2015

Guidance for Approval of Risk-based Ship Design

GC-16-E

KR

APPLICATION OF
"GUIDANCE FOR APPROVAL OF RISK-BASED SHIP DESIGN"

Unless expressly specified otherwise, the requirements in the Guidance apply to review and approval of risk-based ship design for which the application for approval are submitted to the Society on or after 1 July 2015.

CONTENTS

CHAPTER 1 GENERAL

Section 1 General

101. Purpose

This Guidance provides the process for the Society's approval of the novel concept design or the alternative design which is deviated from existing prescriptive regulations and rules.

102. General of Risk-based Approval

1. Prescriptive regulations which is based on empirical knowledge is difficult to apply to the unprecedented novel concept design and may sometimes restrain the level of innovation that is feasible in design.
2. An essential prerequisite for widespread use of novel concept design is a predictable and reliable process of submitting and approving the design making full use of latest risk assessment tools and techniques. Risk-based Approval is the approval of such risk-based design.
3. Prescriptive regulations prescribe each requirement for certain components, systems or functions of the whole ship. Risk-based design may deviate from all or part of such prescriptive requirements and there may be different levels of approval depending on how deviate from the prescriptive requirements.
4. An risk-based design and approval is expected to be carried out only for ship functions, systems or components that either directly or indirectly deviate prevailing regulations.
5. One approach to the approval of the risk-based design is to compare the innovative design to existing designs to demonstrate that the design has an equivalent level of safety. In order to demonstrate an equivalent level of safety, functional requirements and performance criteria are to be established for essential ship functions, which are to be met by the risk-based design. An alternative approach could be to carry out a risk analysis of the risk-based design and compare it to overall risk evaluation criteria.
6. A structured approval processes is necessary in order to confirm that the risk-based design can obtain the approval of the Society. This Guidance prescribes such a structured process that is predictable and reliable. By adhering to this Guidance, clients and the Society would be working in cooperation to evaluate that risk in all aspects of safety and environmental protection are adequately assessed and controlled to an acceptable level.
7. In a risk-based approval process, the approval basis is to be defined based on the submitted design in terms of risk, and design analysis and review of result are to be carried out according to the approval basis. Therefore, in a risk-based approval process, the approval basis is to be newly defined wherever the design is modified.

103. Application

1. This guidance prescribes process of review and approval of equivalent and novel feature specified in the classification technical rules such as **Pt 1, Ch 1, 104., 105.**, of **Rules for the Classification of Steel Ships, Ch 1, 104.** of **Rules for the Classification of Mobile Offshore Units, Ch 1, 104.** of **Rules for the Classification of Mobile Offshore Drilling Units, Ch 1, 103.** of **Rules for the Classification of Fixed Offshore Structures, Ch 1, 103.** of **Rules for the Classification of Floating Production Units**, etc. This guidance apply to following designs of ships and offshore units(hereafter, referred to as ships in this Guidance).
   (1) Designs of ships and ship systems which intend to apply novel concept and non-proven technology which can not directly apply existing regulations.
   (2) Designs which intend to apply a equivalent or alternative at higher level of existing regulations.
2. The risk-based approach and the risk-based approval process defined in this Guidance may be applicable to all area related to ship design, but are not limited to specific technical, regulatory field.

3. The risk-based approval process is to take into account relevant risk which can occur during the whole life cycle in course of design, construction, operation and dismantling.
4. When applying this Guidance, substitution of design measures to reduce risk with operational or procedural measures is not permitted. Design measures are to take priority over operational or procedural measures.
5. For successful application of this Guidance, all stakeholders are to exchange their opinions from the start of design to final approval through continuous mutual discussion.

Section 2 Definition

201. Definition

The definitions of terms which appear in this Guidance are to be as specified in this Section.

1. **New technology or novel design** is a technology or design that has no documented track record in a given field of application. This implies that a new technology is either:
   (1) a technology that has no track record in a known field;
   (2) a proven technology in a new environment; or
   (3) a technology that has no track record in a new environment.
2. **Risk-based design** is a design where the design process has been supported by a risk assessment or the design basis has resulted from a risk assessment. That is, it is a structured and systematic methodology aimed at ensuring safety performance and cost-effectiveness by using risk analysis and cost-benefit assessment.
3. **Risk-based approval** is to review and approve of an innovative novel design or a risk-based design.
4. **Design team** is the entity that carries out the design development and analyses for a novel design or a risk-based design. The team is established by the owner, builder or designer, which may include a representative of the owner, builder or designer and experts having the necessary knowledge and experience for the specific evaluation at hand. Other members may include marine surveyors, ship operators, safety engineers, equipment manufacturers, human factor experts, naval architects and marine engineers.
5. **Approval team** is the entity that approve a novel design or a risk-based design. The team is established by the Society' staff in charge of approval of risk-based design and experts designated by the Society.
6. **Generic design** is a design at a level where at least an estimate may be possible. In the generic design, ship's primary system and target function are to be clearly defined. The generic design is to include the whole shape of the ship, arrangement of major compartment, structural features and material of main part, dimension of main structural member, arrangement and specification of major systems, manner to obtain target system function and major operating characteristic.
7. **Detailed design** is a design at a level where a purchase, manufacture and installation may be possible. All details to concerning construction of target ship are to be completed, and all information related to installation or operation is to be specifically identified. In addition to the completed generic design, the detailed design complies with the results of the generic design with respect to specific dimension of all structures, detailed arrangement and specification of all installed equipments, detailed specifications of related components, construction methods, work methods etc.
8. **Validity demonstration of design** is to confirm realization possibility for intentive target functions. The main works are to confirm compatibility with the requirements identified by operating risk-based approval process.
9. **Safety demonstration of design** is to confirm that risks of design are at acceptable level. Risk levels are estimated through risk analysis and safety is demonstrated by comparing them with risk evaluation criteria.

10. **Survey requirements** are requirements for an assortment of surveys, checks, monitors, maintains, tests, etc. during construction/operation; the least restrictions necessary to continually ensure/maintain safety level confirmed by final approval, related to construction, manufacture, and operation phases of design target.
11. **Accident** is an unintended event involving fatality, injury, ship loss or damage, other property loss or damage, or environmental damage.
12. **Accident scenario** is a sequence of events from the initiating event to one of the final stages.
13. **Design casualty scenario** is a set of conditions that defines the development and severity of a casualty within and through ship space(s) or systems and describes specific factors relevant to a casualty of concern.
14. **Reliability** is the probability that a component or system performs its required function without failure during a specified time interval.
15. **Failure mode** is the observed mechanism or manner in which a failure can occur.
16. **ALARP(As Low As Reasonably Practicable)** refers to a level of risk that is neither negligibly low nor intolerable high. ALARP is actually the attribute of a risk, for which further investment of resources for risk reduction is not justifiable.
17. **Safety** is the freedom from unacceptable risk or the absence of unacceptable levels of risk to life, limb and health from unwilful acts.
18. **Risk** is a measure of the likelihood that an undesirable event will occur together with a measure of the resulting consequence within a specified time, i.e. a combination of the frequency and the severity of the consequence.
19. **Hazard** is a potential to threaten human life, health, property or the environment
20. **Hazard identification(HAZID)** is a process to find and list hazards.
21. **Risk assessment** is 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.
22. **Risk evaluation criteria** are formally recognized objective criteria defining the acceptable risk.
23. **Risk control measure(RCM)** is a means of controlling a single element or risk; typically, risk control is achieved by reducing either the consequences or the frequencies; sometimes it could be a combination of the two.
24. **Preliminary approval** is the process by which the Society issues a certificate that a proposed generic design complies with the intent of the rules or recognized standard, subject to a list of conditions that must be addressed in the final design stage.
25. **Final approval** is the process by which the Society issues a certificate that a proposed novel design complies with the intent of rules or recognized standard and conditions identified during the preliminary approval stage are to be demonstrated to the satisfaction of the Society.
26. **Approval in Principle(AIP)** is the process by which the Society issues a certificate that a proposed novel design complies with the intent of rules or recognized standard from both safety and functional perspectives although the design may not yet be fully evolved.
27. **Safety Management System** is a structured and documented system enabling company personnel to effectively implement the company safety and environmental protection policy.⚓

