



MARITIME SAFETY COMMITTEE 86th session Agenda item 5

MSC 86/5/3 9 February 2009 Original: ENGLISH

GOAL-BASED NEW SHIP CONSTRUCTION STANDARDS

Guidelines on approval of risk-based ship design

Submitted by Denmark

SUMMARY

Executive summary: This document contains a guideline for the approval process of

risk-based designed ships.

12 Strategic direction:

12.1.2 High-level action:

12.1.2.2 Planned output:

Action to be taken: Paragraph 16

MSC/Circ.1002; MSC.1/Circ.1212; MSC/Circ.1023-MEPC/Circ.392; Related documents:

> MSC 83/INF.2; MSC 83/21/1; MSC 83/21/2; MSC 83/21/INF.3; MSC 83/21/INF.8; MEPC 58/17/2; MEPC 58/INF.2; MSC 85/17/1;

MSC 85/17/2; MSC 85/INF.2 and MSC 85/INF.3

- The ongoing debate on goal-based standards at IMO may result in a new regulatory framework for shipping, which will then be applicable to rule makers. The goal-based standards will not be related to risk-based design and approval of individual ship designs. However, there are strong arguments for the development of a generic approach to GBS which would be in line with the philosophy of risk-based approaches in design and approval of ships.
- Presently, there are provisions in many IMO conventions for acceptance of alternatives to prescriptive requirements in many areas of ship design and construction which can pave the way for risk-based approaches to ship design and approval.
- 3 In the International Convention for the Safety of Life at Sea (SOLAS), 1974, as amended, there are general provisions for equivalents in regulation 5 of chapter I. Furthermore, the new regulation 17 of chapter II-2 provides a methodology for alternative design and arrangements for fire safety.
- 4 Recent amendments to SOLAS, adopted by resolution MSC.216(82), which will enter into force on 1 July 2010, provide similar methodologies for alternative design and arrangements of machinery and electrical installations (new regulation II-1/55) and for life-saving appliances and arrangements (new regulation III/38). Moreover, extended use of systems-, risk- and reliability analyses will be required in order to demonstrate fulfilment of the performance

MSC 86/5/3 - 2 -

standards for safe return to port of passenger ships required by new SOLAS regulations II-1/8-1, II-2/21.4, II-2/21.5.1.2 and II-2/22.3.1 – all related to the safe return to port agenda item – as adopted by resolution MSC.216(82).

- The International Convention for the Prevention of Pollution from Ships (MARPOL), regulation I/5, contains general provisions on equivalents similar to those found in SOLAS regulation 5 of chapter I. Furthermore, regulation I/19(5) provides for the acceptance of alternative oil tanker design provided that at least the same level of protection against oil pollution in the event of collision and stranding compared to prescriptive design is ensured.
- The International Convention on Load Lines (LL) contains provisions on equivalents (article 8) and approvals for experimental purposes (article 9).
- IMO has issued several guidelines on the analyses required by such regulations on alternative design and arrangements. MSC/Circ.1002 provides guidelines on alternative design and arrangements for fire safety, MSC.1/Circ.1212 provides guidelines on alternative design and arrangements for SOLAS chapters II-1 and III, and resolution MEPC.110(49) adopted interim guidelines for the approval of alternative methods of design and construction of oil tankers.
- MSC/Circ.1023–MEPC/Circ.392, with a consolidated text incorporating the amendments adopted by MSC 80 and MSC 82 contained in MSC 83/INF.2, provides guidelines for Formal Safety Assessment (FSA) for use in the IMO rule making process. A number of FSA studies that have been submitted to IMO have demonstrated the applicability of risk-based approaches in rule development, many of which have been based on work carried out within SAFEDOR (e.g., generic FSAs on LNG carriers, container ships, oil tankers, cruise ships and ro-ro passenger ferries). The FSA studies were performed to document the risk level of various standard ship types for future reference in risk-based ship design.
- 9 Thus, documentation related to risk-based design and approval of ships is available at IMO level, albeit somewhat fragmented.

Guideline for risk-based approval

- Alternative designs and approval are already made possible by existing IMO regulations. What has been missing is a unified process for the practical application of risk-based approval, applicable regardless of the type of project.
- 11 This document contains a guideline for an approval process dedicated to risk-based designed ships. The definition of 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.
- The guideline as set out in the annex is developed as a part of the outcome of the research project SAFEDOR, where the guideline already has been used and tested on risk-based design projects. The enclosed annex is intended for the use of both authorities and clients/design teams when confronting an approval process for a risk-based design. It serves to provide guidance on a variety of aspects requiring consideration when entering into the process. Furthermore it tends to be applicable in all areas of ship design and is not restricted to specific technical or regulatory areas.
- 13 The approval process as set out is a structured way of treating the various fragmented references throughout, e.g., SOLAS and MARPOL.

- 3 - MSC 86/5/3

- The guideline has already been put to use and may, in spite of the fact that it may require refinement at later stages, be applied for both ships, ship systems and subsystems on board.
- The Danish Maritime Authority has actively participated in the development of the approval process contained in the annex and applied it on a major conversion of a ship intended for offshore support functions where the intended use of the ship required solutions equivalent to prescribed requirements. The Danish Maritime Authority has concluded that the process provides a helpful tool when dealing with the approval of alternative designs and systems. Hence, the Danish Maritime Authority intends to apply the procedure in such cases.

Action requested of the Committee

The Committee is invited to consider the guideline set out in the annex and take action as deemed appropriate.

ANNEX

GUIDELINES ON APPROVAL OF RISK-BASED SHIP DESIGN

Table of Contents

I	Intro	duction	2
	1.1	Risk-Based Ship Design and Approval.	2
	1.2	Introduction to the Guidelines.	
	1.3	Application	4
2	Defir	nitions	6
3	High	-Level Approval Process for Novel and Risk-Based Design	9
	3.1	Steps in the High-Level Risk-Based Approval Process	10
	3.2	Communication between Approval Authority and Client/Design Team	18
4	Risk	Evaluation Criteria	
	4.1	High-Level Risk Evaluation Criteria	19
	4.2	Evaluation Criteria for Systems and Functions	
5	Docu	mentation Requirements	21
	5.1	Documentation	21
	5.2	Approval Matrix	23
	5.3	General Considerations	24
	5.4	Generic Design Description	28
	5.5	Definition of Approval Basis	32
	5.6	Analysis of Generic Design (including the HazId Report)	33
	Pr	reliminary Approval Statement with Conditions	34
	5.7		
	5.8	Description of Specific Design, Risk Assessment Report Review and Qualification Method	
	Descrip	tion	35
	5.9	Definition and Description of Detailed Requirements	38
	5.10	Statement of Approval of Design Basis	
	A	nalysis and Testing Reports/Additional Documentation	39
	5.11		39
	5.12	Issuance of Certificate of Approval with Conditions	39
6	Qual	ification Requirements	
7	Oper	ation of Risk-Based Designed Ships	45
	7.1	Requirements Pertaining to the Operation of Risk-Based Designed Ships	45
	7.2	Onboard Documentation	
	7.3	Inspections and Surveys	
	7.4	Change of Flag	
	7.5	IMO reporting	48
8	Refe	rences	51

1 Introduction

1.1 Risk-Based Ship Design and Approval

Methods of risk and reliability analyses gain more and more acceptance as decision support tools in engineering applications. Integration of these methods into the design process leads to risk-based design. Risk-based ship design is a new engineering field of growing interest to researchers, engineers and professionals from various disciplines related to ship design, construction, operation and regulation. Applications of risk-based approaches in the maritime industry started in the early 1960s with the introduction of the concept of probabilistic ship's damage stability. In the following decades, they were widely applied within the offshore sector and now they are being adapted and utilized within the ship technology and shipping sector.

1.1.1 Motivation for Risk-Based Design

- 1.1.1.1 Risk-based ship design is a methodology that integrates probabilistic and risk-based approaches in the design process of individual ship designs and ship system designs. In the following, both are designated as ship design. Ship design could be based on first principles to challenge areas where the traditional approach of prescriptive regulations based on empirical knowledge implies limitations to what design solutions are possible. Hence, risk-based design extends the conventional design space to include novel ship designs with the potential of offering benefits to the shipowner, the shipyard and the system supplier. Benefits could be that completely new ships and ship systems can now be realised or that conventional designs could be optimised cost-effectively.
- 1.1.1.2 Recently, there have been many incentives for accelerated innovations and the introduction of novel technologies in ship design and shipbuilding. This is a trend that is likely to persist. For example, persistently high fuel prices together with stricter regulations on emission from ships will motivate the development of new solutions for fuel saving and efficiency within shipping. This can for example be achieved through novel machinery technologies or by reducing weight by utilizing different materials in ship construction. Other motivating factors for innovations may be the need for new and modified designs to fulfil new operational requirements.
- 1.1.1.3 Innovations may also be required in order to meet new regulatory requirements in a cost-effective manner, e.g. the new requirements on damage stability and on the protection of cargo tanks may inspire to innovative design solutions. Innovative solutions may also be important in many other areas related to the efficiency, safety, security and environmental friendliness of ship operations.
- 1.1.1.4 Innovations will spur the interest in risk-based design as an alternative design philosophy within the maritime industries, as opposed to conventional design processes based on prescriptive solutions and empirical knowledge. A number of research and development projects have been initiated on this topic, involving many organisations representing all stakeholders of the maritime industry and focusing on the many aspects of risk-based ship design.
- 1.1.1.5 Another motivation for risk-based approaches is optimized ship design. Utilizing a risk-based approach, an existing ship design may be optimized beyond what would be possible through a conventional design process. Benefits from such optimised designs could be reaped in terms of increased safety, improved environmental protection, reduced cost, including increased payload during the operational life of the ship, or a combination of all or some of these.

1.1.2 Risk-Based Approval

- 1.1.2.1 Strict prescriptive regulations may restrain the level of innovation that is feasible in ship design and there are numerous examples of innovative solutions that have been effectively stopped by safety regulations. Hence, an essential prerequisite for widespread use of innovative and risk-based design is a predictable and reliable approval process for risk-based designed ships. Risk-based approval is the approval of such risk-based designed ships.
- 1.1.2.2 There may be different levels of risk-based approval dependent on how challenging the actual design is in light of prescriptive regulations. Novel solutions may deviate from prescriptive requirements related to certain components, systems or functions or the whole ship. Risk-based design and approval is expected to be carried out only for ship functions, systems or components that either directly or indirectly violate prevailing regulations as a consequence of causal dependencies on systems. Approval of designs with small deviations from conventional designs where equivalent safety may easily be demonstrated and handled within the current framework will not necessarily be considered by the complete risk-based approval process.
- 1.1.2.3 One approach to risk-based approval is to compare the innovative design to existing designs to demonstrate that the risk-based design has at least equivalent safety. In order to demonstrate equivalent safety, functional requirements for essential ship functions should be established, which are to be met by the risk-based design. An alternative approach could be to carry out a full risk analysis for the complete ship and compare it to overall risk evaluation criteria, but this will normally not be necessary other than in exceptional cases where many aspects of the ship design are innovative and challenge existing prescriptive rules and regulations.
- 1.1.2.4 Structured risk-based approval processes will be necessary in order to ensure that innovative ship designs can obtain the required approval along with the necessary certificates related to class and statutory requirements for their intended operation. The guidelines on risk-based approval presented herein describe such a structured process that is predictable and reliable and that will facilitate innovation and the use of risk-based approaches in ship design. Furthermore, by adhering to these guidelines it should be ensured that all aspects of safety and environmental protection of risk-based designed ships is adequately assessed and controlled to an acceptable level.

1.2 Introduction to the Guidelines

- 1.2.1 Currently, there are provisions in many IMO conventions for acceptance of alternatives to prescriptive requirements in many areas of ship design and construction, allowing for risk-based approaches to ship design and approval.
- 1.2.2 In the International Convention for the Safety of Life at Sea (SOLAS), 1974, as amended, there are general provisions for equivalents in regulations 5 of chapter 1. Furthermore, the new regulation 17 of chapter II-2 provides a methodology for alternative design and arrangements for fire safety.
- 1.2.3 Recent amendments to SOLAS, adopted by resolution MSC.216(82), which will enter into force on 1 July 2010, provide similar methodologies for alternative design and arrangements of machinery and electrical installations (new regulation II-1/55) and for life-saving appliances and arrangements (new regulation III/38). Moreover, extended use of systems-, risk- and reliability analyses will be required in order to demonstrate fulfilment of the performance standards for safe return to port of passenger ships required by new SOLAS regulations II-1/8-1, II-2/21.4, II-2/21.5.1.2 and II-2/22.3.1 as adopted by resolution MSC.216(82).
- 1.2.4 The International Convention for the Prevention of Pollution from Ships (MARPOL), regulation I/5, contains general provisions on equivalents similar to those found in SOLAS regulation 5 of

- 1.2.5 The International Convention on Load Lines (LL) contains provisions on equivalents (article 8) and approvals for experimental purposes (article 9).
- 1.2.6 The ongoing debate on Goal Based Standards at IMO may result in a new regulatory framework for shipping, which will then be applicable to rule makers. The Goal Based Standards will be rules for rules, and as such they will not be related to risk-based design and approval of individual ship designs. However, there are strong arguments for the development of a safety-level approach to GBS which would be in line with the philosophy of risk-based approaches in design and approval of ships.
- 1.2.7 IMO has issued several guidelines on the analyses required by such regulations on alternative design and arrangements. MSC/Circ.1002 provides guidelines on alternative design and arrangements for fire safety, MSC.1/Circ.1212 provides guidelines on alternative design and arrangements for SOLAS chapters II-1 and III, and resolution MEPC.110(49) adopted interim guidelines for the approval of alternative methods of design and construction of oil tankers. However, all these guidelines have in common that they provide only limited guidance with respect to the approval process of risk-based ship design.
- 1.2.8 MSC/Circ.1023 MEPC/Circ.392, with a consolidated text incorporating the amendments adopted by MSC 80 and MSC 82 contained in MSC 83/INF.2, provides guidelines for Formal Safety Assessment (FSA) for use in the IMO rule making process. A number of FSA studies that have been submitted to IMO have demonstrated the applicability of risk-based approaches in rule development.
- 1.2.9 Thus, documentation is available at IMO level related to risk-based design and approval of ships, albeit somewhat fragmented. In the following, an interpretation of the use of risk-based approaches in ship design and of risk-based approval is presented. This interpretation is applicable in all areas of ship design and is not restricted to specific technical or regulatory areas.
- 1.2.10 These guidelines are intended for the use of both authorities and client/design teams when confronting an approval process for a risk-based design and serve to provide guidance on a variety of aspects requiring consideration when entering into the process. This includes the process in general, shortlists of required documents and considerations hereto as well as assessments of necessary qualifications to complete the process successfully. In a final chapter on operation of risk-based ships or ship systems, a discussion of challenges and suggestions for necessary onboard documentation are provided.

