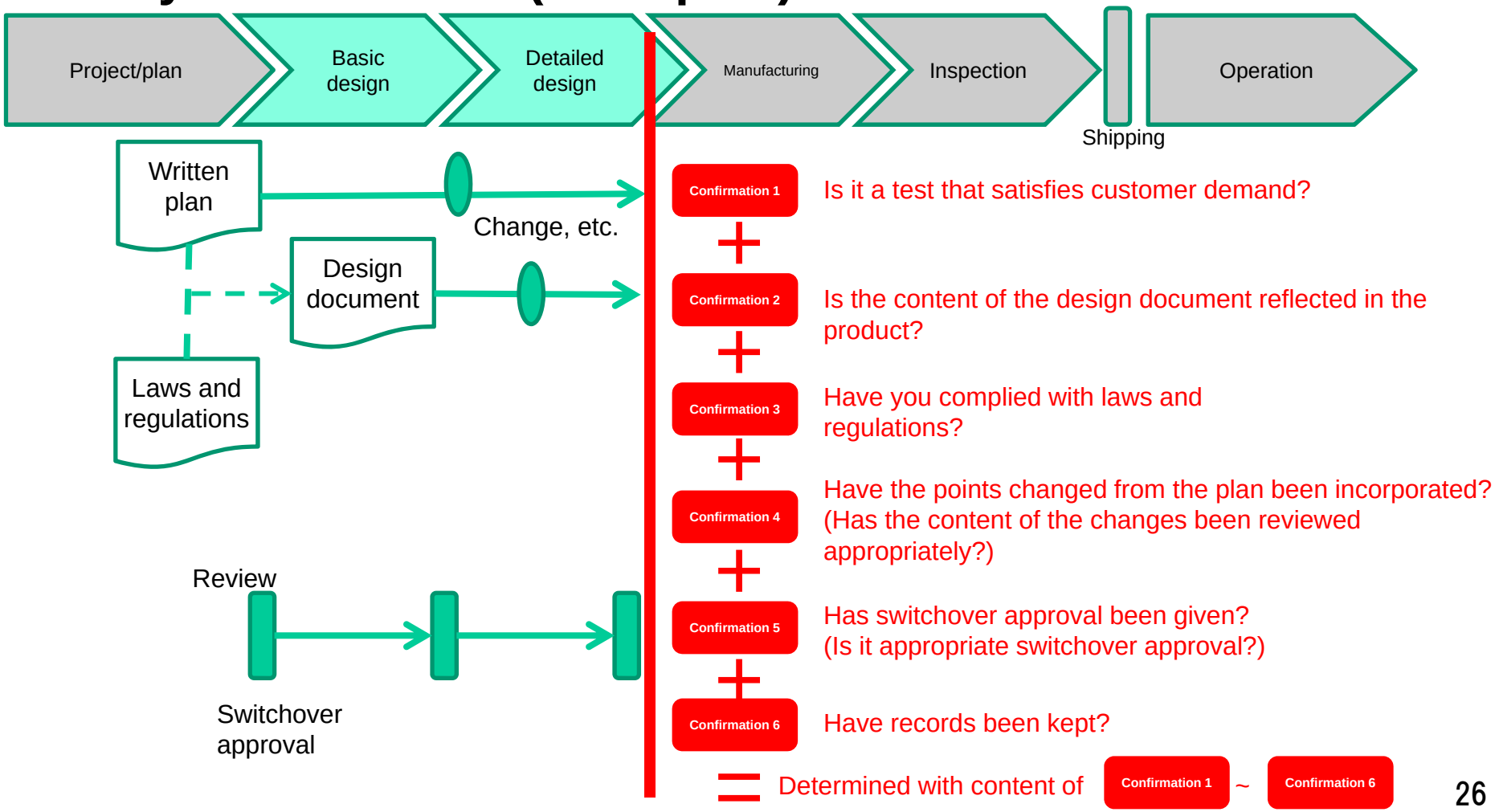
5.3 Confirmations that should be implemented before the validity confirmation (examples)



5. Examples

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5.4 Checklist to review at each design stages (examples)