CHAPTER 2 STAKEHOLDERS AND QUALIFICATION

Section 1 General

101. General

1. Approval process of risk-based design is performed by the design team and approval team. Each team consists of the owner, builder and class that are based on the specific roles. This chapter specifies major task and qualification of key personnel involved in the different stages of the risk-based approval process.

Section 2 Design team

201. General

1. The design team is the entity (e.g. yard, supplier, owner and operator) that carries out the design development and analyses for the risk-based design.
2. They need to be in a position to assess safety and environmental protection holistically and will also be responsible for the education of operations personnel, documentation on board and the safety management system relevant with construction and operation.
3. Operational and technical experts in the relevant field or from similar operations are to be involved and assist the design team in the review of hazards as well as supply expertise to the initial risk assessment sessions.

202. Designer

1. The designer is the developer of the design seeking approval.
2. The designer is to be familiar with risk-based design approaches in order to utilize them.

203. Yard and subcontractor

1. Yard and subcontractor are mainly responsible for construction of ship and manufacture of equipment which is installed in the vessel.
2. The yard and subcontractor are to provide information for the analyses carried out in order to achieve the approval by the Society.
3. The yard and subcontractor's main concern will be to have concise information at an early stage because contract is normally promoted based on information at early stage and depending on the contract, an risk-based design may have both advantages and disadvantages.
4. Since the new building schedule process and milestones will invariably be influenced by decisions made in the process, yards and subcontractors need to be able to account for the differences in time allocation compared to conventional designs in order to be able to optimize their building.

204. External experts

1. External experts perform tests, analyses, calculation, simulation and development and validation of software and reviews of modeled used.
2. It is to be ensured that external experts obtain the relevant experiences, research accomplishments and credentials for performing the analyses, the tests or simulation. For certain types of tests, the recognized institutes and personnel may also be required. It may equally be considered whether adequate supervision is available and whether the provided supervision warrants a sound review of results.

3. They are to be able to provide references and results from similar operations for the personnel involved in a project.

205. Crew

1. The crew is responsible for operating a ship applying risk-based design ship and performs voyage, operational tasks, maintenance and self-inspection in accordance with the prevalent requirements, as stated in the management system on board.

2. It is anticipated that the risk-base will be documented in the safety management system, and thus it is a part of familiarization routines. The crew needs to comprehend the nature of the risk-based safety management system and any differences in operation as well as in maintenance and inspection routines compared to a conventional ships.

Section 3 Approval team

301. General

Approval team is mainly responsible for approval of risk-based design and confirms safety of risk based design and performs overall approval for commencement of construction and operation, survey and audit.

302. Society′s staff in charge of design approval

1. Society's staff in charge of design approval performs risk-based design procedure.

2. The society's staff in charge of design approval performs overall progress of risk-based approval process, carries out of decision-making, documentation and review of assessment at each stage, and finally approves the design.

303. Society′s Survey

1. Society's surveyors perform compliance verification in the construction phase and compliance review through the operational life of an ship, i.e. they perform the survey of construction and operation

2. The surveyors will require an introduction to risk-based design approaches. An understanding is to be developed that compliance is generally to be viewed as compliance with the intent of regulations, and not necessarily with prescriptive content.

304. External Expert

1. External experts specified in **204.** may be involved in the approval team. ⚓

CHAPTER 3 APPROVAL PROCESS

Section 1 Approval Process

101. General

1. The risk-based approval process is to be clear, transparent and well described in order to avoid misinterpretations.
2. The risk-based approval process is intended for validity and safety demonstration of target design, which especially focuses on design stage specially. It consists of three steps of preliminary approval, final approval and survey. (See **Fig 3.1**)
3. The details of the risk-based approval process depend also on the design process of the design team. The design stage is subdivided into three stages: design concept, generic design, and detailed design. It is linked with preliminary approval and final approval. Risk-based approval on safety in generic design is to be carried out through preliminary approval and the same in detailed design is to be carried out through final approval. However, the design team may wish to carry out the approval process using a detailed design, i.e. without an analysis of a generic design. In such cases both parties may agree to skip the analysis of the generic design and adjust accordingly the approval process including the documentation of analyses. Independent of such details, the approval process to be consider among others the definition of the approval basis, the hazard identification, review of approval basis after HAZID and quantitative risk assessment.
4. At the final stage, the survey requirements are applied to ensure that the original assumption of risk is satisfied for classification and continuation of the classification.
5. Requirements of associated hazards are to be identified and are directly reflected to the generic design and detailed design as a means of controlling the risk of vessel during preliminary approval and final approval.
6. The risk-based survey requirements are prepared by using various requirements related to construction and operation obtained through preliminary approval and final approval process. It would be a basis of safety management as a standard of work, monitoring, tests, audit and control during construction and operation of ships.
7. The entire structure, primary step, stages and the order of preliminary approval and final approval is specified as **Fig 3.2**.