1.3 Application

- 1.3.1 These guidelines are intended for application when approving risk-based ship designs in general and specifically according to the provisions given for alternative design and arrangements in applicable statutory regulations, e.g.:
 - SOLAS
 - Regulation I/5
 - Regulation II-2/17
 - New regulation II-1/55
 - New regulation III/38

- MARPOL
 - Regulation I/5
 - Regulation I/19(5)
- Load Lines
 - Article 8
- 1.3.2 The guidelines serve to outline the methodology for the risk-based approval process for which the approval of an alternative design deviating from prescriptive requirements is sought.
- 1.3.3 For approval of alternative designs for oil tankers according to MARPOL regulation I/19(5), it is noted that such concept designs are subject to approval in principle by the Marine Environmental Protection Committee (MEPC). This does not mean that the methodology and processes outlined in these guidelines are not applicable but in such cases the Approval Authority for the concept design will be the MEPC.
- 1.3.4 When applying these guidelines, a caveat is to be observed regarding substitution of design measures to reduce risk with operational or procedural measures. Normally, this is not permitted, and special care is taken in order to ensure that design measures take priority over operational or procedural measures.
- 1.3.5 For the application of these guidelines to be successful, all interested parties, including the Administration or its designated representative, owners, operators, designers and classification societies, are in continuous communication from the onset of a specific proposal to utilise these guidelines. This approach usually requires significantly more time in calculation and documentation than a typical design prescribed by regulation because of increased engineering rigor. The potential benefits include more options, cost-effective designs for unique applications and an improved knowledge of loss potential.

2 Definitions

For the purposes of these guidelines, the following definitions apply:

- 2.1 **ALARP.** ALARP (As Low As Reasonably Practicable) refers to a level of risk for which further investment of resources for risk reduction is not justified. When risk is reduced to ALARP, it is acceptable.
- 2.2 *ALARP area* refers to risks neither negligibly low nor intolerably high where a cost-benefit analysis is used to identify cost-effective risk control options.
- 2.3 Approval. Approval means that the Approval Authority issues an approval certificate as proof of verification of compliance with the regulations, standards, rules, etc. which are aimed at ensuring safety against hazards to the ship, personnel, passengers and cargo, and against hazards to the environment.
- 2.4 **Approval Authority.** Approval Authority is defined as a general term for the organisation responsible for the approval. It includes flag administrations, classification societies and other organisations approving ship designs and ship system designs. When the Approval Authority is a class society, it is important to note the distinction between the two roles it may assume: class society or recognized organization.

Note: For approval of alternative oil tanker design according to MARPOL I/19(5), it is noted that the Marine Environmental Protection Committee (MEPC) is the Approval Authority for the preliminary approval (referred to as approval in principle in MARPOL) of the concept design.

- 2.5 **Approval team.** For a specific application, the Approval Authority will in most cases set up an approval team. The team may include representatives from the flag administration, class society and other recognized organisations as relevant for the application.
- Client/design team. A design team acceptable to the Administration established by the owner, builder or designer, which may include, as the alternative design and arrangements demand, a representative of the owner, builder or designer and expert(s) having the necessary knowledge and experience in ship design, fire safety, and/or operation as necessary 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 (MSC. Circ.1002).
- 2.7 *Failure mode.* The observed mechanism or manner in which a failure can occur.
- 2.8 *FME(C)A*. Failure Mode, Effect (and Criticality) Analysis.
- 2.9 **GCAF.** Gross Cost of Averting a Fatality. A cost-effectiveness measure in terms of ratio of marginal (additional) cost of the risk control option to the reduction in risk to personnel in terms of the fatalities averted, i.e.

$$GCAF = \frac{\Delta Cost}{\Delta Risk}$$

2.10 *Generic Design.* Design developed for the design preview and the first analysis phase. The generic design is a high-level design taking into account the general arrangement, major systems, components, etc.

- 2.11 *HazId.* Hazard Identification, a process to find, list and characterise hazards.
- 2.12 *HazOp.* Hazard and operability study.
- 2.13 *NCAF*. Net Cost of Averting a Fatality. A cost-effectiveness measure in terms of ratio of marginal (additional) cost, accounting for the economic benefits of the risk control option to the reduction in risk to personnel in terms of the fatalities averted, i.e.

$$NCAF = \frac{\Delta Cost - \Delta EconomicBenefit}{\Delta Risk} = GCAF - \frac{\Delta EconomicBenefit}{\Delta Risk}$$

- 2.14 **Novel/new technology or design.** A new technology is a technology that has no documented track record in a given field of application, i.e. there is no documentation that can provide confidence in the technology from practical operations, with respect to the ability of the technology to meet specified functional requirements. This implies that a new technology is either:
 - a technology that has no track record in a known field,
 - a proven technology in a new environment, or
 - a technology that has no track record in a new environment.
- 2.15 **Preliminary approval/approval of generic design.** Preliminary approval is the process by which the Approval Authority issues a statement that a proposed concept design complies with the intent of the rules, regulations and/or appropriate criteria set by the Approval Authority even though the design may not be fully evolved. The preliminary approval is subject to a list of conditions that are addressed in the final design stage.
- 2.16 **Proven technology.** Proven technology has a documented track record in the field for a defined environment.
- 2.17 **Risk.** 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. (This can be either a quantitative or qualitative measure.)
- 2.18 **Risk analysis.** Risk analysis is the science of risks, their probability and consequence.
- 2.19 **Risk assessment.** 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.
- 2.20 *Risk evaluation criteria.* Risk evaluation criteria are formally recognized objective criteria defining the acceptable risk.
- 2.21 **Risk-based design.** 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.
- 2.22 **Risk control measure.** 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.
- 2.23 *Risk control option (RCO)*. A combination of risk control measures.

- 2.24 *Safety.* Absence of unacceptable levels of risk to life, limb and health (from non-wilful acts).
- 2.25 *Safety critical.* Containing an element of risk. Necessary to prevent a hazard.
- 2.26 **Safety equivalency.** Safety equivalency makes use of provisions other than the specific regulations with the purpose of achieving a safety standard or pollution prevention equivalent to (or higher than) the standard required by the regulations.
- 2.27 **Specific design.** Elaboration of the generic design. The specific design complies with the results of the generic analysis, e.g. with respect to risk control options already identified, and the requirements of the Approval Authority. The specific design is developed on the basis of the statement by the Approval Authority.

3 High-Level Approval Process for Novel and Risk-Based Design

The following process, illustrated in Figure 1, is intended to describe the procedure for obtaining and maintaining approval for designs that are novel or risk-based taking into account the client/design team and the Approval Authority. Even though the diagram in Figure 1 may suggest a strictly linear or sequential process, this is not the intention, and it is important to note that each step may be a series of iterations in a loop. As seen from Figure 1, the process, which covers concept development through operation, includes the following milestones:

- Approval of generic design/preliminary approval (if requested by the client/design team);
- Approval.

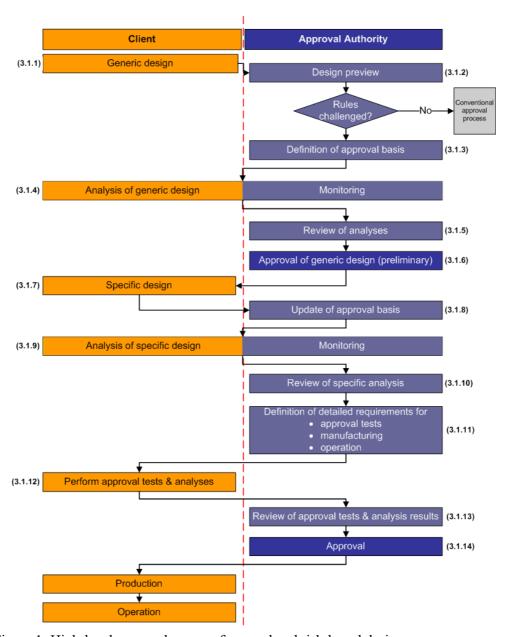


Figure 1: High-level approval process for novel and risk-based design

Clients often approach the Approval Authority early in the concept phase in order to seek input from experts and specialist opinions on a novel or risk-based concept — with the motivation of obtaining approval by the Approval Authority. Novel or risk-based design may include the entire concept of a ship, a system, a subsystem or an individual component. Furthermore, the needs of clients with respect to planning reliability may deviate significantly. Consequently, the details performed in each step of the approval process shown in Figure 1 may also deviate in the individual case. However, the basic process outlined in this document is generally applicable.

3.1 Steps in the High-Level Risk-Based Approval Process

- 3.1.0.1 In the following sections, the steps of the process for approving a novel or risk-based concept are outlined taking into account the roles of the Approval Authority and of the client/design team.
- 3.1.0.2 The novel or risk-based design approval process is different from the traditional approval process, and therefore the documentation process needs to be clear, transparent and well described to avoid misinterpretations. The results of non-traditional assessments need to be fully documented in a manner readily accessible to a third party. Documentation and the exchange of documents between the Approval Authority and the client/design team are highlighted in the description of the high-level risk-based approval process. A summary of the documentation and the exchange of documents between the parties is provided in section 5.

3.1.1 Generic Design

- 3.1.1.1 In the first step of the risk-based ship system approval process, the generic ship design is carried out by the client/design team. During the generic design phase, a draft of the system under consideration (ship or ship system) is developed, taking into account among other things general arrangement, components as well as the boundary conditions of the system, including physical boundaries and system interfaces.
- 3.1.1.2 The objective of this step is to develop a common level of understanding of the system sufficient to enable the subsequent tasks of the approval process to be carried out. The challenges of existing rules are identified by the client/design team. Draft requirements for the system under consideration and its components are defined. Furthermore, prior to the start of the project, a selection may be made of the appropriate terminology and semantics. The definition of the terminology and semantics used in the approval process avoids misinterpretation and thus increases the efficiency of the process.
- 3.1.1.3 The client/design team submits the generic design description addressing the above-mentioned aspects to the Approval Authority.

3.1.2 Design Preview

- 3.1.2.1 In the next step in the approval process, the client/design team may organise a design preview meeting in order to discuss the concept, the novel or risk-based features, relevant rules/guides/codes/standards as well as the further steps involved in the approval process.
- 3.1.2.2 The purpose of this meeting is to identify and describe items requiring special attention and to plan how these items are handled by the Approval Authority and client/design team with respect to approval.

- 3.1.2.3 The aim of the preview is also to decide whether the novel design challenges the prescriptive rules in such a way that a risk analysis is required. Crucial for this decision are the safety and environmental aspects as well as the requirements of the classification society. If the Approval Authority comes to the conclusion that there is no need of a risk-based evaluation, the supplier can follow the conventional approval process. The decision is to be transparently documented by the Approval Authority (for the purpose of objectivity). The decision whether the novel design requires a risk-based analysis may be supported by an evaluation of the degree of novelty as outlined above.
- 3.1.2.4 In order to gain an understanding of the novelty of the design, the categorization illustrated in table 1 (DNV, 2001) may be used. Technology in category 1 is proven technology where proven methods for classification, tests, calculations and analyses may be used. Technology in categories 2-4 is defined as new technology and may follow the procedure described in this report. The distinction between categories 2, 3 and 4 makes it easier to focus on the areas of concern. The objective of using the categorisation is to establish whether or not the design qualifies as a novel design and to gain a general understanding of the variation from proven designs. The categorization will also assist in defining the level of detail of the different analyses that will be required in the following phase.

		Table 1: Categorization	on of new technology	
		Technology status		
Applicati	on Area	Proven 1	Limited field history 2	New or unproven 3
Known	0	1	2	3
New	1	2	3	4

- 3.1.2.5 The design preview includes relevant people from the client/design team and professionals from the different disciplines (including risk assessment) within the Approval Authority.
- 3.1.2.6 Usually, the representatives of the Approval Authority who take part in the initial design preview meetings will also take part in the definition of the approval basis, will monitor the subsequent analyses and will be the ones that will follow the project until final approval since they are experts that build up a technical understanding of the concept.
- 3.1.2.7 During the design preview phase, the client/design team may be required to submit the following documents:
 - Description of novel or risk-based concept design;
 - Functional description;
 - Identification of interfaces between novel or risk-based concept and other systems/operations;
 - Preliminary general arrangement drawings;
 - Preliminary detail drawings, if required;
 - List of codes and standards applied;
 - Risk assessment plans;
 - Further design basis documents, if necessary.

3.1.3 Definition of Approval Basis

3.1.3.1 Following the design preview, the next step is for the Approval Authority to define the approval basis with respect to scope of analysis and evaluation criteria. In order to accomplish this, the Approval Authority and the client/design team may have to meet one or several times to discuss the

concept, its purpose and objectives, its novel or risk-based features, deviations from conventional approaches, relevant rules and regulations, possible deviations from or lack of rules and regulations, requirements that may not be covered by the rules, proposed operations and potential impact on other systems, components, etc. During this time, the novel or risk-based concept will have to be well understood. The client/design team and the Approval Authority may also discuss plans for hazard identification and risk assessments (including decision of which evaluation criteria to utilise) and plans for testing and analyses. The scope and extent of the analysis (either qualitative or quantitative analysis or only qualitative analysis) to be performed in the phase *analysis of generic design* is agreed between the client/design team and the Approval Authority considering the requirements of the client/design team with respect to the soundness of the preliminary approval.