Design and development plan review stage

Item	Items for confirmation (check items)
(i) Clarification of the product specifications (Including applications and the background to the development	Are the customer needs (requirements) clear?
	Have the necessary laws and regulations been exhaustively and clearly stated?
	Has the potential required performance been extracted?
	Have requirements, regulations, performance requirements been included in the product specification?
(ii) cost targets	Are the product cost targets in line with the project plan?
(iii) Inputs and outputs	Are the inputs and outputs in the design work clear?
(iv) Restrictions	Are the restrictions for the implementation of design and development clear?
(v) Realization policies and standards	Have the policies for realizing the target product specifications and costs been clearly and specifically stated?
	Are the design standards clear?
(vi) Responsibility and structures	Are the responsibilities and structures of the design and development clear?
	Are the realization policies reflected in each individual scope of responsibility?
	Are the collaboration with and relationship to the project and organization overall clear?
(vii) Stages and schedule of the development	Has the plan been divided into the necessary development steps, and are the work items, necessary resources, responsibilities, content of the design, inputs and outputs, restrictions, and the schedule and attainment goals clear?
	Are all assessment / certification action of customer or legal authorities included in the plan in a reasonable timing?
(viii) Method of design review	Is the person responsible for the design review clear?
	Are the implementation of the design review and the deliberation policies clear?
	Is the timing of the implementation of the design review clear?
	Is the method of design review clear?
	Are the reviewer and the scope of the responsibilities to be reviewed clear?
	Are the target of the review, policies for target selection, and focal point clear?
	Does the approach take risks into consideration and is it well tailored to individual situations?
	Are the gate conditions clear?
	Is the record-keeping method clear?
	Are the management and succession methods of the action items clear?
(ix) Method of verification	Is the person responsible for verification clear?
	Are the timing, method, and target of the verification (the verification matrix) clear?
	Does the approach take risks into consideration and is it well tailored to individual situations?
	Is the record-keeping method (what is created and how the records are kept) clear?
(x) Method of validity confirmation	Is the person responsible for validity confirmation clear?
	Is the timing, method, and target of validity confirmation clear?
	Are the pass/fail standards clear?
	Is the record-keeping method (what is created and how the records are kept) clear?
(xi) Method of configuration management	Are the scope, implementation policies, selection standards for configuration commodities, the baseline, reports to the customer, the related documents (change control procedures, etc.), identification of the configuration, change control, reporting of the configuration status, configuration audits, etc. clear?
(xii) Method of sharing with the project and line organization	Is the cost management method clear?
	Is the method of sharing the necessary testing equipment, manufacturing equipment, area, etc. with the project (through issuance/maintenance, etc. of a basic necessary equipment table, etc.) clear?
	Is the method of sharing the competence necessary for key personnel with the project overall including the manufacturing division (through issuance/maintenance, etc. of a special process application plan) clear?
	Is the method of sharing information such as special suppliers and long lead time items, authorized suppliers, etc. (through issuance/maintenance, etc. of a procurement management plan) with the project including the supplies division clear?
	Is the method of sharing the necessary storage method and the transportation method, etc. (through creation/maintenance, etc. of written plans for age control products storage management) with the project overall including the manufacturing division clear?
	Is the method of sharing management methods, etc. for specified important parts (through issuance/maintenance, etc. of written plans for specified important parts management) with the project overall including the manufacturing division clear?
	Is the method of sharing special inspection methods, etc. in cases where this is necessary (through an inspection demand form, etc.) with the project overall including the inspection division clear?
	Have the necessary fool-proof application policies taking into consideration manufacturability been made clear, and are the methods of sharing them with the project overall including the manufacturing division clear?
(xiii) Setting of design risks	Have the design and development risks been identified and the methods for managing them clearly stated? Or are there no omissions in the identified design and development, and the acceptable levels and risk mitigation measures are valid?

Basic design review stage

Item	Items for confirmation (check items)
(i) Status of achievement of the design development plan	Has the design development plan been achieved? Have the necessary amendments been made?
(ii) Status of compliance with the upper level plan	Has compliance with the upper level plan (business plan, project plan) been ensured?
(iii) Change in product specifications	Have there been any changes to the customer requirements, laws and regulations, or potential required performance? If there have, have the changes been reflected in the product specifications?
(iv) Confirmation of the results of the design and development	Do the results of the design and development (design document, schematic drawing, basic concept, basic diagram, basic specs, etc.) satisfy the requirements? In particular 1) Is procurement of the Long Lead Time procurement items possible? 2) Is the design of the high risk level items to be confirmed in the design review valid? 3) Are the verification methods/results of the high risk level items for which the verification methods/results are to be reviewed valid? 4) Are the validity confirmation methods/results of the high risk items for which the validity confirmation methods/results are to be reviewed valid?
(v) Confirmation of the status of the reduction in design risks	Is the status of achievement of the compliance matrix according to plan?/Have there been any changes to the outlook? (Have the risk evaluation and mitigation measures until product realization been updated appropriately?)
(vi) Status of reflection of past non-compliance	Have past instances of non-compliance that should be reflected been identified?
(vii) Method of sharing with the project and line organization	Have the various written plans and lists that are necessary for commercialization (commodification) been issued? In particular Are there any omissions in the conditions for the commodification of the high risk level items to be confirmed in the design review? Furthermore, has roll out to the manufacturing division, etc. been completed and have the necessary preparations been made? Have the examination and authorization acts of customers and legal authorities been included exhaustively and at a valid time?