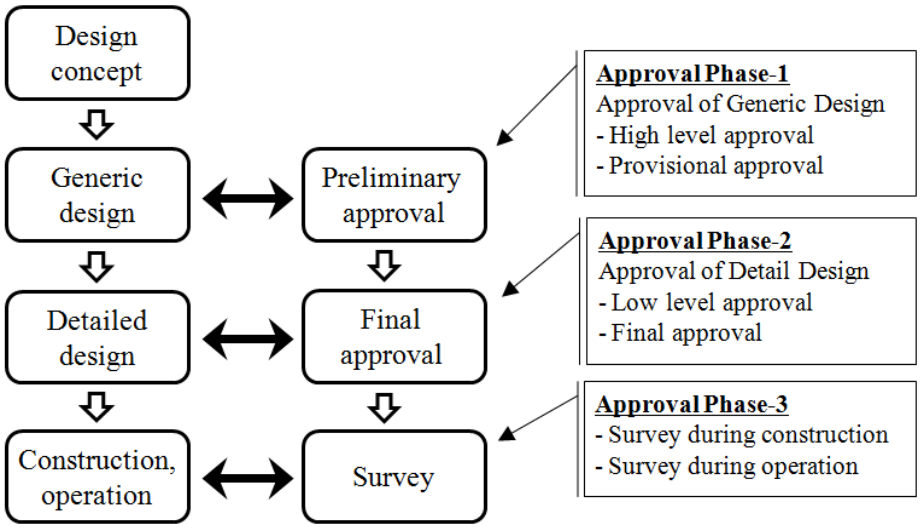

Fig 3.1 Stage of Approval Process

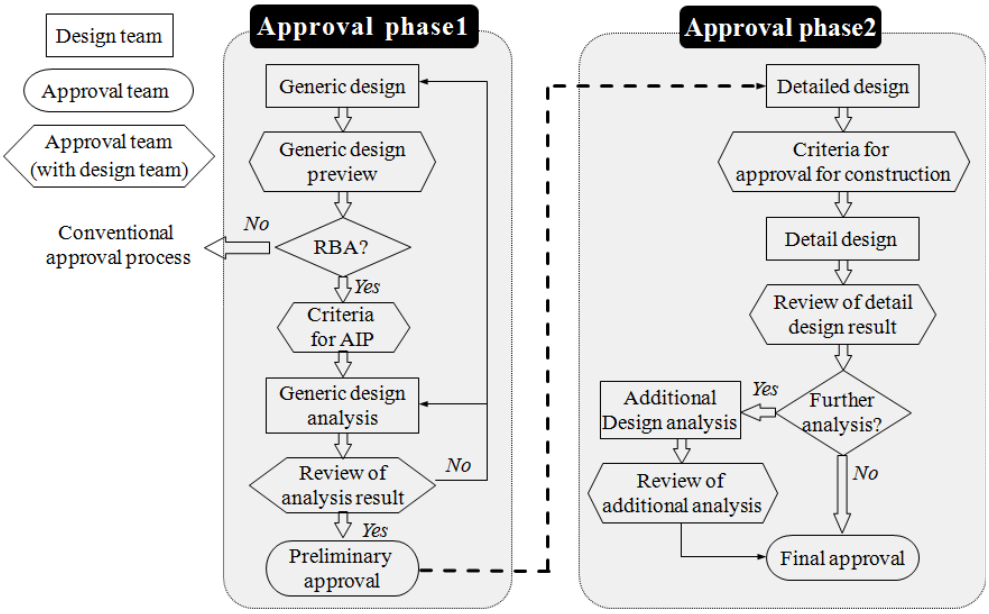

Fig 3.2 The structure of preliminary approval and final approval

Section 2 Preliminary Approval

201. General

1. Preliminary approval is a validity approval process on generic design, and the order of preliminary approval process is specified as **Fig 3.3**.

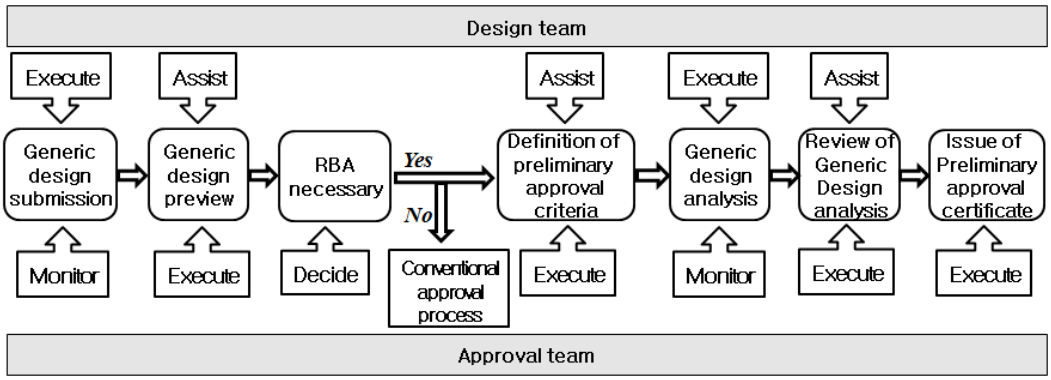

Fig 3.3 Preliminary approval process flow

2. This section may also apply to Approval in Principle(AIP).

202. Submission of generic design

1. The design team is to prepare novel design or risk-based design and submit it and relate documents to the approval team.

2. Overall shape of the ship, configuration of main compartments, structural configuration of main part, material, material and dimension of primary members, arrangement of primary systems, boundary condition, main specification, realizing methods of target function and operation characteristics are to be included in generical design.

3. The design team is to identify existing standards, regulations and rules that the design deviated from, and explain them to the approval team.

4. If necessary, terms and meanings concerning design and approval procedure are to be defined at the initial stage. The definition of these terms increases efficiency by avoiding misinterpretations and confusion.

203. Preview of generic design

1. The approval team previews the submitted generic design with respect to safety of life and environment protection and understands clearly the characteristics of the target design. The team considers if risk-based approval procedure is to be applied to the subjected design.
2. The approval team and the design team are to discuss the contents of the submitted generic design at the generic design preview phase. The aim of the generic design preview phase is also to decide whether the risk-based design challenges any existing rules, regulations or standards to such an extent that a risk analysis is required. If risk-based approval procedure is decided not to be applied by an approval team, existing prescriptive regulations and rules may be applied to approve.
3. The approval team and the design team are to identify and describe items requiring special attention and to plan how to handle these items with respect to approval.
4. The decision whether the design requires a risk-based approval may be reached by using **Table 3.1** to determine the degree of novelty.

Table 3.1 Categorization of novelty

Technology status / Application area	Proven	Limited field history	New or unproven
Known	1	2	3
New	2	3	4

5. A Matrix as shown in **Table 3.2**. may applied for guidance to the design team when performing preliminary estimates on the extent of work to be performed and submitted for approval.

204. Definition of preliminary approval criteria

1. The approval team is to define the required conditions and formal procedures based on the results on preview discussion of generic design.
2. The specifications which are to be included, but are not limited to, in preliminary approval criteria are as follows:
   (1) Definition of main risk concerned, and its evaluation criteria
   (2) HAZID plans (including methods and scopes)
   (3) Risk analysis and assessment plans (including methods and scopes)
   (4) Work plan for generic design analysis such as experiments, calculations, analysis, simulation tests, etc. (including methods and scopes)
   (5) Functional requirement and safety requirement list (Draft requirements)
   (6) Assumptions, exemptions and restrictions
3. The approval team defines preliminary approval criteria to advise to the design team. Preliminary approval criteria are defined through several meetings led by the approval team and the design team is to participate in the discussions.
4. The following agenda is to be discussed in preliminary approval criteria meeting.
   (1) Design concepts
   (2) Design objectives
   (3) Design novelty
   (4) Risk-based features in design
   (5) Violations and potential violations related to the existing prescriptive regulations, rules and standards, etc.
   (6) The deficiencies or limitations of existing prescriptive regulations, rules and standards
   (7) Potential hazards which may happen to all systems and functions of ships
   (8) Necessary items to realize target functions

Table 3.2 Level of detail of risk-based approval corresponding to degree of novelty

Category	Novelty 1[(1)]	Novelty 2[(2)]	Novelty 3[(2)]	Novelty 4[(3)]
Risk Assessment	Not required	Required (partly) * Violation of primary regulations * Depending on risk assessment outcome * Semi-quantitative risk assessment on hazards medium or high[(4)]	Required (partly) * Quantitative risk assessment on hazards medium or high[(5)]	Required (overall) * Quantitative risk assessment on all hazards[(5)]
Qualifications of a design team	Not required	Required * Design, operational experience experts * Individuals having general knowledge of risk assessment	Required * Design, operational experience experts * Risk assessment experts	Required * Design, operational experience experts * Risk assessment experts
Applicable regulations	*Existing prescriptive regulations and rules	* Existing prescriptive regulations and rules * Parts of risk-based approval process * Applicable standards if available from other industrial sectors	* Risk-based approval process * Applicable standards if available from other industrial sectors	* Risk-based approval process
Surveys	*Existing regulations of surveys	* Internal surveys * Additional surveys at related safety events	* Internal/external surveys * Additional periodic surveys at hazards	* Continuous monitoring and reporting