- 3.1.3.2 The definition of evaluation criteria may be made in cooperation between the client/design team and the Administration (if not the same as the Approval Authority). If possible, the evaluation criteria may be derived from existing rules based on an equivalence assessment with respect to the intention of the specific rule and functional requirements. If this is not possible, evaluation criteria will typically be based on the principles of safety equivalence. In some cases, the client/design team proposing the novel/risk-based concept may have defined company wide risk evaluation criteria that may be met (typically companies within the offshore industry). In some cases, the client/design team has developed risk acceptance for a specific application. In cases of truly novel designs, it may not be possible to define the evaluation criteria early in the process, and therefore it is necessary to agree on the strategy for defining the evaluation criteria. Regardless of how the evaluation criteria are derived, the client/design team will need to document the risk criteria, the basis for the criteria selection, and how it fits in with the overall total risk.
- 3.1.3.3 Safety equivalence is an approach which offers the designer freedom with respect to alternative arrangements and equipment. Using safety equivalence to demonstrate compliance calls for provision of "a degree of safety not less than that achieved by using the prescriptive requirements." Depending of the field of application, the proof of compliance is generally supported by analyses that follow MSC Circ. 1002 or MSC Circ. 1212. The challenge of using safety equivalence is to define an equivalent design and its implicit safety. The safety equivalence approach is similar to the comparative risk assessment approach, in which a concept is compared to risk categorization of another system rather than to a specific criterion.
- 3.1.3.4 The risk assessment plan identifies appropriate types of assessment techniques. The plan clearly states the proposed risk evaluation criteria and the basis for the criteria.
- 3.1.3.5 The testing and analysis plan identifies appropriate types of test and engineering analyses. The plan is only a preliminary plan, as it will most likely be revised following the results of the analysis for the generic design (in the client/design team's "selection of qualification method" phase).
- 3.1.3.6 The work performed within this phase will result in a document issued by the Approval Authority describing the requirements and the formal process for achieving preliminary approval.

3.1.4 Analysis of Generic Design

3.1.4.1 The scope of this analysis is the generic design specified in the previous step of this process. At a minimum, a HazId is required to request for preliminary approval. It may be mentioned that the analysis of the generic design is a stepwise process monitored by the Approval Authority that may be terminated in case so-called showstoppers are identified.

- 3.1.4.2 The client/design team is responsible for facilitating all analyses agreed with the Approval Authority. It is highly recommended to invite Approval Authority representatives to attend the meetings to provide a close dialog between the Approval Authority and the client/design team in order to ensure that all relevant issues are taken into consideration. For the HazId the benefits of including Approval Authority representatives are:
 - The Approval Authority representatives will be able to point to issues relevant for approval that may be discussed.
 - The Approval Authority representatives may have expertise within certain areas of the novel or risk-based design and therefore may be able to contribute by drawing attention to issues that may unintentionally have been left out of discussions.
 - The amount of questions and misunderstandings will be reduced during the review of the HazId and in the overall approval process.
- 3.1.4.3 All novel or risk-based designs will be subject to a HazId requirement. That is, the client/design team will be required to arrange a HazId (or similar such as HazOp, FME(C)A, etc.), which is a structured brainstorming with the purpose of identifying all relevant hazards and their consequences and mitigating measures already included in the design. The HazId provides a unique meeting place for designers, engineers, operational and safety personnel as well as Approval Authority representatives to discuss the novel or risk-based concept and associated hazards. Typically, results of the qualitative analysis (HazId) will include the following:
 - Identified hazards associated with the novel or risk-based design;
 - Identified potential safeguards already included in the design.
- 3.1.4.4 The results of the HazId (HazId report) will be documented by the client/design team and submitted to the Approval Authority.
- 3.1.4.5 Depending on the scope defined by the client/design team and the Approval Authority, the generic design analysis might consider a risk assessment. Then, a risk model may be developed based on the HazId. The quantitative risk analysis may be carried out using specified risk evaluation criteria. The scope of the evaluation of risk control options depends on the outcome of the risk evaluation.
- 3.1.4.6 The scope related to the risk assessments will depend on the degree of novelty of the concept and the risk assessment plans defined at the previous stage. Typically, the risk assessments will include the following (which is also documented and submitted to the Approval Authority):
 - Ranking of hazards (identification of frequencies and consequences) and selection of hazards for risk model:
 - Development of a risk model in order to perform quantitative analyses;
 - Description of data references, assumptions, uncertainties and sensitivities;
 - Comparison of the risk levels with the evaluation criteria;
 - Identification of potential risk reducing measures;
 - Cost-benefit assessments in order to select the most appropriate risk reducing measures;
 - Description of selected risk reducing measures;
 - Re-evaluation of risk level taking into consideration the additional risk reducing measures and comparison with evaluation criteria;
 - Identification of issues that may require further analyses and testing;
 - Identification of issues that may require special attention with respect to operations, accessibility and inspections.
- 3.1.4.7 The risk model may be developed using fault tree analyses, event tree analyses, Markov models, Bayesian networks, structural reliability analyses, etc. Description of the proposed qualitative and quantitative methods as well as the objectives, scope and basis of the assessments may be included in the risk assessment plan submitted at the time of *definition of approval basis*.

3.1.4.8 The work performed related to risk assessments will be documented by the client/design team and submitted to the Approval Authority. Eventually, the risk assessments will be included as the basis for approval.

3.1.5 Review of Analysis for Generic Design

- 3.1.5.1 The HazId will be formally reviewed by the Approval Authority to ensure that the:
 - Team is qualified;
 - Standard procedures for HazIds (e.g. IMO FSA guidelines) are followed;
 - Identified hazards are ranked.
- 3.1.5.2 The HazId will further increase the understanding of the novel or risk-based features, and the list of requirements will be revised based on the findings from the HazId.
- 3.1.5.3 The risk model and the results of the evaluation will be formally reviewed by the Approval Authority. If the risk evaluation criteria cannot be fulfilled even with the implementation of risk control options, the approval process may be terminated at this point or may be restarted with a modified design.
- 3.1.5.4 Any risk control measures that may have been considered in the generic design will be formally reviewed by the Approval Authority.

3.1.6 Preliminary Approval

- 3.1.6.1 Typically, the client/design team will seek a statement from the Approval Authority (preliminary approval). The purpose of the preliminary approval is to verify that the design concept is feasible and acceptable. The preliminary approval may therefore not be granted until all hazards and failure modes related to the design are identified and until control (or plans for how to achieve control) of these hazards and failure modes are demonstrated. The following conditions are satisfied when granting preliminary approval:
 - There should not exist any "showstoppers" (if so a re-evaluation of the concept phase and possibly concept improvement may be carried out);
 - The design is found feasible and suitable for its expected application.
- 3.1.6.2 The preliminary approval enables the client/design team to demonstrate that an independent third party attests to the novel or risk-based design. Such a preliminary approval may be useful with respect to project partners, financial institutions and regulatory agencies. The preliminary approval may also assist the client/design team in staying focused on the most important issues.
- 3.1.6.3 The basis for preliminary approval may consist of:
 - A description of the concept, its specifications, its functional requirements, its operation and maintenance, health, safety and environmental issues, its interface with other systems, etc.,
 - Preliminary drawings,
 - Specifications of codes and standards applied (including specification of the applicable classification rules or part of rules),
 - Specification of the applicable administration requirements,
 - Hazard identification results,
 - Risk assessment plans or results of risk assessment for generic design,
 - Testing and analyses plans,
 - Special requirements for the project,
 - Description of the approval process.

- 3.1.6.4 The preliminary approval is to be issued with a set of conditions outlining the requirements and necessary steps the client/design team needs to satisfy in order to achieve approval. It will also include a list of documents required (section 5) to be submitted in order to achieve approval. The submittals typically cover completion of project description, specifications and drawings as well as outstanding reports documenting risk assessments, tests and analyses.
- 3.1.6.5 It may be noted that the issue of statement by the Approval Authority does not imply that final approval will be granted. However, at this stage, the underlying analyses (e.g. the risk analysis) may define the basis for design, sometimes referred to as the design basis or the design specification. This may be approved by the Approval Authority at this point so that the client/design team can bring them into technical discussions and contract negotiations.

3.1.7 Specific Design

- 3.1.7.1 Following the preliminary approval, the client/design team will advance into the next phases of the project, involving specific design and subsequently required risk assessments, testing and analyses. These phases are more detailed versions of the phase prior to preliminary approval. It will result in an increased understanding of the novel or risk-based design features, and both the client/design team and the Approval Authority will gain confidence in the design as the level of accuracy increases.
- 3.1.7.2 The objective of this step is to elaborate the generic design to a corresponding specific design. This specific design complies with the results of the generic analysis with respect to risk control options already identified and the requirements of the Approval Authority. The detailed design is developed on the basis of the statement by the Approval Authority.

3.1.8 Update of Approval Basis

As previously discussed, the preliminary approval is issued with a set of conditions outlining the requirements and necessary steps the client/design team should satisfy in order to achieve approval. Following the client/design team's specific design phase and the risk assessment of the generic design, the level of understanding of the concept has increased. The preliminary approval conditions may be revised as a consequence. That is, the requirements to be met in order to achieve approval will be described in more detail. In addition, as the client/design team is in the process of selecting testing and analysis methods, the Approval Authority will have an opportunity to influence and potentially specify explicit requirements for this selection.

3.1.9 Analysis of Specific Design

3.1.9.1 The tasks to be performed in this analysis phase are similar to the analysis of the generic design. In a first sub-step, a review of the analysis of the generic design is performed to determine the difference between generic design and specific design in order to specify the scope of the analyses that have to be considered in this phase. Thus, this analysis phase may contain an update of the HazId, a quantitative risk analysis and risk evaluation. There is a close dialog between the Approval Authority and the client/design team with respect to the risk assessment. In some cases, it is necessary that a representative from the Approval Authority participate in some of the meetings and/or workshops (e.g. workshops with the purpose of obtaining expert opinions) in order to ensure that all relevant issues are taken into consideration. The Approval Authority representative may be an expert within respective areas of the novel or risk-based design and qualitative and quantitative risk assessment.

- 3.1.9.2 The requirements related to the risk assessment of the specific design will be based on the novelty of the design, the risk assessment plans defined for the previous phase and the differences between the generic and the specific design. Typically, the risk assessment will address the following:
 - Identified hazards associated with the novel or risk-based design (update of generic analysis);
 - Identified potential safeguards already included in the design;
 - Identification of frequencies and consequences associated with the hazards, and the resulting risks:
 - A risk model in order to perform quantitative analyses;
 - Description of data references, assumptions, uncertainties and sensitivities;
 - Comparison of risk levels with evaluation criteria;
 - Identification of potential risk reducing measures;
 - Cost-benefit assessments in order to select the most appropriate risk reducing measures;
 - Description of selected risk reducing measures;
 - Re-evaluation of risk based on the additional risk reducing measures and comparison with evaluation criteria;
 - Identification of issues that may require further analyses and testing;
 - Identification of issues that may require special attention with respect to operations, accessibility and inspections.
- 3.1.9.3 The work performed related to risk assessments will be documented and submitted to the Approval Authority in order for the Approval Authority to stay informed of the processes and to intervene, if necessary. Eventually, the risk assessments will be included as the basis for approval.

3.1.10 Review of Analysis for Specific Design

All results of the analyses for the specific results will be reviewed by the Approval Authority.

3.1.11 Definition of Detailed Requirements

Detailed requirements will be defined for the novel design by the Approval Authority and the client/design team on the basis of the quantitative risk analyses in order to achieve approval. These requirements address the following topics:

- Approval tests: testing and analysis methods required to confirm assumptions used for the quantitative risk analysis.
- Manufacturing: level of quality control during manufacturing and installation,
- Operation: operational boundary conditions and maintenance, including definition of operation and maintenance procedures, as well as data acquisition and assessment during operation.

3.1.12 Perform Approval Tests and Analyses

- 3.1.12.1 If required, further engineering analyses are used to verify that the design is feasible with respect to intentions and overall safety in all phases of operation. That is, the analyses and tests will ensure that the novel or risk-based design will meet expectations from a functional and safety point of view. The engineering analyses are performed by the client/design team. Models used for the analyses, input data and results are documented and submitted to the Approval Authority for review.
- 3.1.12.2 The types and extent of the analyses and tests required depend on the technology type, confidence in analyses and the extent of experience with similar concepts. While the objectives of the analyses are primarily to verify function and reliability, additional objectives of the tests are also to obtain data for analyses and verify the results obtained from analytical methods (DNV, 2001). The analyses and tests are meant to demonstrate additional safety margins compared to target limits defined in the design

basis. The tests are performed in accordance with the requirements specified under 3.1.11. The Approval Authority may survey these tests with experts within the test areas.

- 3.1.12.3 Submittals required with respect to the analyses and tests include:
 - Statements of relevant codes and standards applied and deviations made to their application;
 - Selection of appropriate evaluation criteria used to assess the design;
 - Design calculations;
 - Analyses reports (including objectives, scope, assumptions, results, conclusions and recommendations);
 - Test reports, including descriptions of modelling/test set-up, as well as test objectives, scope, results, analyses, conclusions and recommendations;
 - Error and uncertainty discussions.

3.1.13 Review of Approval Tests and Analyses

The Approval Authority needs to review both the manner in which the analyses and tests are performed and the result itself. The results of the analyses and testing need to fulfil the test purpose and scope previously defined in the analysis and test plan. Typically, the Approval Authority does not need to monitor and participate in the execution of analyses and tests performed in the previous step; however, the attendance of an Approval Authority representative may be considered in each case.

3.1.14 Approval

- 3.1.14.1 The Approval phase will cover typical approval submittals, such as drawings, specifications, and support documentation, in addition to the submissions specified at the time of achieving preliminary approval.
- 3.1.14.2 At the time of approval, all potential hazards and failure modes for the novel or risk-based design will have been assessed versus evaluation criteria, to a level of confidence necessary to grant approval.
- 3.1.14.3 In most cases, approval of novel and risk-based design will involve conditions related to inservice surveys, inspections, monitoring, and possibly testing. In most cases, the conditions will be fixed already during the design phase. The periodic surveys may be extended with respect to scope and frequency in order to maintain and review the class certificate. As experience accumulates and confidence in the novel or risk-based design is gained, these additional conditions and requirements may be relaxed.
- 3.1.14.4 Following approval, in the construction and in-service phase the Approval Authority needs assurance that knowledge related to the novel or risk-based features is fed into the quality control process. In order to achieve this, communication between the approval team and the survey team is strongly encouraged.
- 3.1.14.5 All documents and drawings required to be submitted by the client/design team are verified by the Approval Authority. This process is the same as for traditional ship design approval processes. For novel or risk-based features, the documents and drawings are to be approved based on requirements defined in the preliminary approval and the detailed requirement phases.