Detailed design review stage

Item	Items for confirmation (check items)
(i) Status of achievement of the design development plan	Has the design development plan been achieved? Have the necessary amendments been made?
(ii) Status of compliance with the upper level plan	Has compliance with the upper level plan (business plan, project plan) been ensured?
(iii) Changes to product specifications	Have there been any changes to the customer requirements, laws and regulations, or potential required performance? If there have, have the changes been reflected in the product specifications?
(iv) Confirmation of the results of the design and development	Do the results of the design and development (design document, detailed drawing, detailed concept, detailed specs, etc.) satisfy the requirements? In particular 1) Is the design of the high risk level items to be confirmed in the design review valid? 2) Are the verification methods/results of the high risk level items for which the verification methods/results are to be reviewed valid? 3) Are the validity confirmation methods/results of the high risk items for which the validity confirmation methods/results are to be reviewed valid?
(v) Confirmation of the status of the reduction in design risks	Is the status of achievement of the compliance matrix according to plan? / Have there been any changes to the outlook? (Have the risk evaluation and mitigation measures until product realization been updated appropriately?)
(vi) Status of reflection of past non-compliance	Have past non-compliance countermeasures been reflected?
(vii) Method of sharing with the project and line organization	Have the various written plans and lists that are necessary for product realization (commodification) been issued? In particular Are there any omissions in the conditions for the commodification of the high risk level items to be confirmed in the design review? Furthermore, has roll out to the manufacturing division, etc. been completed and have the necessary actions been taken?
	Are manufacturability and the fool-proof measures being implemented according to the plan?

5. Examples

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5.5 Examples of Design review methods

Ways of implementing design review

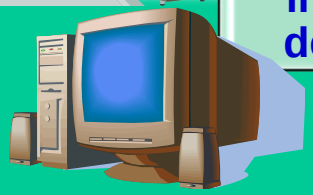
[Verbal screening meeting method]

• A method in which the subject of the review gives an explanation to the persons conducting the review in a conference room, etc. and answers questions. The applicable reviewers get together at the decided date and time to implement it.

[Drawing publication method]

• Post/disclose the drawing (outputs) for a fixed period in the places decided in advance. The reviewers inspect them at the time they like during that period and if they have ay comments, suggestions, etc. they record them in sticky notes and the decided format.

[Prior question & answer method]



• Disclose the drawing (outputs) in the places and folders decided in advance. Before the review meeting, the reviewers ask about the necessary questions and matters for confirmation in advance and confirm the answers on the day of the review meeting.

[Mini design review method]

• Not only the person in charge of the project but also the people in charge in each specialized field get together and conduct a review of the individual issues.

Highly novel design	• Screening meeting method
Application of similar designs	• Combined use of the mini design review method and the drawing publication method
Application of existing designs	• Drawing publication method