Note :
(1) 'Novelty 1' refers to a conventional design and the risk-based approval process need not be applied unless having a special intention or reason. Therefore existing prescriptive regulations, rules and standards may be applied.
(2) 'Novelty 2-3' correspond to the middle level not belonging to Novelty 1 and 4 and may take existing approval process and risk-based approval process depending on the situations. Basically, they follow existing approval process according to design and may apply risk-based approval process only for important part systems and functions. If necessary, they may apply risk-based approval process for overall design.
(3) 'Novelty 4' correspond to a design with a totally new concept which is lack of experience and verification. As there is no existing prescriptive regulations, rules and standards applicable to this, this is to follow risk-based approval process except special cases.
(4) Semi-quantitative risk assessment is a method of quantitative estimates. It defines indexes on frequency and consequences of accidents in advance to give an index of the most appropriate grade.
(5) Quantitative risk assessment is a method of completely estimating quantitative values. It estimates frequency and consequences of accidents in specific numbers through records, experiments, calculations, simulation tests etc.

5. Appropriate types of risk-based or reliability analysis techniques are to be identified in risk analysis and assessment plans. The features, limitations, application methods etc. are to be definitely mentioned.

6. Appropriate types of experiments, theoretical analysis and calculations, possible simulation tests are to be identified in generic design analysis plans. The features, limitations, application methods etc. are to be definitely mentioned.

7. Generic design analysis plans may be changed by results of generic design analysis and they are to be reflected to specify design analysis plans.

8. Risk of major interest is to be identified, proper evaluation criteria corresponding to the risk are to be defined and identified.

9. Objective safety level inherent in existing prescriptive regulations, rules and standards etc. may be

referred to define risk evaluation criteria. Available risk evaluation criteria in other industrial sectors may be referred to. However, an approval or design team is to newly develop specific risk evaluation criteria in case of novel design.

205. Analysis of generic design

1. The design team is to analyse risks involved in generic design relating to preliminary approval criteria under the supervision of the approval team. The team identifies design items which require specific analysis, carries out experiments, calculations, analysis and simulation tests etc.
2. If necessary, analysis results of generic design may be utilized to risk analysis works again and risk assessment is to be carried out by preliminary approval criteria. Safety of generic design is to be judged.
3. At a minimum, a hazards identification is to be included in risk analysis works. Besides, other risk analysis methods such as FSA, FMECA, HAZOP, FTA, ETA, structural reliability analysis etc. may be applicable.
4. The design team is to carry out hazards identification on novel design or risk-based design. Related hazards and consequences are to be identified, also safety systems(accident prevention and mitigation measures) are to be found. Through the procedure, the requirements are to be identified to ensure or improve the design safety. Preliminary approval criteria are to be revised. General risk analysis flow is specified as **Fig 3.4**.

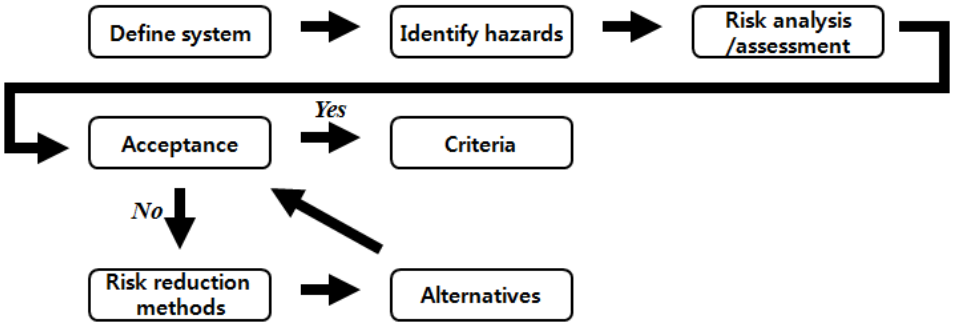

Fig 3.4 Risk analysis flow

5. The design team is to carry out risk assessment at the end, after preparing risk model based on risk analysis results. Risk control measures are to be prepared according to risk assessment results and risk evaluation criteria defined in preliminary approval criteria.
6. The specifications to be considered in risk assessment works. are as follows:
   (1) Identified hazards, frequency, consequence
   (2) Safety systems included in the design which may be identified
   (3) Risk model for quantitative risk analysis
   (4) Reference, assumption, uncertainty, sensitivity etc.
   (5) Comparison of the calculated risk levels and evaluation criteria
   (6) Risk control measures and risk reduction level
   (7) Items which need additional risk analysis, experiments, calculations, analysis, simulation tests.
   (8) Notices related to construction, operation
7. Documents related to procedures and results are to be properly prepared, because risk assessment results are the most important data for preliminary approval.

206. Review of analysis results for generic design

1. To ensure rationality and adequacy of process and results of generic design, the approval team is to review hazards identification results and confirm that:
   (1) participants have appropriate qualifications;
   (2) standard procedures(eg. 「Guidelines for Formal Safety Assessment(FSA) for use in the IMO

Rule-Making Process(MSC-MEPC.2/Circ.12)」) for hazards identification works were followed.
(3) the rank of identified hazards is considered properly.
(4) the identified safety systems are reflected to the design properly.
(5) features of novel design or risk-based design are reflect to identified hazards and safety systems properly.
(6) if necessary, preliminary approval criteria are revised according to identified design requirements.

2. The approval team is to review rationality and adequacy of risk model

3. The approval team is to review rationality and adequacy of risk assessment results.

4. The approval team is to review rationality and adequacy of risk reduction level where risk control measures are applied by the design team.

5. The approval team is to review that experiments, calculations, analysis, simulation tests etc related to the generic design have been carried out appropriately and transparently, and their results are reasonable.

207. Issuance of preliminary approval certification

1. The approval team is to review the analysis results for generic design in accordance with preliminary approval criteria and decide issuance of preliminary approval certification after judging realization possibility and safety level of generic design. The certification is not to be issued until all hazards, faults related to generic design are identified and their control is demonstrated.

2. The approval team is to consider the following specifications to issue preliminary approval certification.
(1) Possible to realize generic design
(2) May all identified and calculated risk levels be acceptable
(3) Are there omitted or ignored risks
(4) Comply with design requirements
(5) Is risk reduction level by risk control measures reasonable

3. It is noted that preliminary approval certification is not guaranteed for final approval. It is only possible through the final approval.

4. The form of preliminary approval certificate is to be in accordance with the form defined in **Annex 2**.

Section 3 Final Approval

301. General

1. Final approval is a procedure of detailed design preparation and analysis. The procedure step is specified as in **Fig 3.5**.