3.2 Communication between Approval Authority and Client/Design Team

Throughout the approval process, continuous communication between the Approval Authority and the client/design team is important. As seen from the discussions in Chapter 3, the process requires the Approval Authority and the client/design team to work together on a number of occasions:

- **Design preview:** In order to decide whether the novel design requires observance of the approval process as outlined in this document or whether a conventional approval process can be followed, the Approval Authority and the client/design team will have to meet and discuss the generic design developed by the client/design team.
- **Definition of approval basis:** In order to define the approval basis, the Approval Authority and the client/design team will need to meet one or several times to discuss the concept, applicable codes/standards/rules/etc., plans for risk assessments (including decision of which evaluation criteria to utilise) and plans for testing and engineering analyses. The definition of evaluation criteria may require additional meetings with the relevant administration to discuss and evaluate the selected criteria.
- Monitoring of analysis of generic design: The Approval Authority may participate in the HazId, which is mandatory for all novel and risk-based designs. Furthermore, if a risk assessment and an identification of risk control options are agreed between the Approval Authority and the client/design team, the Approval Authority may monitor the activities of the client/design team.
- Review of analysis of generic design: The Approval Authority reviews the results of the analyses for the generic design.
- **Approval of generic design:** The preliminary approval will be given with a set of conditions that are to be met to achieve full approval. The Approval Authority and the client/design team need to arrange a meeting to discuss the steps forward in the process.
- **Update of approval basis:** In order to consider the results of the analyses performed for the generic design and the information provided by the specific design in the further risk analysis process, the approval basis is updated.
- Review of analysis of specific design: The Approval Authority reviews and eventually evaluates the necessary risk assessments necessary to satisfy the conditions outlined in the approval for the generic design.
- **Definition of detailed requirements:** There may be arranged for a meeting to discuss specific design and results from risk assessments and to further detail and revise the conditions given together with the approval for the specific design.
- Review of approval tests and analyses: The client/design team submits the required documentation and evidence of the testing and analyses to the Approval Authority. Whether or not a meeting is required depends on the complexity of the testing and analyses.
- Approval: The certificate may be issued with some additional conditions assigned, such as additional survey scope and frequency, condition monitoring, or requirements related to maintenance and inspection. Of course, there will also be a meeting between the Approval Authority and the client/design team when issuing the approval certificate. For receiving the approval, additional documents and drawings are submitted to the Approval Authority without any meeting (unless found necessary).

4 Risk Evaluation Criteria

In order to facilitate risk-based approval of novel designs or novel systems, there is a need for different risk evaluation criteria, sometimes also referred to as risk acceptance criteria or risk tolerability criteria. The actual approval process may be considered independent from the risk evaluation criteria and the criteria may be derived from high-level goals independent of the actual design or system that seeks approval.

4.1 High-Level Risk Evaluation Criteria

- 4.1.1 High-level risk evaluation criteria may at least cover the risk to human life, including injuries and ill health, and the risk to the environment. Other types of risk could also be covered, as appropriate for the design or system in question. Different criteria for each type of risk could also be employed and typically the following risk evaluation criteria are needed:
 - Criteria for individual and societal risk;
 - Criteria for risk to crew, passengers and people ashore, as appropriate;
 - Limits between negligible, ALARP area and intolerable levels of risk;
 - Cost-effectiveness criteria defining when risks are considered ALARP.
- 4.1.2 A thorough review of existing risk evaluation criteria was presented by Skjong et al. (2005). This included a review of different approaches to establish limits between the ALARP area and negligible and intolerable levels of risk to human life and cost-effectiveness criteria for risks to human life as well as a new approach to cost-effectiveness criteria for environmental protection against oil spills.
- 4.1.3 The revised IMO guidelines on Formal Safety Assessment in IMO contain two appendices that discuss risk evaluation criteria and also propose GCAF and NCAF criteria for cost-effectiveness. Risk evaluation criteria are also addressed in Norway (Norway, 2000). Such criteria may have to be updated from time to time and are therefore kept separate from these guidelines. However, the importance of having adequate risk evaluation criteria in place when performing risk-based approval of ship designs and systems is emphasized.

4.2 Evaluation Criteria for Systems and Functions

- 4.2.1 Risk-based design is an alternative to the present prescriptive rules, replacing the actual design regulations by goals and functional requirements. The risk-based ship system approval process requires suitable evaluation criteria. These criteria may be defined for the overall ship level, but also for specific ship functions. For the risk-based design of a specific ship system, evaluation criteria for this system may be provided. The relation between the overall risk and the risk contribution of a specific system is defined by the risk model and the risk analyses that have been performed as part of the risk-based design and approval process.
- 4.2.2 Based on the ALARP principle, a general procedure for how to derive risk evaluation criteria for ship functions may be described as follows:
 - Develop a risk model, including all scenarios that are affected by the function in question;
 - Use the decision criteria for cost-effectiveness for the function in question;
 - Derive the target reliability or availability by cost-effectiveness criteria;
 - Use this optimum reliability (or availability) as a target for the function that is analysed.

This procedure is a simplified FSA limited to the relevant function and it is implicitly assumed that the risk level is in the ALARP area, rendering cost-effectiveness criteria applicable.

- 4.2.3 It may be noted that risk evaluation criteria derived in this way may not be dimensioning for the function in question, e.g. if purely commercial considerations impose stricter requirements.
- 4.2.4 Examples of functional risk evaluation criteria that have been derived from high-level criteria can be found in the literature, e.g. in Hørte et al. (2007), Rüde and Hamann (2008) and IACS (2006). These are referred to in these guidelines as illustrative examples, and it is emphasized that adequate risk evaluation criteria may always be used, at all relevant levels, in risk-based approval of ship designs and systems.

5 Documentation Requirements

5.1 Documentation

- 5.1.1 The novel or risk-based design approval process is different from the traditional approval process, and therefore the documentation process needs to be clear, transparent and well described to avoid misinterpretations. The results of non-traditional assessments need to be fully documented in a manner readily accessible to a third party.
- 5.1.2 As illustrated in Figure 2, documentation of a novel or risk-based design may comprise but is not limited to the following:

5.1.2.1 From client/design team to Approval Authority:

- Design documents:
 - Description of novel or risk-based concept;
 - Functional description;
 - Identification of interfaces between novel or risk-based concept and other systems/operations;
 - Preliminary general arrangement drawings;
 - Preliminary detail drawings of subsystems;
 - List of codes and standards applied;
 - Risk assessment plans;
 - Testing and analysis plans;
 - Further design basis documents, as necessary;
- Analysis reports for assessment of generic design:
 - Identified hazards;
 - Safeguards included in the design;
 - Evaluation criteria;
 - Frequencies and consequences associated with the hazards and resulting risks;
 - Risk models;
 - Data references, expert judgements, assumptions, uncertainties and sensitivities;
 - Cost-benefit assessments;
 - Selected risk reducing measures;
 - Issues that may require further analyses and testing;
- Issues that may require special attention with respect to operations, accessibility and inspections;
- Description of specific design (including revisions to "concept design description" submittals);
- Analysis reports for assessment of specific design including information regarding:
 - As specified for assessment of generic design;
- Analyses and testing reports including information regarding:
 - Statements of relevant codes and standards applied, and deviations made to their application;
 - Selection of appropriate evaluation criteria used to assess the design;
 - Design calculations;
 - Analyses reports (including objectives, scope, assumptions, results, conclusions and recommendations):
 - Test reports, including descriptions of modelling/test set-up, as well as test objectives, scope, results, analyses, conclusions and recommendations;
 - Error and uncertainty discussions;
- Design specifications:
 - Underlying analyses, testing and calculations that define the basis for design;

 Additional documents and drawings – including final general arrangement drawing and final detailed drawings of subsystems.

5.1.2.2 From Approval Authority to client/design team:

- Description of approval requirements and process;
- Preliminary approval statement with conditions;
- Description of detailed requirements;
- Statement of approval of design specifications;
- Certificate with conditions.

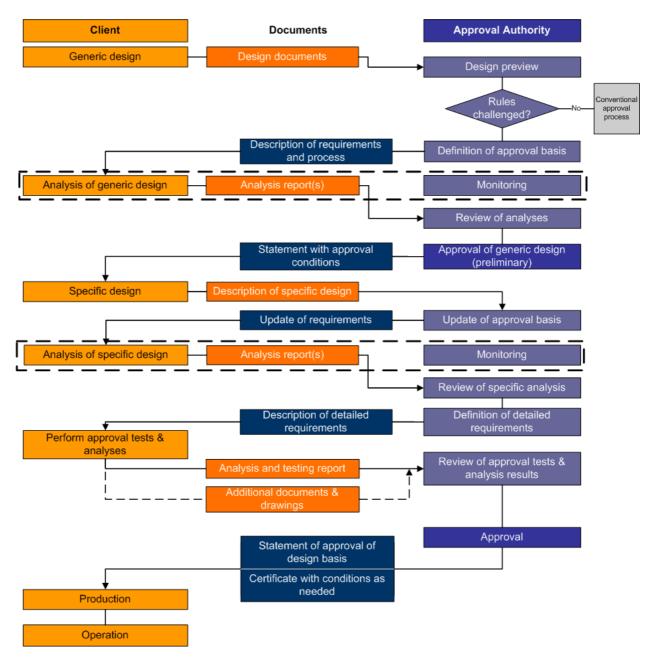


Figure 2: Documentation flowchart for the approval procedure

This section of the guidelines addresses the requirements for documentation in the approval process, as indicated in Figure 2. The documentation that is required to be exchanged between the Approval

Authority and the client/design team in the approval process of a risk-based design is summarized in Figure 3, and this chapter of the guidelines outlines requirements pertaining to this documentation.

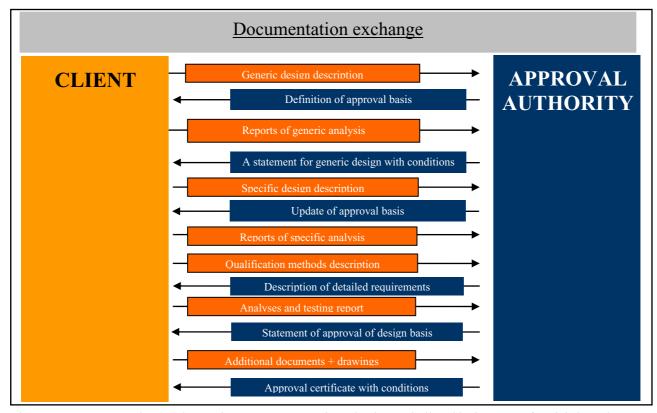


Figure 3: Documentation exchange between Approval Authority and client/design team for risk-based approval

5.2 Approval Matrix

A matrix as shown in Table 2 may be applied for guidance to the client/design team when performing preliminary estimates on the extent of work to be performed and submitted for approval. The matrix has two axes: one referring to the level of novelty in the design (project category); the other referring to requirements in the risk assessment and to the amount of documentation (row A-E). The level of novelty may be determined by means of Table 1. The following paragraphs are explanatory notes to the approval matrix.

5.2.1 Header Row: Project Category

In order to rank the novelty of a design, the categorization from Table 1 may be used.

5.2.2 Row A: Basic Risk Assessment

This row contains information on description of hazards to individuals, arising from a specific setup or operation. Reference can be made to existing practice; hazards are ranked in qualitative terms.

5.2.3 Row B: Further Analysis Requirements

- 5.2.3.1 Due to the difference in complexity in the various ship designs, differentiation in the documentation requirements is required.
 - Semi-quantitative risk assessment: A qualitative or quantitative estimate of frequency and consequences of an activity or operation. Scenarios are described and categorized according to their probability and impact. Elements are prioritised by using frequency and severity indices in MSC 83/INF.2 or similar...
 - Quantified risk assessment: A description of frequency and consequence of defined hazards (usually to a well defined group of people) through a specific operation or activity. The risk levels are represented numerically to be compared with agreed criteria. Varying levels of detail in the quantitative risk assessment may be required.
- 5.2.3.2 If a qualitative risk assessment describes and suggests reduction of risks to a satisfactory level, then requirements for quantitative assessments may be redundant.

5.2.4 Row C: Qualifications of Analysts

The client/design team will to a certain extent be able to perform or contribute to a basic risk assessment by means of own qualified personnel. In-depth analysis, however, may require specific expertise in the field.

5.2.5 Row D: Applied Rules and Guidance:

This element reflects the various sources of regulation and guidance on specific requirements in the individual case.

5.2.6 Row E: Potential Additional Tests, Surveys and Compliance Control

This addresses anticipated follow-up activities after construction.