5. Examples

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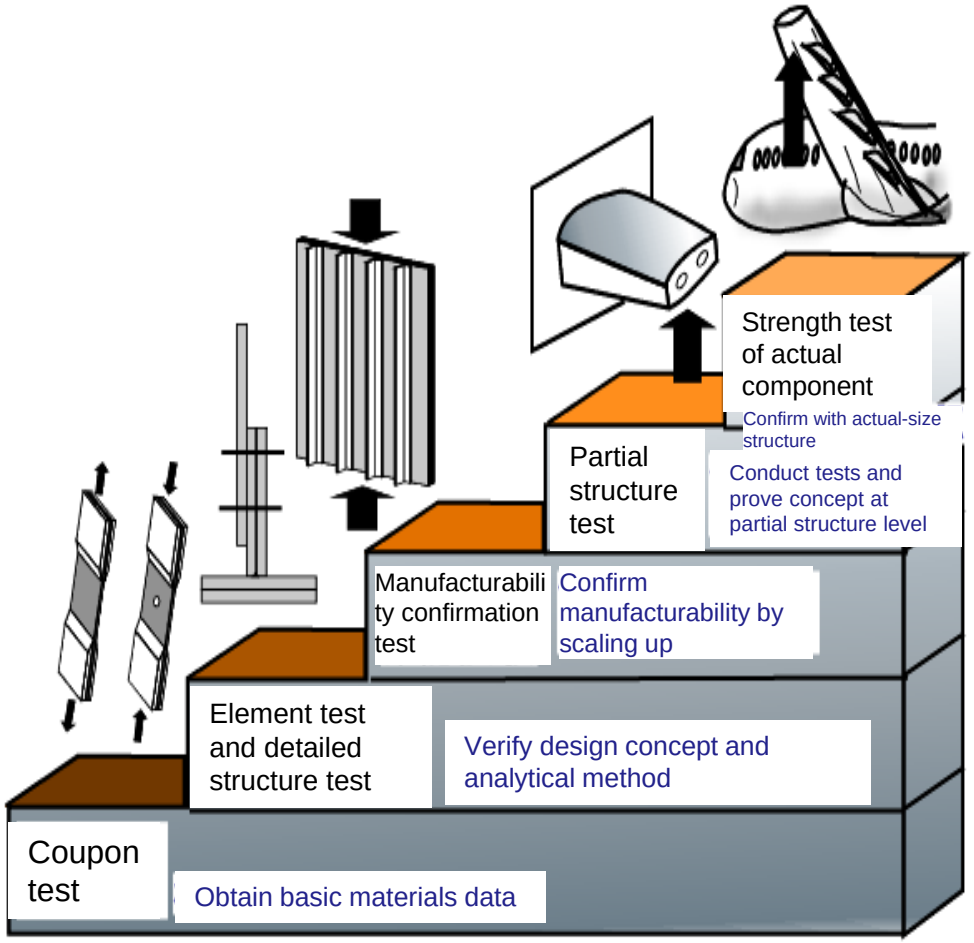
5.6 Examples of Verification/Validation

Example of a verification method 1

			Verification method				
Constituents parts	Demanded item		Document confirmation	Calculation	Demonstration	Test	Comparison with similar designs
Part A	Functions	xx		○	○		
		xx		○			
	Performance	Weight	○				
		Maximum take-off weight	○			○	
		Flight range	○				○
		Fire resistance				○	
	Laws and regulations	xx		○			
		cc				○	
		dd					○
		ee				○	
Part B	Functions	xx		○			
		xx		○			○
	Performance	Weight	○				
		Maximum take-off weight	○				○
		Flight range	○				○
		Fire resistance				○	
	Laws and regulations	xx		○			
		cc		○		○	
		dd					○
		ee				○	

Example of a verification method 2
(Verification using the building block approach)



6. Reference documents/related web sites

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■ Building block approach

• Charles E. Harris, James H. Starnes Jr., Mark J. Shuart "An Assessment of the State-of-the-Art in the Design and Manufacturing of Large Composite Structures for Aerospace Vehicles" NASA/TM- 2001- 210844, April 2001

■ Configuration management

• ISO 10007: Quality management systems — Guidelines for configuration management

■ TRL

• JAXA document "Evaluation of Research and Development in the Japan Aerospace Exploration Agency"

■ DRBFM

• Toyota approach of Design Review based on Failure Mode - GD3, written by Tatsuhiko Yoshimura, Union of Japanese Scientists and Engineers

• Other related web sites: For example:
http://www.juse-sqip.jp/vol15/qualityone_01-03.html

7. Editor’s Note

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One of the background of scandals that occurred recently in Aviation, Aerospace and Defence is a nonconformity that raises at the final confirmation stage (e.g. certification test). This is mainly because of failing to respond appropriately to product designing and development incorporated with new technology in particular at the stage of designing and development where the unexpected event would occur.
Though, it is possible to avoid chances of the risk occurrences at the final stage through the effective management in the stage of plan and development.

In this document, we summarized in the form of a joint approach, from the perspective of risk management, how existing resources can be used to avoid as much as possible the risk that design and development does not proceed in accordance with the prescribed plan.

JIS Q9100 describes the requirements of the design review, verification and the validation. These are the approaches to reduce the risks from the view point of the risk management. This document is a guidance which links these activities to risk mitigation measures.

The guidance working team for planning and development incorporated with risks (March, 2014)