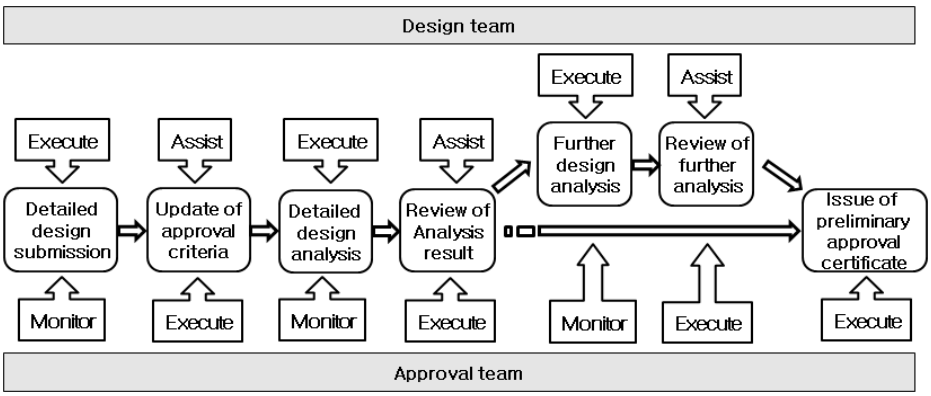

Fig 3.5 Final approval procedure flow

302. Submission of detailed design

1. The design team submits detailed design to the approval team. The design reflects risk control measures, which are identified or created in preliminary approval procedure, in accordance to the analysis results for generic design.
2. Detailed design is to include all details not specifically defined in generic design. For example, detailed structural arrangement and the shape in all parts of the ships, dimension of all structures, construction method, detailed layout and final specification of all equipment systems, specification and installation information of all equipments, operating conditions with all purposes and related loads, operating system, detailed information etc. related to propulsion and maneuver are to be developed in detailed design.

303. Definition of final approval criteria

1. The approval team is to identify the differences between generic and detailed design based on detailed information by detailed design as well as additional, detailed design information and revised design contents. The team is to define necessary requirements and formal procedure for final approval.
2. Final approval criteria are intensified and expanded types of preliminary approval criteria. In other words, general things which are considered in preliminary approval criteria are the same as in final approval criteria, but preliminary approval criteria stated requirements which are to be complied with for approval are to be written in detail in final approval criteria.
3. Items not recorded in preliminary approval criteria may be newly identified in detailed design. Risk evaluation criteria, detailed design analysis plans, the other requirements etc. of newly identified items are to be added to final approval criteria.
4. If necessary, operation methods related to experiments, calculations, analysis, simulation tests etc. on risk analysis, assessment and detailed design in final approval criteria may be additionally assigned by approval team.

304. Analysis of detailed design

1. The design team is to identify risks related to detailed design in accordance with final approval criteria, carry out accompanied experiments, calculations, analysis, simulation tests etc. The team is to submit proper documents on the results of detailed design analysis to the approval team.
2. The approval team is to supervise frequently that the design team carries out detailed design analysis suitably by final approval criteria. The representative in the approval team may attend the meeting of the design team.
3. In case contents of generic design in detailed design stage are changed, hazards identification, analysis and assessment are to be carried out again overall.

305. Review of analysis results for detailed design

1. The approval team is to review that experiments, calculations, analysis, simulation tests etc. related to the detailed design have been carried out appropriately and transparently, and their results are reasonable.
2. The list of requirements for final approval is to be prepared based on the results of preliminary approval criteria, final approval criteria, generic design and detailed design analysis. The following specifications are to be included to issue final approval certification.
   (1) Possible risk categories and risk evaluation criteria
   (2) Reasonable basis of limitations and restrictions applied to risk analysis
   (3) Requirements to meet applied assumptions and conditions for identifying risks
   (4) Requirements for successful functions of safety systems and risk control measures
   (5) Requirements for achieving target functions of design
   (6) If necessary, verifications for demonstrating satisfaction of requirements above

3. Items recorded with list of requirements for final approval are related with the following directly, they are draft requirements of construction and survey related to operation.
   (1) Related to construction : safety and quality management requirements related to construction, manufacture and installation etc.
   (2) Related to operation : restrictions, maintenance requirements, procedure during operation

306. Issuance of final approval certification

1. The design team is to submit all necessary documents (specifications, drawings, calculations etc.) to the approval team prior to issuance of final approval certification. Basically documents related to development and analysis of detailed design are to be submitted, and relevant document list to be submitted may be adjusted by an agreement between the design team and approval team.
2. All possible hazards of novel design or risk-based design are to be identified to issue final approval certification, they are to be reflected to risk analysis and assessment. Whether all risks are within risk acceptance level is to be verified comparing all risks to all risk evaluation criteria. It is to be verified that the developed detailed design is able to carry out target functions sufficiently.
3. The approval team is to confirm the list of requirements for final approval and the suitability of the design. The team is to decide issuance of final approval certification after judging that detailed design or realization possibility of the target design, safety level are acceptable.
4. Commencement of construction and manufacture may be possible after issuance of final approval certification. In other words, final approval is a formal and final design approval procedure to verify safety and adequacy on entire design including generic design and detailed design. ⚓

CHAPTER 4 SURVEY REQUIREMENT

Section 1 Survey Requirement

101. General

1. The design team is to prepare survey requirements during construction and operation based on identified safety systems, risk control measures, notices, restrictions in final approval procedure. The team is to submit a document of safety management system to the approval team for approval.

2. The safety level of the proven design in final approval procedure is to be kept within an acceptance level in construction and operation step. It may be possible by safety management system ultimately. The system integrates quality management procedures, requirements, restrictions, maintenances to keep safety adequacy during ship's construction and operation.

3. The approval team is to carry out verification of safety adequacy(surveys, checks, audits, monitors etc.) according to the approved safety management system. The verification performances and results of safety adequacy are essential to keep certification, this work is to be carried out by traditional surveys and verification procedures similarly.

4. Periods, scopes and points of verification of safety adequacy are to be as defined by safety management system. Generally verification requirements of safety adequacy may be complicated if features of design are more innovative. The requirements may be reduced if experience on novel design or risk-based design is accumulated and reliability is verified enough.

5. The design and assumption confirmed in final approval procedure may be changed in construction and operation step. If they affects the risk of the ship, the approval team is to decide to carry out risk analysis and assessment again. According to the results, survey requirements and safety management system may be revised.

6. If necessary, reliability centered maintenance procedures on the basis of ship's major system, failure rate of function or reliability may be included additionally.

102. Survey requirements during construction

1. Survey requirements during construction are to guarantee that safety level of the proven design by final approval is sufficiently maintained without decline at construction and manufacture procedure of ships. The follows as specified are to be considered.

(1) Existing prescriptive regulations, rules and standards related to construction and manufacture
(2) Qualification verification of yards, factories, worker related to construction and manufacture
(3) The adequacy of construction and manufacture process (including restrictions/limitations)
(4) The adequacy of construction and manufacture procedure (including restrictions/limitations)
(5) Notices on quality management procedure of construction and manufacture
(6) Necessary tests and verification methods during or after construction and manufacture
(7) Necessary survey and verification methods during or after construction and manufacture
(8) Sea trial verification items and methods after construction and manufacture
(9) Other related safety systems and procedures

103. Survey requirements during operation

1. Survey requirements during operation are to guarantee that safety level of the proven design by final approval maintains without lowering sufficiently at operation of built ships and the purpose of providing services. The follows as specified are to be considered.