5.3 General Considerations

In the following, general issues and procedural considerations are dealt with. Prevalently, the responsibility for ensuring documentation quality rests with the client/design team. A party wishing to enter into the approval process may therefore preferably operate safety and quality management systems to own processes as well as subcontracted processes, as this substantially supports a controllable documentation. 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:

- project title
- responsible person(s)
- scope statement/project description
- project identification number
- distribution list

- authorization signatures
- date
- revision number/letter
- other controlling documents/processes if necessary

Table 2: The approval matrix

	Project Category	Known application of proven technology (conventional process)	Known application of a technology with a limited field history/New application of proven technology	New application of a technology with a limited field history/Known application of a new or unproven technology	New application of novel or unproven technology	Activity performed by:
Redu	Requirements	(1)	(2)	(3)	(4)	
4)	Basic risk assessment	Not required	Required (unless rule challenge deemed insignificant or of negligible impact on safety and environment)	Required	Required	Client/design team (yard, supplier)
_ B)	Further analysis requirements	Not required	Depending on basic risk assessment outcome. Hazards medium or high, if any, may be examined further, at least by semiquantified analysis	Semi-quantified assessment. All hazards medium and high may be examined by means of quantified analysis	Quantified risk assessment to all risk contributions (due to the novelty of the design, it may not be possible to rank such hazards credibly. Hence, all may be examined in depth)	Client/design team in cooperation with the AA
6	Qualifications of analysts	N/A	Operational experience General knowledge of risk assessment techniques	Operational experience. In-depth experience with risk assessment. Some knowledge of analysis techniques	Operational experience Risk assessment and analysis experts	N/A
(a	Applied rules and guidance	Existing prescriptive rules (SOLAS, MARPOL, relevant codes, national, regional and international legislation, prescriptive class rules)	Existing prescriptive rules where no rule challenge prevails (SOLAS, MARPOL, relevant codes, national, regional and international legislation, prescriptive class rules) applicable standards if available from other industrial sectors, class guidance on risk-based approval as applicable	IMO circulars on alternative arrangements, class guidance on risk-based approval, other relevant industry standards	IMO circulars on alternative arrangements, class guidance on risk-based approval	N/A
<i>E</i>)	Potential additional tests, surveys and compliance control (after commissioning)	As per Safety Management System (SMS) and existing regulation	Internal surveying. Additional review at safety related events subject to recording and corrective action	Internal/external surveying, recording and additional intermediate surveys of riskbased features, if deemed necessary	Continuous monitoring and review subject to reporting to the AA until a sufficient level of experience is gained	Client/design team (operator)

I:\MSC\86\5-3.doc

25

5.3.1 Drawings and Layouts

- 5.3.1.1 Any design detail deviating from conventional best practice should be presented comprehensively to facilitate a full understanding of the extent of the novel type equipment or detail.
- 5.3.1.2 Safety critical details will always have to be documented.

5.3.2 Design Parameters

All parameters applied to the design process should be explicit. Processes may be presented as diagrams or described in prose. The method (how) and stage (when) of application should be clear from the description.

5.3.3 Requirements for Risk Control Measures

- 5.3.3.1 Risk control measures are usually identified during the risk assessment phase. Identified risks will usually be categorised to belong to three categories: intolerable risks which should be reduced irrespective of costs, negligible risks which do not require any action, and risks in the ALARP area which may be reduced to ALARP with cost-effective risk control options (MSC 83/INF.2).
- 5.3.3.2 Adopted risk control options should be cost-effective, and sensitivity tests to document this may be required before the options are agreed upon.
- 5.3.3.3 If several possible options can efficiently reduce the same risk, the passive options, which are usually more verifiable and reliable, should be chosen. As a majority of incidents are strongly influenced by human error and operational faults, the team may seek solutions that minimize potential human error, if at all viable and cost-efficient. Therefore, passive measures are generally preferred over active measures.
- 5.3.3.4 If such measures are operational, though, then their implementation into management systems should be documented, and it may be ensured that the crew is informed of such special measures.
- 5.3.3.5 When evaluating the cost-efficiency of measures, both the lowest cost estimate and the highest cost estimate may be part of the evaluation. The calculations should be available in a transparent format for evaluation. Sources of cost estimates should be documented.

5.3.4 Reporting Formats

- 5.3.4.1 The documentation of the project prerequisites, any assumptions and exclusions made, the HazId, the risk assessment, the cost-benefit analysis, recommendations and conclusions as per mentioned process may take several forms, all with their own advantages and drawbacks, such as:
 - PC based work sheets and documents;
 - Paper reports;
 - Programs tailored to the purpose.
- 5.3.4.2 Regardless of the format, given the prerequisite that the content is verifiable, any format applied may deliver the information required. Also, as the HazId and ensuing conclusions will be reviewed during follow-up meetings, means of document control should be applied to ensure that only controlled versions of the information yielded are distributed.
- 5.3.4.3 These requirements take a parallel approach to the international standard on risk assessment for machine safety (ISO, 2007), being non-prescriptive on the type of risk assessment technique applied,

provided it yields a comprehensive picture of all risks inherent and of their satisfactory reduction in a consistent and credible manner.

5.3.5 Calculation/Analysis Requirements

- 5.3.5.1 When making decisions based on analysis techniques, care may be taken to evaluate their adequacy. This requires expertise on various types of risk assessment methods to ensure that the most suitable will be selected for the application in question. As is deductible from prior elaborations, the level of novelty/rule challenge is variable and, depending hereon, the most applicable methodologies may also vary.
- 5.3.5.2 Below are nine reminders when performing in-depth risk analyses:
 - 1. Apply best industry practice and be consistent with IMO FSA guidelines when selecting risk assessment techniques;
 - 2. Perform a generic high-level assessment of the design type for which approval is sought;
 - 3. Ensure that the specific risk assessment (based on the generic high-level assessment) meets the requirements for methodology and depth level specified by the Approval Authority;
 - 4. Ensure that the applied model reflects the as built and operated ship or system as accurately as possibly viable. If necessary, the process is to be conducted iteratively, as the design process progresses, to ensure that any previously un-described safety critical aspects are covered;
 - 5. Apply assumptions on a sound basis and apply frequency and consequence analyses based on relevant and consistent data;
 - 6. Check for consistency between the level of detail in the assessment and the assumed risk control measures and the system safety testing and -management program (programmed maintenance, safety management systems), especially if such assumed control- or mitigating measures are of an operational character;
 - 7. Include internal and external events in the analysis (events to persons voluntarily entering into an area of risk, societal risk):
 - 8. Include normal operative states as well as states of emergency in the analysis;
 - 9. Include sensitivity analysis, uncertainty analysis and importance measures.

5.3.6 Errors and Uncertainties

- 5.3.6.1 To be able to compute or determine the different parameters which are to be applied in the risk analysis or which are found in any form of design equation, it is necessary to have access to various types of data.
- 5.3.6.2 Uncertainty reflects either lack of knowledge about the actual value of a variable (epistemic uncertainty) or variability to which the parameter is subject (aleatory uncertainty). The latter implies random variation, which remains unpredictable. In standard risk assessment methods, however, uncertainties involved can be accounted for within the method (e.g. conservative assumptions), even if this is not always explicit. For structures, however, the treatment of uncertainties is done explicitly and included in the analysis according to well defined standards ISO (1998), EUROCODE (2002).
- 5.3.6.3 A number of questions may arise during the approval process, such as:
 - What is the character of the reference design or system?
 - What event sequence would be most likely to occur?
 - What is the worst case scenario?
- 5.3.6.4 No absolutes may be stated to answer such questions, as results will often be derived from the use of expert judgement in the HazId.

- 5.3.6.5 Although uncertainty on variables may be considerable, estimates of expected values are possible. Therefore it may be sensible to choose a reasonable estimate reference. At all times choosing a value implying the worst conceivable consequences would yield an exaggerated picture of the risks involved.
- 5.3.6.6 To examine the impact of a particular variable on the final result, a sensitivity analysis should be carried out, where the effect of for example doubling the size of the variable may be examined to decide whether the selected values are conservative enough.
- 5.3.6.7 Hence the following matters which may require investigation at any given stage require consideration:
 - variation in the input data;
 - the impact of simplification of problems;
 - the effects of various aspects of the scenario;
 - the reliability of the technical system.
- 5.3.6.8 Variables which are found to have a major impact in the sensitivity analysis may justify a more conservative approach than variables of lesser importance. The sensitivity analysis may indicate the variables of major impact and how uncertainties of such variables are handled.

5.4 Generic Design Description

A concept design description comprises the material available on the design, including any risk-based features, describing the project to the extent possible in the initial phase, as follows. Such a description comprises many elements which are of importance in relation to the understanding of the approval procedure. Thus, when submitting a concept design description, the issues described in the following may be identified and documented. This section provides guidance on documentation to be submitted as well as considerations by the Approval Authority upon receipt. Documentation on every quoted item is dealt with separately below.

5.4.1 Procedural Intent, Initial Considerations

5.4.1.1 Description of Novel/Risk-Based Concept Design

High-level description of the design submitted for approval, including the documentation quoted in the documentation section.

5.4.1.2 Functional Description

The scope of the design in operation must be described in detail.

5.4.1.3 Identification of Interfaces between Risk-Based Concept and Other Operations

This applies only to project categories 2-4, Table 2. The description comprises interfaces between a novel electronic feature or machinery subsystem and conventional systems, interactions deemed to take place in a novel context, or a novel type of safety or lifesaving equipment operated from a conventional ship.

5.4.1.4 Design Approval Basis Documents

The design approval basis documents outline how initial owner requirements are met and provide information on tools applied, statements of preliminary tests/simulations performed, and ensuing decision support processes.

5.4.1.5 Preliminary General Arrangement Drawing

Provides an overview with dimensions of the project (identical to conventional process).

5.4.1.6 Preliminary Detail Drawing of Subsystems

Provides an overview of the systems and their function within the ship (identical to conventional process).

5.4.1.7 List of Codes and Standards Applied

The list of codes and standards applied is needed for transparency. If ambiguity exists on the applicability of any codes and standards adhered to, statements of further intended examinations to document applicability of such standards or intentions of testing to marine codes or standards may be submitted with the documentation as per below.

5.4.1.8 Risk Assessment Plans

This applies only to project categories 2-4, Table 2. This describes risk assessment as deemed necessary by the client/design team at the concept stage. This allows the Approval Authority to evaluate whether the detail level assumed is sufficient. The effort applied and the detail of assessment and analysis depend mainly on two factors:

- Experience with the design (or similar designs) in the intended application;
- Adequate reduction of risk.

5.4.1.9 Testing and Analysis Plan

This applies to project categories 1-4, Table 2. Any plans for testing or analysing materials, structures or systems which require documentation beyond what is currently available. Tests may be substituted by documentation of the material or system having a track record in another but relevant field.

5.4.1.10 High-Level Conclusion

Provides a brief summary, conveying the options to commence the detailed process.

5.4.2 Documentation to Be Delivered

5.4.2.1 Description of Novel/Risk-Based Concept Design

The client/design team supplies (the below are examples referring to risk-based ship design):

- Preliminary main dimensions, calculations of weights, hydrostatics, isoclinic data, stability calculations, etc.
- Speed, capacity and any further relevant particulars.
- Material data sheets for materials planned for use during construction, particularly where restrictions on the application of such materials exist.
- A list of rules challenged at this stage, if any, to the best knowledge of the client/design team.

The Approval Authority previews to provide verification of the documentation on:

- Whether the description supplied is sufficient information to commence the process.
- Whether agreement persists on the rule challenges identified.

5.4.2.2 Functional Description

The client/design team supplies:

- Description of modes of operation and intended area of service;
- Specific operational parameters, including estimates of limitations bearing in mind any novel characteristics;

- Function statements of main systems and planned inherent safety features (electric/hydraulic, power packs, redundancies, overload switches), main pressures and voltages where applicable;
- Drawings, wiring diagrams and piping plans as well as presumed maintenance and operating requirements.

The Approval Authority previews to provide verification of the documentation on:

• Whether all safety critical functions and processes have been included and described concisely.

5.4.2.3 Identification of Interfaces between Risk-Based Concept and Other Operations

The client/design team supplies:

• A description of the items where risk-based features are deemed to interact with conventional features.

The Approval Authority previews to provide verification of the documentation on:

- Whether all potential items of interaction are included and described to a comprehensive level of detail;
- Whether all identified rules challenged as shown in the list are addressed and the presumed impact described.

5.4.2.4 Design Approval Basis Documents

The client/design team supplies:

- Identification of the design parameters, addressing the nature of operational requirements;
- The principles underlying the design;
- Calculations and descriptions of assumptions made, including limitations.

The Approval Authority previews to provide verification of the documentation on:

- Whether the design approval basis documents are considered to be complete;
- Whether safety has been considered and included as a design parameter;
- Whether simplifications applied when analysing the design provide an adequate level of accuracy;
- Whether tools applied in the process are approved or subject to approval.

5.4.2.5 Preliminary General Arrangement Drawings

Identical to conventional approval process.

5.4.2.6 Preliminary Detail Drawing of Subsystems

Identical to conventional approval process.

5.4.2.7 List of Codes and Standards Applied

The client/design team supplies:

- Codes or standards adhered to;
- Scope of codes and standards adhered to;
- Rules and requirements challenged in the risk-based ship design;
- Type approvals achieved for components or subsystems, if any;
- Documentation of applicability of any code or standard, as well as any exemption, deviation or non-compliance.

The Approval Authority previews to provide verification of the documentation on:

• Whether standards complied with are relevant and sufficient;

- Whether applicability is documented to the satisfaction of the Approval Authority;
- Whether certificates or statements of compliance are available and recent;
- Whether intended examinations are carried out by accredited bodies or labs.

5.4.2.8 Risk Assessment

The client/design team supplies:

- Risk assessment as deemed necessary by the client/design team in accordance with the assessment of deviation from a conventional design;
- A description of proposed risk evaluation criteria;
- A description of risk assessment with regard hereto, including statement on techniques of choice, the applicability of techniques, tools, and proposed preliminary depth level;
- A list of proposed participants in the risk assessment team and their qualifications.

The Approval Authority previews to provide verification of the documentation on:

- Whether the risk assessment planned by the client/design team would provide an adequate level of assessment and analysis;
- Whether the evaluation criteria chosen are acceptable;
- Whether the techniques chosen by the client/design team are adequate for the scope of assessment/analysis;
- Whether the aggregate qualifications of the risk assessment team are considered adequate for the task.

5.4.2.9 Testing and Analysis Plan

The client/design team supplies:

- Tests and analyses plans to validate the applicability of materials or systems for their intended use;
- Statements of methods and details of labs performing tests and analyses to validate materials or systems.

The Approval Authority previews to provide verification of the documentation on:

- Whether all relevant materials and systems will be tested or analysed;
- Whether methods are approvable;
- Whether the labs performing the tests are recognized and accredited or subject to accreditation within a reasonable timeframe.

5.4.2.10 High-Level Conclusion

The Approval Authority supplies the following to the client/design team:

- High-level conclusion of the preview (acceptable/conditionally acceptable/not acceptable);
- Statement of areas which may contain further challenges;
- Terms of adherence to intended approval method (viability considerations);
- Evaluation of the timeframe for approval, if possible.

Queries by the Approval Authority, preceding preliminary approval:

- Does the concept design description supply sufficient information to give a broad understanding of the project?
- Does the Approval Authority agree with the rules applicable and challenged (potential further rule challenge);
- Is it possible to initiate the process on the basis of the documentation submitted and available?
- Have provisions for dealing with any instances yet to be evaluated been considered?
- Do these provisions appear adequate?

• Do all stakeholders participating in the process understand the implications in terms of resources assigned, time limits, etc.?

5.5 Definition of Approval Basis

5.5.1 Procedural Intent

- 5.5.1.1 As a consequence of reviewing the documentation supplied and based on the results from the preview of the documentation, the Approval Authority is in a position to define the approval basis.
 - If rule challenges are negligible or their impact minor (subject to exemption by the Approval Authority), the design can be approved by means of a conventional process;
 - If rule challenges or the impact of challenge is significant, a risk-based approval process ensues.
- 5.5.1.2 Project categories 1-4 (Table 2): The Approval Authority will, as a basic initial evaluation method, require the client/design team to perform a HazId, supporting any further decision making on evaluating and mitigating risk. A description of the process for a HazId to be followed by the client/design team is submitted with the statement. The description also serves as guidance for extended analysis which may be required based on the outcome of the basic risk assessment.
- 5.5.1.3 Project categories 2-4 (Table 2): Where no reference designs exist, and the client/design team intends to claim equivalent levels of safety by means of alternative designs or materials, the Approval Authority may require an assessment of both novel design and presumed reference design. Prior to the assessment, the Approval Authority needs to agree on an acceptable reference design.
- 5.5.1.4 The sequence takes place based on the outcome from the preview. First, it consists of an evaluation by the Approval Authority of which elements or operational circumstances (if not all) of the project may be covered by the risk analysis to be compiled. Also, if any elements exist which may be approvable by means of simpler methods, this information is rendered to the client/design team or client/design team representative. In principle, this step in the process requires the owner to have selected a flag State, as the design will be subject to the requirements given both internationally, regionally, nationally and by class.
- 5.5.1.5 The Approval Authority may detail appropriate or equivalent requirements and standards to serve as means of compliance, along with the requirements for the risk analysis. This evaluation eventually leads to a detailed description of the applied requirements, the necessary process, and the selected means of compliance, which is submitted to the customer responsible for the documentation of compliance with the requirements imposed and implementing improvement measures where necessary or requested by the supervising body.

5.5.2 Documentation to Be Delivered

- 5.5.2.1 *The Approval Authority supplies the following to the client/design team:*
 - Statement from the Approval Authority on those operations (if not all) which may be evaluated in depth through the risk assessment.
 - Concise statement from the Approval Authority on intended sets of rules/standards and processes applicable to the project.
 - The segments (if any) which may be subject to simple compliance with existing rules.
 - Summary conditions of compliance and approval from the Administration.

- 5.5.2.2 *Queries by the Approval Authority preceding preliminary approval:*
 - Are all operational segments dealt with, either by standard compliance verification or by evaluation through risk analysis?
 - Are alternative industry standards, which may have been chosen, relevant and applicable?
 - Have evaluation criteria been assigned?

5.6 Analysis of Generic Design (including the HazId Report)

5.6.1 Procedural Intent

- 5.6.1.1 For risk-based designs (unless the rule challenges are deemed insignificant or of negligible impact in terms of safety), a HazId will always be required, as it fulfils the requirement that the basic risk assessment must address the parameters of the submitted design known to this point and evaluate where further scrutiny is justified and necessary. The analysis of the generic design includes, but is not limited to, the HazId.
- 5.6.1.2 *The client/design team may consider:*
 - Statements of main conclusions from initial meetings, including key elements of risk that may be examined further;
 - Documentation in support of any assumptions made;
 - Documentation of existing safeguards and control measures;
 - Plans and means for proposed safeguards and control measures;
 - Levels of agreement within the team;
 - Points of discussion and further examination, including further analysis and applicable techniques;
 - Needs for further in-depth examination of historical evidence/expert judgment or calculations;
 - Sources of information.
- 5.6.1.3 When receiving the HazId report and monitoring the session(s), the Approval Authority may consider:
 - Whether safety issues have been comprehensively covered (whereas commercial risks in this context are beyond the scope of the Approval Authority);
 - Whether all relevant, conceivable scenarios have been considered, ranked and prioritized;
 - Whether the composition of the HazId team ensures that all relevant areas of expertise are represented and heard in the process, both from a scientific, theoretical, operational and practical standpoint;
 - Whether the qualifications and experience of the participants are verifiable upon request;
 - Whether existing and proposed safeguards and control measures are adequate and viable. (The adequate reduction of risk to ALARP, or plans to perform such reduction in the specific design process, is a condition of preliminary approval);
 - Whether identified significant hazards can be adequately analysed and reduced by means of the planned detailed risk analysis processes.
- 5.6.1.4 The Approval Authority reserves the right to request further participants if certain areas of expertise or experience have not been adequately covered by the team composition as described. (An Approval Authority representative may participate to ensure that potential comments from the Approval Authority to the client/design team are covered to the maximum extent possible).
- 5.6.1.5 The Hazld serves to address the basic risk assessment requirement for identification of any relevant scenarios and elements of scenarios eventually to be accounted for through the risk analysis.

- 5.6.1.6 The HazId further serves to clarify and rank any significant past and future scenario. As mentioned above, the HazId is a meticulous, formalized brainstorming process, documenting any valid contributory factor impacting on safety critical elements on board. The documentation derived from the process is submitted to the Approval Authority.
- 5.6.1.7 If the expert group does not agree on the prioritization of scenarios (or at any other stage where expert judgment is applied), the level of disagreement may be reflected and documented where the scope would be to achieve a "good" level of consensus within the expert group performing the task.

5.6.2 Documentation to Be Delivered

- 5.6.2.1 *The client/design team supplies the following to the Approval Authority:*
 - Full HazId report (also see recommendations in the FSA guidelines), considering the following issues:
 - Prioritized lists of hazards and scenarios (ranking).
 - Causal sequences assumed.
 - Documentation on background information applied (historical data, sources, impacts, effects, relevance).
 - Desired field verifications of measures.
 - Related or equivalent systems or subsystems (can equivalence be applied/documented at any given instance).
 - Details of the qualifications of the HazId team members as well as the project team members (to ensure the application of sound operational principles and adequate expertise within the team).
 - Details on how and based on which evidence impacts and probabilities have been ranked.
 - Any supporting documentation which may potentially validate estimates during the HazId.
- 5.6.2.2 *Queries by the Approval Authority preceding preliminary approval:*
 - To what extent are known and standardized techniques applied in the identification of hazards and which techniques have been applied?
 - Have all relevant areas of expertise contributed to achieve the most comprehensive overview possible?
 - To what extent is the data material (such as material applied for the evaluation of frequencies and consequences) relevant (i.e. derived from similar industries)?
 - To what extent can reliance be placed in the applicability of the data material?
 - Are references made to all applied information sources to enable fact-checking?
 - ALARP considerations and corresponding cost-benefit analysis of control options have criteria for individual risk and societal risk been accepted.

5.7 Preliminary Approval Statement with Conditions

5.7.1 Procedural Intent

5.7.1.1 Following the achievement of a satisfactory level of confidence in the concept, a statement of preliminary approval (of the design as evaluated to this point) may be issued to the client/design team, taking into account any limitations and conditions of later approval of the detailed design.

5.7.1.2 *The Approval Authority has to consider:*

A description of requirements, in accordance with the outcome and the results from the design preview, identifying information gaps, conditions resting on further information or analysis as well as any further queries identified during preview.

- 5.7.1.3 The report from the HazId is submitted to the Approval Authority for review, thereby assuring that all hazard aspects which may be found to be safety critical are covered and accounted for. Final approval may still be conditional or pending if the agreed safety standards are not reached or if certain aspects of the design are inadequately documented.
- 5.7.1.4 Particular requirements prevail with regards to the ensuing risk assessment session, quoted evaluation criteria and further risk assessment.
- 5.7.1.5 The statement to the client/design team at this point will concern:
 - The specific design characteristics with requirements for any areas of particular concern identified;
 - Requirements for the specific risk analyses performed in the next step of the process (project categories 2-4);
 - Assumptions in the high-level process to be verified through the detailed design sequences;
 - Missing test and analysis results;
 - Missing general documentation comprehensively describing the ship (manuals, system specifications, data sheets).
- 5.7.1.6 The conditions imposed depend on the outcome of the "definition of approval basis" phase along with the HazId; some conditions will be a consequence of the determination of major hazards resulting from novel features, whereas other conditions result from the project moving from a high/generic level to a specific detailed level of examination.

5.7.2 Documentation to Be Delivered

- 5.7.2.1 *The Approval Authority supplies the following to the client/design team:*
 - Preliminary approval statement, with any conditions as applicable, including requirements for further risk analyses.
- 5.7.2.2 *Queries by the Approval Authority:*
 - Are the conditions of final approval stated in a manner that adequately explains the need for their fulfilment?
 - Are the conditions reasonably and rationally argued for?
- 5.7.2.3 If no medium or high risks have been identified in the basic risk assessment at the preliminary stage, and the Approval Authority has no further queries hereto, the process will continue as a conventional approval process. Hence, all segments described hereafter concern project categories 2-4, as applicable.

5.8 Description of Specific Design, Risk Assessment Report Review and Qualification Method Description

The following applies to project categories 2-4, as appropriate.

5.8.1 Procedural Intent

- 5.8.1.1 Upon receipt of the preliminary approval statement, the description of the detailed design may commence. The detailed design segments and the scenarios imposed by the operational conditions will at this stage be subject to a risk assessment of all vital/safety critical segments.
- 5.8.1.2 The risk assessment is to live up to the detail level necessary to examine and reduce risks to a tolerable level as well as follow approved methods (qualification of the methodology is to be part of the report submitted).
- 5.8.1.3 Initially, the required level of detail mainly depends on the novelty impact of the issue addressed. The review should not be performed by the party granting final approval to ensure unbiased evaluation of results (i.e. the party setting the requirements to the risk assessment and eventually approving it is not the party performing and delivering it).
- 5.8.1.4 *The client/design team has to consider:*
 - Further information, plans and drawing details in the course of such information being produced;
 - Documentation on any previously unidentified risks, rendered evident by the increased comprehensiveness of the design, analysis of such risks and reduction to ALARP, and information on the analysis methods selected;
 - Risk assessments performed and submitted, supplying sufficient information to render both method and content transparent to an external auditor (without requiring redundant documentation, testing or analysis from the client/design team);
 - Applied evaluation criteria (relative or absolute, qualitative or quantified), examined and explained. If a reference design exists, or equivalent arrangements can be found, then relative criteria should be applied;
 - When applying absolute evaluation criteria, information on the source, derivation and relevance of such criteria;
 - A description of sources of frequency and consequence estimates, documenting relevance for the design in question;
 - Statement on assumptions, exclusions, limitations and uncertainties;
 - Cost-benefit calculations, both high cost and low cost cases may be considered, to account for cost ambiguity;
 - A list of the risk control measures to be implemented on the basis of such calculations;
 - A description of further planned tests and analyses of materials and systems;
 - All calculations performed and historical data applied may be obtainable and reproducible by an independent third party to ensure that the methods and techniques are sufficiently robust and remain objective.
- 5.8.1.5 The Approval Authority has to consider:
 - Whether the documentation supplied renders a complete picture of the design to the extent known at the given stage;
 - Whether all previously and newly identified risks have been analysed
 - by means of applicable/approved tools;

Analyses performed by means of new tools may be considered, but observing that application of such tools may generate a request for further independent verification of the tools or independent analysis with alternative tools.

- by personnel with adequate knowledge and experience. The adequacy of personnel qualifications depends on the required analysis depth level;
- at an adequate depth level. The analysis may yield information to support confidence in the safety of the design and document risks being ALARP at the highest level possible;

- by means of adequate techniques. As stated, a HazId prevails as a minimum basic requirement. (Further analysis to be conducted if and as required if a qualitative evaluation does not provide for conclusive confidence in the safety of the design e.g. HazOp, what-if, FMECA, etc. as applicable to the level and extent of the design or system assessed, the adequacy of technique chosen may be explained);
- sequentially and iteratively to ensure that any potential new or altered elements of risk are covered as the design process progresses.
- Whether agreement prevails on the selected evaluation criteria;
- Whether assumptions, exclusions and limitations are justified and whether the approach is sufficiently robust to retain confidence in the design;
- Whether the applied risk control options are considered effective and viable;
- Whether historical/statistical data is as recent as possible and is relevant for the application;
- Whether evidence prevails that intended or planned further tests and analyses will have an acceptable outcome.

5.8.2 Documentation to Be Delivered

- 5.8.2.1 *The client/design team supplies the following to the Approval Authority:*
 - Description of risk model(s), calculations and analyses (methodology, frequency and consequence estimates, sensitivity analysis, limitations of methods, assumptions made, reproducibility/falsification tests applicable);
 - Basic source information (related work tasks, the origin of database material and its applicability, source of FN-diagram figures on societal risk, sources of individual risk, fatalities, lost time accidents, evaluation/evaluation criteria (for subsidiary operations/ship system operations));
 - Documentation on tools performing acceptably;
 - Level of expert judgment applied (where no data is available);
 - Level of agreement in the expert group (concordance, see FSA guidelines);
 - Applicable risk control options and associated considerations, including the analysis of costefficiency of proposed options;
 - Error/uncertainty/sensitivity discourse;
 - Main risk contributory factors;
 - Cost-efficiency of risk control options, including source of cost estimates (if following ALARP principle).
- 5.8.2.2 *Queries by the Approval Authority preceding approval:*
 - Are the models used of an approvable methodology (recognized risk assessment techniques, adequate for the task)?
 - If requirements exist from the definition of approval basis stage (such as certain safety features or margins), does the documentation comply with these requirements as well as with the design specification?
 - Has an acceptable methodology and degree of consensus been achieved when applying expert judgment?
 - Can the results be reproduced by a third party having knowledge of the case?
 - Have limitations of the methodologies applied been accounted for?
 - Have all main risk contributory factors been accounted for and evaluated?
 - Is the documentation supplied clear, transparent, complete and adequate for its purpose (i.e. is the information supplied sufficient for a person of adequate knowledge in the field to comprehend it by means of the sources and methodologies quoted)?
 - Have issues of interaction effects or interface issues been considered (among other things aggravating or mitigating conditions)?