(1) Existing prescriptive regulations, rules and standards related to operation
(2) Qualification verification of complements
(3) The adequacy of sea routes and services (including restrictions and limitations)
(4) The adequacy of operating conditions and procedures (including restrictions and limitations)
(5) The adequacy of necessary work procedures on-board (including restrictions and limitations)
(6) The adequacy of operating procedures for emergency (including restrictions and limitations)

(7) The adequacy of maintenance procedures by itself during operation(including restrictions and limitations)
(8) Items to be verified by surveyors and verification methods during operation
(9) Document requirements to be on-board during operation
(10) Other relevant safety systems and procedures ⚓

CHAPTER 5 RISK EVALUATION CRITERIA

Section 1 General

101. General

1. The expected safety performance of the risk-based design is to be quantitatively specified in the form of the evaluation criteria.

2. The approval of the risk-based design requires the development, review, and selection of appropriate evaluation criteria. Before evaluation the alternative and/or equivalent design, the Submitter and the Administration need to agree on established evaluation criteria.

3. Safety objectives and functional requirements available in IMO instruments are to be taken into consideration when developing the evaluation criteria.

102. Validity of design

1. Validity of design means compatibility with requirements identified by performing risk-based approval process.

2. Requirements could be divided into following functional requirements and safety requirements. When the design is satisfied with both of them, validity of design is proven.

(1) Functional requirements: essential requirements to obtain target system function
(2) Safety requirements: requirements related with maintenance or development of safety(including risk control options and safety systems)

3. These requirements are included in several documents prepared during performing risk-based approval process and finally integrated and organized in the document of final approval requirements list.

103. Safety of design

1. Safety of design means acceptance possibility of an assortment of risk identified through risk-based approval process.

2. Risks are divided into followings according to level and scope of the subjected design.

(1) High-level risk is the integrate risk for entire design and commonly dealt with in the preliminary approval phase.
(2) Low-level risk is local risk for specific components, functions, systems, etc. and commonly dealt with in final approval phase. If necessary, this can be dealt with in the preliminary approval phase.

3. Safety of design is proven by confirming that identified risks of **Par 2** is satisfied with defined risk evaluation criteria.

4. Identified risks and relevant evaluation result are included in documents and specified overall in the design analysis report and design review opinion.

104. Definition of risk evaluation criteria

1. Risk evaluation criteria are defined and revised at the time of definition of preliminary approval basis phase and final approval basis phase respectively. If necessary, already defined risk evaluation criteria may be revised additionally after review of design analysis result and agreement between the approval team and the design team.

2. Following items are to be described in detail where defining risk evaluation criteria.

(1) Type of risks
(2) Risk acceptance criteria
(3) Identification scope of risks

3. The design team calculates various risk levels by performing risk analysis for the design and car-

ries out risk assessment with comparing to the risk acceptance criteria, and then they are to submit the result to approval team. The approval team reviews the risk assessment report submitted by design team and ascertain the suitability of procedures and adequacy of result and may consequently approve the design based on the result.

4. In the definition of the risk assessment, economic criteria is not considered in principle. However, it can be properly consulted when reviewing the adequacy of the risk control measures.

5. Risk acceptance criteria is to be in accordance with **Annex 1**.

Section 2 Types of Risk

201. General

1. It is changed the characteristics of the risk that is to be considered by major interest of the safety assessment, i.e. the target object of the safety assessment and correspondent risk assessment criteria accordingly is changed. Therefore various types of risk can be applied in accordance with the purpose of approval and the contents of the subjected design.

2. Generally the type of risk is as followings. In addition to the followings, new type of risk can be defined and applied if necessary.

(1) Risk to human
(2) Risk to environment
(3) Risk to asset

3. This section prescribes risk to human and environmental risk that are considered as important risk. However, if necessary, it may also be considered risk to asset in approval process by the consensus of the approval team and design team.

202. Risk to human

1. Risk to human includes fatality risk and health risk for direct workers, indirect workers, passengers or other related people.

2. Usually risk to human is taken to be the risk of death and health risk are ignored or can be considered in terms of the risk of death in accordance with the appropriate criteria. The equivalent fatality concept is applied in order to convert the health risk to the risk of death, For example, one(1) fatality and ten(10) severe injuries may be considered equal.

3. Risk to human can be divided into individual risk and social risk depending on the number of target persons as following. Calculation and evaluation of the individual risk will be sufficient if contents of subjected design are simple and a small amount of people are associated. However, if the subjected design is complicated and a large number of people are associated, both of the individual risk and the social risk are to be calculated and evaluated.

(1) Individual risk
  (A) Individual risk is respective risk when specific individual(one or several people) is exposed to the risk of danger in the particular place(work place or residence place).
  (B) The purpose of estimating the Individual Risk is to ensure that individuals, who may be affected by a possible accident, are not exposed to excessive risks.
  (C) Individual risk is to be calculated differently for each work location and work time. Individual risk considers the individuals fractional exposure to that risk such as working hours and operating distance. For example if an explosion is occurred in the particular place in the ship, the individual risk for a crew in the vicinity of the explosion position will be higher than for a crew in the distance.

(D) Individual risk can be calculated quantitatively using the following formula.

$$IR = F \cdot P \cdot E$$

IR = Individual Risk

F = Frequency

P = Resulting casualty probability)

E = Fractional exposure to that risk)

(2) Social risk

(A) Social risk is the group risk for all individuals when entire persons(all workers and all passengers, etc.), who are directly and indirectly related to the target vessel, are exposed to risk.

(B) The purpose of calculating the social risk is to understand comprehensively safety of the target design by identifying a large-scale accidents and the resulting number of deaths that may occur.

(C) Social risk is not limited to a particular individual or a particular place and is the integration of life-risk for all persons(crew, passenger, port workers and third party, etc.) exposed to all possible accidents that may occur at any place. That is to say that social risk is the integration result of individual risk according to a specific method.

(D) Social risk may be calculated with respect to each incident type and also be represented for the entire target design with a combination of social risk for all types of accident.

(E) Social risk is mainly indicated as the risk of death, i.e., fatality risk and can be quantitatively represented by the following method.

(a) FN curve(frequency-fatality curve)

(i) FN curve is a diagram continuously indicated the excess cumulative probability of accident deaths of more than N that has occurred. In other words, it is shown the relationship between the fatality N and cumulative probability F of the accident in which the number of fatalities can be N or more. For example, F at N=1 is the probability of entire fatality accident.

(ii) FN curve is made by calculating the number of deaths taking into account all the hazards and accident scenarios in a sequence. It can be effectively represented the social risk.

(b) Potential loss of life(PLL)

(i) The potential loss of life is defined as the estimated number of annual deaths(fatality per ship-year), which is simply summed all human risk(risk of death) of the accidents that may occur.

(ii) The potential loss of life has the benefit of being able to indicate the social risk simply and clearly than FN curve but it is not able to figure out the relative importance of individual accidents. For example, the single accident that kills 1,000 people and 1,000 accidents that kill a single person has a same risk level in accordance with potential loss of life. Attention is to be paid in this regard when using PPL.

4. In order to ensure sufficient life safety for the design, not only required reduction of the average integrated risk to human but also necessary to reduce the maximum individual risk is necessary. Therefore, all risks can be fully understood and controled when usually considering the individual risk and social risk simultaneously.

203. Risk to environment

1. Risk to environment is the factors that may affect the ecosystem, i.e., it is mainly the risk to the safety of environmental protection against pollution.

2. Since the results of the accident regarding the atmosphere and ocean pollution is very broad and complex, it is difficult to estimate the exact damage scale. Therefore, precautionary principle is most effective to reduce the risk to environment by removing the hazards that may cause environmental pollution.

3. The main sources of material that is to be considered when dealing with the environmental risk of ship is as follows.

(1) Discharge during ship operation
  (A) Exhaust gas (CO2, NOx, SOx, etc)
  (B) Sewage and wastewater

(2) Cargo
  (A) Grain
  (B) Coal and Minerals
  (C) Oil
  (D) Refinery petroleum products
  (E) Toxic liquids and chemicals
  (F) Radioactive material ⚓

CHAPTER 6 DOCUMENTATION REQUIREMENTS

Section 1 General

101. General

1. The process method, necessary period, result of work and etc. of the risk-based approval process, unlike a existing conventional approval process, may not be the same according to contents and characteristics of the subjected design, and therefore the documentation process needs to be clear, transparent and well described to avoid misinterpretations. The result of non-traditional assessments need to be fully documented in a manner readily accessible to a third party.

2. All documents are to be able to exhaustively transfer necessary information for the progress of the risk-based approval process. Means of document control such as document management control are to be applied to ensure that only controlled versions of the information yielded are distributed.

3. Any design detail deviating from conventional best practice is to be described comprehensively in drawings. Contents which are difficult to be indicated in drawings may be additionally described in other documents.

4. All parameters applied in the design process are to be explicit by being presented as diagrams or described in prose. The type, characteristic and the method (how) and stage (when) of application of parameters are to be clear from the description.

5. All ships are required to carry necessary documentation for verification of safety compliance during operation on board by survey requirements and safety management systems. Essential safety elements are to be explicitly indicated in this documentation, and are to be well-acquainted by crews and the Surveyor.

Section 2 Documentation and Exchange of Documents

201. General

1. Documentation in risk-based approval process may comprise, but is not limited to, documents specified in **202.** and **203.**.

2. Documentation that is required to be exchanged between the approval team and the design team in the approval process is summarized in **Fig 6.1**.

202. From Design Team to Approval team

1. Risk-based design documents:

(1) Design concepts and objectives;
(2) Specification and general description of generic design and detailed design;
(3) Relevant drawings (generic design, system arrangement, structural drawing, production drawing, lines, etc.);
(4) Detail drawings of subsystems;
(5) Description of target system function and required sub function;
(6) Novel characteristics or risk-based characteristics of design (including operational characteristic);

2. Analysis reports of generic design and detailed design:

(1) List of existing prescriptive regulations/rules/standards that are considered to be applied;
(2) Identified hazards reports;
(3) Safeguards included in the design;
(4) Results of risk analysis and risk assessment(including risk models);
(5) Safety critical elements;
(6) Applicable risk control option and consequent reduced level of risk;

(7) References and relative inter/external experts opinions;
(8) Applicable techniques or methods of test, calculation and analysis, simulation relative to the design;
(9) Objectives, scope and boundary conditions of test, calculation and analysis, simulation relative to the design;
(10) Result report of test, calculation and analysis, simulation relative to the design;
(11) Discussion about assumptions, error and uncertainties;
(12) If necessary, items which require additional further design analysis;
(13) If necessary, cost-benefit assessments

3. Documents relative to construction and operation:

(1) Safety management procedure

203. From Approval team to Design Team

1. Result of generic design preview

2. Preliminary approval criteria and final approval criteria

(1) Documentation of applicability of any regulations, rules or standards as well as any deviation;
(2) Risk analysis and assessment plans;
(3) Plan of test, calculation and analysis, simulation relative to the design;
(4) Documentation requirements and process;

3. Review opinion on design analysis

4. Opinion on preliminary approval review and final approval review

5. List of final approval requirements

6. Preliminary approval certificate and final approval certificate with conditions

7. Survey requirements and safety management system approval opinion

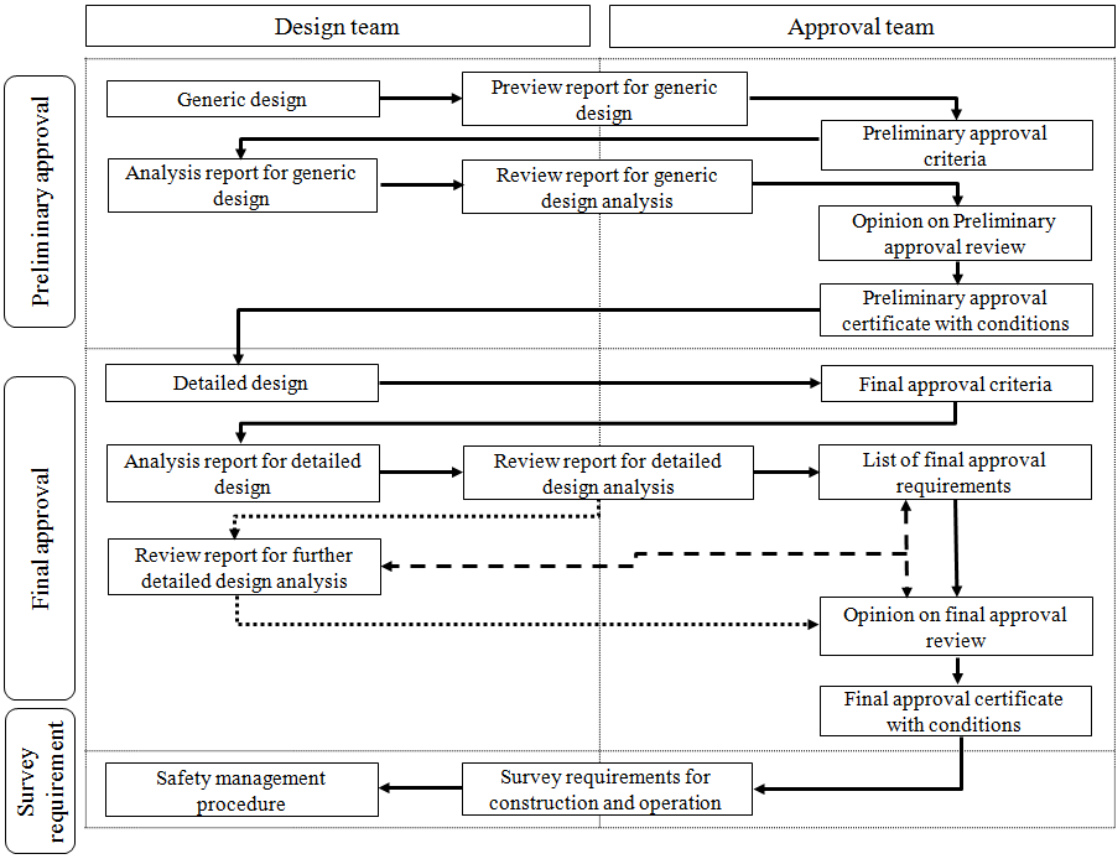

Fig 6.1 Documentation between design team and approval team

Section 3 Reporting format

301. General

1. Prevalently, the responsibility for ensuring documentation quality rests with the design team. A party wishing to enter into the risk-based approval process(i.e. design team) is therefore to be able to manage their own document control processes.

2. The documentation may take several forms, all with their own advantages and drawbacks, such as electronic file and hard copy. If necessary, the documentation is to take both of them.