5.9 Definition and Description of Detailed Requirements

The following applies to project categories 2-4, as appropriate.

5.9.1 Procedural Intent

- 5.9.1.1 The description of detailed requirements is based on the outcome of the risk assessment review, as per above, and refers to the detailed design and the qualification of method descriptions provided by the client/design team.
- 5.9.1.2 *The Approval Authority has to consider:*
 - A description of further requirements emanating from the review of the risk assessment, including conditions of approval, resting on outstanding test results, further analysis requirements, or revised measures for risk reduction, including operational requirements throughout the lifetime of the ship and/or any specific requirements with regard to manufacturing, maintenance and monitoring.
 - Conditions of approval are linked to the outcome of tests, reports, detail drawings and achievement of third party approval, where applicable.
 - To detail requirements, relative to the steps leading to the preliminary approval. A risk control measure may correspond to a detailed requirement, or a number of detailed, technical requirements may be required to achieve the intended safety standard in the design.

5.9.2 Documentation to Be Delivered

- 5.9.2.1 The Approval Authority delivers the following to the client/design team:
 - Concise reference to facilitate the adherence to imposed standards or regulations;
 - Statement of options of compliance (if one exists);
 - Drawings, measurements, tables, written documentation on equipment specifications.
- 5.9.2.2 *Queries by the Approval Authority preceding approval:*
 - Is the system well evaluated bearing in mind the intended life cycle of the ship in terms of maintenance, availability of spare parts, repair and reliability?
 - Which risk control measures form the basis of the chosen regulatory option; do the risk control measures build on design/engineering improvements and, hence, will they be based on inherent safety or on operational and organizational changes?
 - Have any such organizational or operational requirements been sufficiently documented, such as to become part of a safety management system?
 - Has assessment taken place of effects of novel designs interacting with the equipment and manning needed on board (tools, measuring equipment, monitoring)?
 - Are the risk control options in fact cost-effective, and prevailingly so throughout the lifetime of the ship?
 - If general industry standards are applied, are certificates and reports made available?
- 5.9.2.3 The description, documented as per above, is submitted to the customer, who is obliged to answer, qualify and document any open queries as well as to perform any additional tests, analyses and improvements, which are submitted upon request.

5.10 Statement of Approval of Design Basis

Upon delivery of the necessary documentation as stated in the previous paragraphs, the statement of approval of the design basis will be issued to the client/design team by the Approval Authority.

5.11 Analysis and Testing Reports/Additional Documentation

The following applies to project categories 2-4, as appropriate.

5.11.1 Procedural Intent

5.11.1.1 *The client/design team has to consider:*

The submitted documentation has the scope of covering any remaining open questions of principal significance, such as previously untested methods, materials or applied processes.

5.11.1.2 Reports of tests (as agreed in the preliminary approval phase) may be delivered at this stage, along with any other relevant documentation stated as necessary to gain full comprehension of the project.

5.11.2 Documentation to Be Delivered

- 5.11.2.1 The client/design team delivers the following to the Approval Authority:
 - Test reports;
 - Results of further analyses conducted as a consequence of the detailing of the design and the increased understanding of the concept;
 - Detailed drawings of the design, equally as a consequence of detailing;
 - Tabulated values, achieved figures, measurements;
 - Possible errors and uncertainties in the applied methods;
 - Additional drawings.
- 5.11.2.2 Queries by the Approval Authority preceding approval:
 - Has the criticality of any errors or uncertainties (with sensitivity analysis) been considered?
 - Have any novel processes, materials or methods been documented to an extent granting adequate reliability?
 - Does all documentation submitted live up to formal requirements (such as readability, comprehensiveness, language, documented audit trail)?
 - Are test methods of a nature which is trusted or sufficiently documented elsewhere to be relied upon?

5.12 Issuance of Certificate of Approval with Conditions

This includes approval of documents, drawings and submission of approval to the client/design team. The following is applicable to project categories 2-4, as appropriate.

5.12.1 Procedural Intent

- 5.12.1.1 Provided all outstanding information is submitted as required, the Approval Authority may approve the design.
- 5.12.1.2 Conditions are applicable to the ship or system being constructed, meaning that approval of a ship is conditional on the rectification of any queries or outstanding issues remaining from the design phase.

- 5.12.1.3 At all times both generic requirements and case-by-case system requirements can prevail. Prerequisites for approval may thus vary with the project in question. Once the design is approved, its operability in a controllable process remains to be reviewed and surveyed at intervals to be defined. Conclusively, certificate of approval may be granted, and the construction process can ensue.
- 5.12.1.4 The approval serves to give the client/design team a statement of compliance with the requirements, statutory or class related, as defined by means of the above process, and is in this respect not substantially different from a traditional approval, even if the approval process leading up to the issuance is different. The certificate can contain as conditions which appropriate in-service measures should be implemented before the ship enters into service.
- 5.12.1.5 Provided the documentation lives up to the given requirements, the design approval process as such is concluded.

5.12.2 Remaining Documentation to Be Delivered

- 5.12.2.1 *The client/design team supplies the following to the Approval Authority:*
 - Certificates of process compliance with industry standards (applicability being verifiable). Such certification from other authorities may be deemed acceptable, at the discretion of the Approval Authority;
 - Safety assurance documentation, including any evaluation criteria with their justification agreed within the company or sector, as applicable;
 - Technical documentation relating to the project in question. Technical documentation submitted for review should contain the following information, as a minimum;
 - Details of application for any system or subsystem operated and requiring approval;
 - Specifications, including limitations, disclaimers and tolerances;
 - Material data sheets and/or manufacture certificates where applicable:
 - The quality assurance system applied to maintain the conditions prevalent at the time of certification;
 - Any pertinent or historical test or analysis data, if these are to be considered in the survey plan;
 - Installation manuals, maintenance procedures and operational plans.
- 5.12.2.2 The Approval Authority delivers the following to the client/design team:
 - Statement by the Approval Authority;
 - Class certificate;
 - Statements of conditions;
 - Other certificates.
- 5.12.2.3 *Queries by the Approval Authority preceding release into service:*
 - Whether provisions to rectify or mitigate any conditions are in place;
 - Whether inspection of compliance through the construction phase has been adequately planned and documented.

6 Qualification Requirements

This section of the guidelines addresses requirements to key personnel involved in the risk-based approval process.

6.1 Stakeholders and Target Groups

The various main stakeholders and their involvement in the risk-based design and approval process are illustrated in the involvement map in Figure 4. In the following, the involvement of the different target groups is considered further as well as the anticipated need for qualification upgrades in order to accommodate risk-based approaches in ship design, construction and approval.

In this chapter, the client/design team is to be understood as the shipowner/operator or owners' design department, as qualifications and involvement may vary significantly between shipowners, designers or yards. Thus, the term client/design team is separate from these other target groups in this chapter.

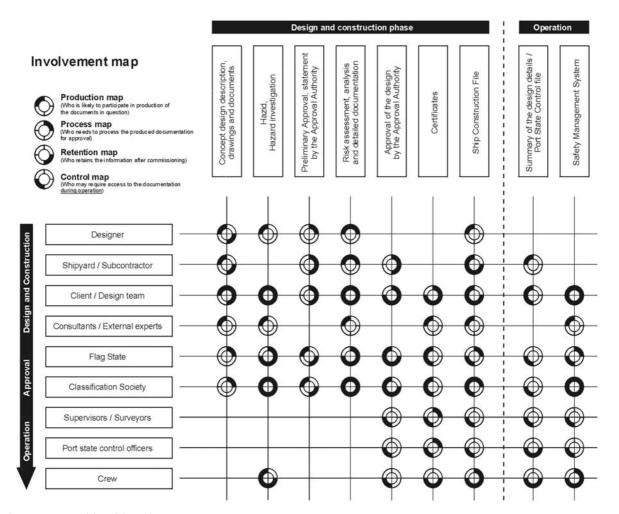


Figure 4: Combined involvement map

6.1.1 Designer

The initiator of a risk-based design approach may be the designer. The designer should be acquainted with risk-based design approaches in order to utilize them. It is not necessary to set substantial qualification upgrade requirements for the designer in a future risk-based regime, as relevant work experience and formal education requirements would be a prerequisite to select a risk-based design approach.

6.1.2 Yard or Subcontractors

- 6.1.2.1 The yard/subcontractor's main concern will be to have concise information at an early stage. Depending on the contract, a risk-based design approach may have both advantages and disadvantages. 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 optimise their building schedule when placing subcontracts and when ordering auxiliary equipment. The new building schedule process and milestones will invariably be influenced by decisions made in the process.
- 6.1.2.2 Recommendations by the Approval Authority affecting the yard are likely to concern the ability of a yard to fulfil requirements of a safety related nature along with the yard's ability to produce documentation of features and measures necessary to approve the new building.

6.1.3 Client/Design Team

- 6.1.3.1 The client/design team may be the initiator of a risk-based design project. (The client can select the designer and the design to be sent for tender based on his specification). They need to be in a position to assess safety holistically and will also be responsible for the education of operations personnel, documentation on board and integration with the safety management system. The client may eventually operate the ship and thus also be in a position to feed back experience with the design.
- 6.1.3.2 The client/design team should supply operational and technical experts in the relevant field or from similar operations and assist in the review of hazards as well as supply expertise to the initial risk assessment sessions. If no common evaluation criteria have been agreed upon, the commercial entity/owner/client/design team may suggest evaluation criteria and risk control measures and document their integration into the design. Hence a high-level of understanding of the concepts is required or will have to be drawn upon from external sources.

6.1.4 Consultants and External Experts

- 6.1.4.1 Consultants, organisations and external experts perform tests, analyses, simulation, software validation and validation of results and reviews of models used. It should be possible to obtain background information and credentials for the personnel responsible for performing the analyses, the tests or simulation. For certain types of tests, the personnel and/or institutes may also have to be certified. It may equally be considered whether adequate supervision is available and whether the provided supervision warrants a sound review of results.
- 6.1.4.2 Having a central verification task, they are anticipated to have expert level knowledge in their respective fields, and the organisation, lab or enterprise they belong to should be able to provide references from similar operations for the personnel involved in a project.

6.1.5 Flag State Administrations

- 6.1.5.1 The flag State administration reviews the delivered documentation, states further requirements for documentation if necessary, can request verification of achieved results and eventually grants approval to let a ship enter into its intended service.
- 6.1.5.2 This means that the flag State administration needs to be in a position to assess whether the design has been sufficiently examined and whether any risks have been reduced acceptably and thus must have sufficient knowledge of the subject to evaluate the adequacy of the delivered information and the assumptions made.

6.1.6 Classification Societies

- 6.1.6.1 Classification societies may have different roles in a risk-based design project. Compliance control with some statutory requirements may be subcontracted to class as recognized organisation and compliance control with classification society rules is exercised for the purpose of the owner achieving classification society notations. They can also be contracted as consultants or external experts.
- 6.1.6.2 Classification societies are tasked with supervision processes and documentation of these during construction as well as during the ship's operative life. They may draw on research departments when specific expertise is required, and some have acquired experience with risk-based approaches from the offshore industry.

6.1.7 Supervisors and Surveyors

- 6.1.7.1 Supervisors and surveyors include the owners' supervisors and flag State surveyors. This group performs compliance verification in the construction phase and compliance review through the operational life of a ship.
- 6.1.7.2 Supervisors and surveyors will require an introduction to risk-based approaches. An understanding should be developed that compliance is generally to be viewed as compliance with the intent of regulations, and not necessarily with prescriptive content.

6.1.8 Port State Control Officers

- 6.1.8.1 Port state control officers perform compliance review throughout the operational life of a ship when it calls at a port and is subjected to port state control, which has become an increasingly important instrument of enforcing rules and regulations.
- 6.1.8.2 Port state control officers need at least an introduction to risk-based approaches equivalent to that given to supervisors and surveyors. It is necessary to promulgate knowledge on the way of work and to provide port state control officers with tools to assure the safety of an inspected ship. A port state control file and physical inspections along the same lines as the inspections performed by the crew can provide such tools and methods of gauging the safety of the ship if doubts prevail after reviewing the documentation.

6.1.9 Crew

6.1.9.1 The crew operating a risk-based designed ship performs operational tasks, maintenance and inspection in accordance with the prevalent requirements, as stated in the management system on board.

MSC 86/5/3 ANNEX Page 44

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

7 Operation of Risk-Based Designed Ships

7.1 Requirements Pertaining to the Operation of Risk-Based Designed Ships

- 7.1.1 This section of the guidelines considers special requirements that apply to the operation of risk-based designed ships. In particular, the requirements for documentation on board such ships are addressed as well as requirements for change of flag of risk-based designed ships.
- 7.1.2 Depending on the particular feature of the risk-based elements, conditions may be imposed on the operation of a risk-based designed ship. Such conditions may be restrictions and limitations on the type of operations and trades the ship can engage in or it may be additional safety procedures or measures that need to be in place. Any operational conditions should be determined during the approval process and be based on the outcome of the HazId and the risk analyses undertaken as a part of this process, and they should be clearly documented and communicated to relevant parties.
- 7.1.3 If, during the operational phase, the initial assumptions made during the design approval are changed, i.e. a change of any aspects of the operation that may influence the risk, it may be necessary to repeat the part of the risk assessment with the adjusted assumptions. Such needs and the extent of work needed will be dependent on the risk-based features, the assumptions changed and the operation of the ship and may be decided by the relevant administration.
- 7.1.4 During the operational phase, inspections and surveys on risk-based designed ships will be performed as on conventional ships. It is therefore important that the risk-based features and possible operational conditions are taken into account and understood by the administrations that check compliance. Thus, clear documentation on the risk-based elements of the ship should be kept on board. In the following, the requirements for onboard documentation of risk-based features are outlined.
- 7.1.5 For risk-based designed ships, amendments to the Safety Management System may be required to integrate the evaluation of any changes in the risk levels. Recurring review of the operational environment may be a requirement and this may be stipulated as an element in the periodic company review and masters' review.

7.2 Onboard Documentation

7.2.1 **Documentation Requirements**

- 7.2.1.1 All ships are required to carry documentation and certificates on board by current regulations. Some documentation and certificates are required for all ships, whereas others are required for specific ship types. In this section of the guidelines, only additional documentation requirements for risk-based ships are addressed. This covers both current documentation that will be affected by risk-based design and additional documentation and certificates that need to be developed.
- 7.2.1.2 In general, three levels of documentation are needed:
 - I. Certificates stating that the ship design is risk based.
 - II. Explanatory notes to port state control officers and surveyors on risk-based elements.
 - III. Details of the risk analyses.
- 7.2.1.3 Whereas the first two levels, levels I and II, should always be carried on board the ship, the third level need not be kept on board.

7.2.2 Documentation Affected by Risk-Based Design

The following describes some current document requirements related to risk-based designed ships as well as some requirements that have been adopted or discussed by IMO, but have not yet entered into force.

7.2.2.1 Alternative Design and Arrangements for Fire Safety

- Presently, SOLAS provides regulation 17 for approving alternative or novel design and arrangements for fire safety systems which do not comply with the prescriptive requirements of SOLAS chapter II-2. This regulation requires an engineering analysis to demonstrate that the alternative design and arrangements provide the same safety benchmark as the prescriptive requirements (MSC/Circ.1002) and the analysis should be evaluated and approved by the Administration. Moreover, the Administration has to communicate the pertinent information concerning the approved alternative design and arrangements to the IMO to enable the latter to inform all member governments (Appendix A of MSC/Circ.1002). Once alternative design and arrangements are approved by the Administration, a copy of the documentation is to be carried on board the ship (Appendix B of MSC/Circ.1002).
- MSC/Circ.1002 requires evidence of Administration approval by maintaining on board the following documentation:
 - Scope of the analysis or design, including the critical design assumptions and critical design features;
 - Description of the alternative design and arrangements, including drawings and specifications;
 - List of SOLAS chapter II-2 regulations affected;
 - Summary of the results of the engineering analysis and basis for approval;
 - Test, inspection and maintenance requirements.
- Resolutions MSC.239(83) and MSC.240(83), which will enter into force on 1 July 2009, provide new clauses to be added to the following existing SOLAS certificates that will indicate whether or not alternative design and arrangements have been made according to SOLAS regulation II.2/17:
 - Safety Certificate for Passenger Ship,
 - Cargo Ship Safety Construction Certificate,
 - Cargo Ship Safety Equipment Certificate,
 - Cargo Ship Safety Radio Certificate,
 - Cargo Ship Safety Certificate,
 - Nuclear Passenger Ship Safety Certificate,
 - Nuclear Cargo Ship Safety Certificate.
- Two statements are to be added to the above-mentioned certificates: Whether or not the ship has an alternative fire safety design and that the 'Document of approval of alternative design and arrangements for fire safety' is attached to the certificate (if applicable).

7.2.2.2 Alternative Design and Arrangements for Machinery and Electrical Installations and for Life-Saving Appliances and Arrangements

Two new SOLAS regulations, which will enter into force on 1 July 2010, pertain to alternative design and arrangements, both adopted by resolution MSC.216(82). Regulation II-1/55 will allow the approval of alternative design and arrangements for machinery and electrical installations, while regulation III/38 will allow the approval of alternative design and arrangements for life-saving appliances and arrangements. Regulations II-1/55 and III/38 are similar to the current regulation II-2/17 and require an engineering analysis to be submitted to the Administration in order to provide technical justification for alternative

design and arrangements approval. Guidelines for the engineering analyses and the form of required documentation very similar to those for alternative design and arrangements for fire safety are provided for these areas of alternative design in MSC.1/Circ.1212.

7.2.3 New, Additional Required Documentation for Risk-Based Designed Ships

- 7.2.3.1 In the following, additional requirements for a dedicated certificate for risk-based designed ships are outlined.
- 7.2.3.2 The new risk-based design certificate may have a multi-level structure. The top-level certificate may contain only general ship data and state that the ship is a risk-based design. At the middle level, the results from risk assessments may be reported and the list of risk-based elements and critical inspection items as well as the adopted risk control options may be included. The level of detail of data and results relevant to the risk assessment contained in this certificate may be similar to what has been reported in previous SLS.14 Circulars on alternative designs (e.g. SLS.14/Circs.226, 235, 294, 297, 232, 293 and 295). The lower level may report the detailed risk analysis methodology. This document may have restricted access and will not need to be carried on board as it may be restricted by intellectual property rights.
- 7.2.3.3 In addition to the new risk-based design certificate, risk-based designed ships should carry a summary document file, which should provide port state control officers an easy means to access information on risk-based features which may be unfamiliar. Such a summary document may contain the following:
 - Statement of challenges (intent of rules, specific regulation, international, regional or national regulations);
 - Statement of auxiliary means of ensuring safety, as required by the Approval Authority;
 - Statement of owners' proposal for solutions;
 - Statement by the Approval Authority of acceptance;
 - Procedures for the control, test and maintenance of any features challenging rules;
 - Copy of Document of Approval;
 - Reporting forms (IMO, Administration);
 - Reference to the appropriate procedures, checks, tests and maintenance routines in the Safety Management System.

7.3 Inspections and Surveys

- 7.3.1 Inspection of a risk-based designed ship will be required as for conventionally designed ships, and class survey, flag state inspection and port state control need to be performed at prescribed intervals. Thus, inspectors and surveyors need an understanding of the risk-based nature of the ship, which may be promoted by means of onboard documentation and certificates, as relevant. Proper authoritative documentation may provide the inspector with evidence that the ship has been built and maintained in a satisfactory manner.
- 7.3.2 A port state control officer may, in addition to checking certificates and documentation, want to perform a physical inspection to achieve hard evidence that the ship is in a proper condition. Risk-based designed ships which are built to different standards or requirements than prescriptive regulations may be inspected against the onboard documentation. Such documentation may also provide guidance with regard to elements adequate for inspection and with regard to gauging points on system details and details of operation.
- 7.3.3 It may be verified through owner's inspections, during annual internal company shipboard audits or visits to the ship by the management or superintendents, whether the initial assumptions made

during the design and approval process have changed. Any changes compromising risk-related design features and operational procedures may be identified and necessary corrective actions may be taken. The inspection may include a review of onboard documentation to ensure that it is kept up-to-date, including documentation on the risk-based elements of the ship. The management should also confirm that the officers and crew are aware of the risk-based design and operational features and verify that they have undergone appropriate training to ensure that these features are not compromised.

7.4 Change of Flag

- 7.4.1 Granting equivalence and exemption from the prescriptive rules rests solely with the Administration. This has the implication that risk assessments and assumptions made, scenarios applied and the original basis of the risk profile to evaluate the alternative features are to be submitted, including any subsequent revisions, via the Approval Authority authorized to issue the certificate which the alternative feature has an impact on.
- 7.4.2 The Administration will examine the documentation, assisted by the classification society or consultants, as appropriate, to ensure that it is formally in compliance with methodologies from the FSA guidelines and MSC/Circ. 1002/1212 (if and as appropriate).
- 7.4.3 Provided these requirements are catered for, the Administration may request an independent validation of prerequisites, original parameters and review of the risk profile to verify whether the original parameters still hold and the originally applied criteria remain acceptable.

7.5 IMO reporting

The Administration shall always submit relevant information to the IMO when granting an approval which goes beyond the IMO Conventions. The following sections contain information on documentation requirements relevant for fulfilling the IMO obligation.

7.5.1 Equivalent solutions

SOLAS Reg. I/5 (b)

Ship category: Cargo ships and passenger ships.

Reporting requirement: Requirement that information shall be communicated to IMO in cases where

equivalent solutions are permitted in relation to SOLAS requirements. Reported

equivalent solutions to IMO are available from SLS.14/Circ.

Responsible: Flag State.

MARPOL Reg. I/3.3 and Reg. II/5.2, and Reg. VI/4.2

Ship category: Cargo ships, passenger ships, MODUs and fishing vessels.

Reporting requirement: Requirement that information shall be communicated to IMO in cases where

equivalent solutions are permitted in connection with MARPOL requirements.

Responsible: Flag State.

The Load Line Convention, Art. 8 (2)

Ship category: Cargo ships and passenger ships.

Reporting requirement: Requirement that information shall be communicated to IMO in cases where

equivalent solutions are permitted in connection with Load Line Convention

requirements.

Responsible: Flag State.

7.5.2 Approvals for experimental purposes

Ship category: Cargo ships and passenger ships.

Reporting requirement: According to Art. 9 (2) of the Load Line Convention, reports must be made to

IMO in cases where special approvals have been made for experimental

purposes. Such reports must contain exhaustive information.

Responsible: Flag State.

7.5.3 Exemptions

SOLAS Reg. I/4 (b) Exemptions – in general

Ship category: Cargo ships and passenger ships.

Reporting requirement: According to SOLAS Reg. I/4 (b), reports must be made to IMO in case

exemptions are granted from certain SOLAS requirements on the basis of features of a novel kind. See SLS.14/Circ. concerning exemptions reported to

IMO.

Responsible: Flag State.

SOLAS Reg. IV/3.3 – Radio communications

Ship category: Passenger ships and cargo ships above 300 GRT.

Reporting requirement: Requirement that an aggregate report be made to IMO for the previous year on

exemptions granted from radio communications requirements. This report must

be made on an annual basis as soon as possible after 1 January.

Responsible: Flag State.

MARPOL Reg. I/3.3

Ship category High-speed craft or any other new type of ship (planning ship, sub-marines,

etc.) of such a construction that the use of one or more provisions in chapters II and III of MARPOL, Annex I, on construction and equipment become

unreasonable or impractical.

Reporting requirement: Requirement that exemptions from the requirements in the MARPOL

convention be reported to IMO as soon as possible and within 90 days after the

exemption was granted.

Responsible: Flag State.

MARPOL Reg. II/4.1.2

Ship category: All ships under Annex II.

Reporting requirement: Report on details of the ship or ships concerned, the cargoes certified to carry,

the trade in which each ship is engaged and the justification for the relaxation, for circulation to the Parties to the Convention for their information and

appropriate action, if any.

Responsible: Flag State.

MARPOL Reg. II/4.3.4

Ship category: Ships constructed before 1 July 1986 which is engaged in restricted voyages as

determined by the Administration.

Reporting requirement: Ships engaged in voyages to ports or terminals under the jurisdiction of other

States Parties to the present Convention, the Administration communicates to the Organization, for circulation to the Parties to the Convention, particulars of

the exemption, for their information and appropriate action, if any.

Responsible: Flag State.

MARPOL Reg. II/4.4.5

Ship category: For ships with structural and buoyancy properties that mean that the intake of

ballast is not required and the washing of cargo tanks is necessary only in

connection with repairs or dry docking.

Reporting requirement: Requirement that reports be made to IMO with detailed information on

exemptions granted.

Responsible: Flag State.

Load Line Convention, Art. 6 (3)

Ship category: Cargo ships and passenger ships engaged on international voyages between

neighbouring ports in two or more states where it is unreasonable or impracticable to apply the provisions of the Load Line Convention and ships with entirely new properties when the provisions of the Load Line Convention may be a serious obstacle to the research necessary to develop these properties

for use on ships engaged on international voyages.

Reporting requirement: IMO must receive exhaustive information about the exemptions granted and the

reasons hereof. As regards exemptions granted in pursuance of the Load Line

Convention that have been reported to IMO, see LL.3/Circ.

Responsible: Flag State.

8 References

DNV, 2001. "Qualification procedures for new technology", Recommended Practice DNV-RP-A203, September.

EUROCODE, 2002, EUROCODE basis for structural design, EN1990.

Hørte, T., Skjong, R., Friis-Hansen, P., Teixeira, A.P. and Viejo de Francisco, F, 2007. "Probabilistic Methods Applied to Structural Design and Rule Development", in Proc. RINA Conference on Developments in Classification & International Regulations, London, January 24-25.

IACS, 2006. "Goal-Based New Ship Construction Standards; Linkage between FSA and GBS", Submitted by the International Association of Classification Societies (IACS), MSC 81/INF.6, IMO.

IMO, 2001. "Guidelines on alternative design and arrangements for fire safety", MSC/Circ. 1002, IMO.

IMO, 2002. "Guidelines for Formal Safety Assessment (FSA) for use in the IMO rule-making process", MSC/Circ. 1023, IMO.

IMO, 2003. "Revised Interim Guidelines for the approval of alternative methods of design and construction of oil tankers under regulation 13F(5) of Annex 1 of MARPOL 73/78, MEPC.110(49), Adopted on 18 July.

IMO, 2006. "Guidelines on Alternative Design and Arrangements for SOLAS chapters II-1 and III", MSC.1/Circ.1212, IMO.

IMO, 2007a. "Formal Safety Assessment; Consolidated text of the Guidelines for Formal Safety Assessment (FSA) for use in the IMO rule-making process (MSC/Circ.1023-MEPC/Circ.392); Note by the Secretariat", MSC 83/INF.2, IMO.

IMO, 2007b. "Adoption of amendments to the International Convention for the Safety of Life at Sea, 1974, as amended", Resolution MSC.239(83), Annex 1 of MSC 83/28, IMO.

IMO, 2007c. "Adoption of amendments to the Protocol of 1988 relating to the International Convention for the Safety of Live at Sea, 1974, as amended", Resolution MSC.240(83), Annex 2 of MSC 83/28, IMO.

IMO, 2007d. "Adoption of amendments to the International Convention for the Safety of Life at Sea, 1974, as amended", Resolution MSC.216(82), Annex 2 of MSC 84/24, IMO.

ISO, 1998, General Principle on reliability for structures, ISO 2394.

ISO, 2007. "Safety of machinery – Risk assessment – Part 1: Principles", ISO 14121-1, International Organizations for Standardization.

Norway, 2000. "Formal Safety Assessment; Decision parameters including risk acceptance criteria", submitted by Norway, MSC 72/16, IMO.

Rüde, E. and Hamann, R., 2008. "Derivation of Ship System Safety Criteria by Means of Risk-Based Ship System Safety Analysis", in Proc. 27th International Conference on Offshore Mechanics and Arctic Engineering, OMAE 2008, Estoril, June 15-20.

Skjong, R., Vanem, E. and Endresen, Ø. 2005. "Risk Evaluation Criteria", SAFEDOR report D 4.5.2, http://www.safedor.org/resources/SAFEDOR-D-04.05.02-2005-10-21-DNV-RiskEvaluationCriteria-rev-3.pdf.