3. Basic formal issues have to be followed, ensuring document control and facilitating the adherence to any existing or future management systems. Such formal issues include stating on the submitted papers:

(1) Project identification number, title, scope and description
(2) Responsible persons for project, responsible persons for document, document preparing person(if necessary, document reviewer)
(3) Authorization signature
(4) Date for prepare and signature
(5) Revision number/letter
(6) Distribution list ⚓

Annex 1 RISK ACCEPTANCE CRITERIA

101. General

1. Risk acceptance criteria is specific numerical value or scope of acceptable risk.

2. For approval of risk-based design, acceptance criteria to be defined in agreement between the approval team and the design team.

3. Risk acceptance criteria is a key of risk evaluation criteria and the specific criteria for evaluation by directly comparing the calculated risk.

4. The risk-based design is to be designed to perform functions related safety with at least equivalent method of prescriptive requirements which the design deviates from.

5. Risk acceptance criteria is to be determined based on the prescriptive requirements or the design applying the prescriptive requirements. Therefore, safety level of prescriptive requirements has to be described explicitly to be able to compare the safety level of risk-based design.

6. Risk acceptance criteria are defined taking into account the followings.

(1) Experience and statistical data
(2) Acceptance criteria applied in a similar design or industry
(3) The basic principles of risk assessment
(4) Relevant social and economic impacts, if necessary

7. Risk acceptance criteria may refer to 「Guidelines for Formal Safety Assessment(FSA) for use in the IMO Rule-Making Process(MSC-MEPC.2/Circ.12)」 that developed by the International Maritime Organization(IMO).

102. Basic Principle

1. General

The basic principle utilized for developing the acceptance criteria can be ALARP principle, absolute risk criteria and safety equivalence. The principles adopted will naturally influence the risk acceptance criteria arrived at.

2. ALARP principle

(1) The ALARP principle dictates that risks are to be managed to be ''As Low As Reasonably Practicable''. Reasonableness of risk reduction is generally described as economic cost. This means both risk levels and the cost associated with mitigating the risk are to be considered, and all risk reduction measures are to be implemented as long as the cost of implementing them is within the reasonably practicable region.

(2) Risk level is divided in to following three regions as shown in **Fig. 1**.
(A) “Acceptable region" in which risk is negligible and no risk reduction required.
(B) “Not acceptable region" in which risk is too high and must be reduced.
(C) “ALARP region" which is in between the two bounds. In this region, risk is to be reduced to according to ALARP principle.

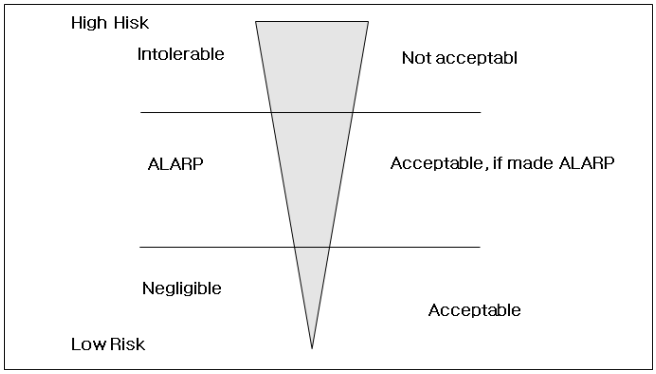

Fig 1 The ALARP principle

(3) Typical indices which express cost-effectiveness in relation to safety of life are GCAF(gross cost of averting a fatality) and NCAF(net cost of averting a fatality).

3. Absolute probabilistic risk criteria

(1) This principle explicitly defines the maximum allowable level of risk or the probability value. An example of a criterion according to this principle could be "the frequency of death due to a single accident is to not exceed 10-3 per person-year(i.e. 1 person per 1000 persons for a year)".
(2) This principle for establishing risk acceptance criteria does not consider the cost associated with achieving the corresponding risk level. This means that where maximum level of risk is higher than explicit absolute probabilistic risk criteria, the risk is to be reduced without due regard to the economic cost associated with it.
(3) The explicit absolute probabilistic risk criteria may be defined for each of the accident or the integrated result of all accidents.

4. Safety equivalency principle

(1) This principle is the principle that compare the risk level of the subjected design with known risk levels for the similar existing design that are widely regarded as acceptable. This is a kind of comparative risk assessment approach and means that the risk level of the risk-based design is not to exceed the risk level of the existing proven design.
(2) The level of the similar existing design, as the comparative risk evaluation criteria, includes a safety level that is aimed for or inherent in prescriptive regulations/rules/standards.
(3) If necessary, a general risk which is commonly regarded in normal human activities(e.g. probability of death from a natural, probability of death in specific age group, etc.) may be used in lieu of risk of similar existing design. In this case, safety equivalency principle is similar with absolute probabilistic risk criteria.
(4) The safety equivalency principle has the advantage that allows the designer to choose an alternative design and arrangement.
(5) Where the safety equivalency principle is applied, the scope and viewpoint of risk comparison is to be decided paying due attention.
(6) Where the quantitative risk of the risk-based design is difficult to estimate, the safety equivalency principle can be an effective method.

301. Definition of Risk Acceptance Criteria

1. The approval team decides appropriate risk acceptance criteria for the subjected design and describes it in the document for preliminary approval and final approval criteria. The design team's confirmation and agreement for defined risk acceptance criteria are necessary for proper progress in the design analysis and the result review.

2. The risk acceptance criteria is defined considering typical basic principle specified in **102.**. The approval team is to specify a reasonable basis of basic principle selected for definition of risk acceptance criteria.

3. The risk acceptance criteria in risk-based approval process can be defined using the ALARP principle or the absolute probabilistic risk criteria basically.

4. Where considering the ALARP principle, the most important risk level is the risk level in upper limit of ALARP region, i.e. lower limit of unacceptable region. This risk level means maximum allowable risk level. This, therefore, has the same meaning of absolute probabilistic risk criteria in deciding to approve the design or not.

5. The design team considers reduction in risk in ALARP region according to cost-effectiveness basis. According to circumstances, the approval team may refer the relative cost-effectiveness assessment result for review of risk control option.

6. In application to safety equivalency principle, the approval team and the design team are to consider the following through continuous mutual discussion.

(1) Selecting a similar design for criteria(including other industries)
(2) Type and estimation method of the compared risk
(3) Scope of the compared design and system

7. Risk acceptance criteria are to be defined separately as high level risks and low level risk and also

defined separately according to the type of risk. Therefore, risk acceptance criteria for high level and low level are defined separately and risk acceptance criteria for safety and environment are also defined separately. Each defined risk acceptance criteria may be different to each other or may be similar to or same as each other in some cases. ⚓

Annex 2 Form of Preliminary Approval Certificate

PRELIMINARY APPROVAL CERTIFICATE

Certificate No. : **Date of Approval :**

Product :

Designer :

THIS IS TO CERTIFY that the generic design of above-mentioned product has been evaluated and approved in accordance with the following Rules and Regulations ;

The evaluation has been based on the submitted technical documents. The approval condition is described on a separate document titled "Preliminary Approval Statement".

Issued at Busan, Korea on

KOREAN REGISTER OF SHIPPING

Approver

GUIDANCE FOR APPROVAL OF RISK-BASED SHIP DESIGN

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