Title	MSC Circulars / MSC.1/Circ.1455

MSC.1/Circ.1455

24 June 2013

GUIDELINES FOR THE APPROVAL OF ALTERNATIVES AND EQUIVALENTS AS PROVIDED FOR IN VARIOUS IMO INSTRUMENTS

1 The Maritime Safety Committee, at its ninety-second session (12 to 21 June 2013), with a view to providing a consistent process for the coordination, review and approval of alternatives and equivalents with regard to ship and system design as allowed by the 1974 SOLAS Convention, as amended, and other mandatory IMO instruments, approved the annexed Guidelines for the approval of alternatives and equivalents as provided for in various IMO instruments.

2 Administrations and non-governmental organizations are invited to bring the annexed Guidelines to the attention of shipowners, shipbuilders, designers and system manufacturers.

***

ANNEX

GUIDELINES FOR THE APPROVAL OF ALTERNATIVES AND EQUIVALENTS AS PROVIDED FOR IN VARIOUS IMO INSTRUMENTS

1 INTRODUCTION

1.1 Alternative and/or equivalent design

1.1.1 Prescriptive regulations may sometimes restrain the level of innovation that is feasible in design. An essential prerequisite for widespread use of innovative and the use of alternative and/or equivalent design is a predictable and reliable process of submitting and approving the design making full use of state of the art risk assessment tools and techniques.

1.1.2 There may be different levels of approval depending on how challenging the proposed alternative and/or equivalent design is in light of prescriptive regulations. Such designs may deviate from prescriptive requirements related to certain components, systems or functions or the whole ship. Alternative and/or equivalent design and approval is expected to be carried out only for ship functions, systems or components that either directly or indirectly proposes alternative ways of compliance with prevailing regulations.

1.1.3 One approach to the approval of an alternative and/or equivalent design is to compare the innovative design to existing designs to demonstrate that the design has an equivalent level of safety. In order to demonstrate an equivalent level of safety, functional requirements and performance criteria should be established for essential ship functions, which should be met by the alternative and/or equivalent design. An alternative approach could be to carry out a risk analysis of the alternative and/or equivalent design and compare it to overall risk evaluation criteria.

1.1.4 A structured approval processes is necessary in order to confirm that the alternative and/or equivalency design can obtain the required approval along with the necessary certificates related to statutory requirements for their intended operation. The Guidelines presented herein describe such a structured process that is predictable and reliable. By adhering to these Guidelines, Submitters and Administrations would be working in cooperation to evaluate that all aspects of safety and environmental protection are adequately assessed and controlled to an acceptable level. Furthermore it will facilitate innovation.

1.1.5 Currently, there are provisions in many IMO conventions for acceptance of alternatives and/or equivalents to prescriptive requirements in many areas of ship design and construction. In this context, the Organization has issued several guidelines, such as Guidelines on alternative design and arrangements for fire safety (MSC/Circ.1002), Guidelines on alternative design and arrangements for SOLAS chapters II-1 and III (MSC.1/Circ.1212) and Interim guidelines for the approval of alternative methods of design and construction of oil tankers (resolution MEPC.110(49)).

1.2 Application of these Guidelines

1.2.1 The Guidelines are intended for use of both Administrations and submitters when dealing with an approval request for an alternative and/or equivalent design and serve to provide guidance on a variety of aspects requiring consideration when applying such a 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.

1.2.2 These Guidelines are intended for application when approving alternative and/or equivalency designs in general and specifically according to the provisions given for alternative design and arrangements in applicable statutory IMO instruments.

1.2.3 The Guidelines serve to outline the methodology for the analysis and approval process for which the approval of an alternative and/or equivalent design is sought.

1.2.4 When proposing an alternative design, one should keep in mind that the substitution of design measures to reduce risk with operational or procedural ones to claim equivalent safety needs to be thoroughly examined. Normally, this should not be permitted, and special care should be taken in order to confirm that design measures take priority over operational or procedural measures.

1.2.5 For the application of these Guidelines to be successful, all stakeholders, including the Administration or its designated representative, owners, operators, designers and classification societies, should be in continuous communication from the onset of a specific proposal. Usually the approval of an alternative and/or equivalent design requires significantly more time in calculation and documentation than a standard design that complies with prescriptive regulation. However, the potential benefits of this approach include more options, cost-effective designs for unique applications and an improved knowledge of safety critical elements and loss potential.

2 DEFINITIONS

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

2.1 *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* means that the Administration 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.

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

2.4 *Design casualty scenario* means a set of conditions that defines the development and severity of a casualty within and through ship space(s) or systems and describes specific factors relevant to a casualty of concern.

2.5 *Design team* is a team 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 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.

2.6 *Failure mode* is the observed mechanism or manner in which a failure can occur.

2.7 *FME(C)A*. Failure Mode, Effect (and Criticality) Analysis.

2.8 *Preliminary design* is a design developed for the design preview and the first analysis phase. The preliminary design is a high-level design taking into account the general arrangement, major systems, components, etc.

2.9 *HazId*. Hazard identification, a process to find, list and characterize hazards.

2.10 *HazOp*. Hazard and operability study.

2.11 *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:

.1 a technology that has no track record in a known field;

.2 a proven technology in a new environment; or

.3 a technology that has no track record in a new environment.

2.12 *Preliminary approval/approval of preliminary design* is the process by which the Administration issues a statement that a proposed concept design complies with the intent of the rules, regulations and/or appropriate criteria set by the Administration – 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.

2.13 *Proven technology* has a documented track record in the field for a defined environment.

2.14 *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).

2.15 *Risk analysis* is the science of risks, their probability and consequence.

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

2.17 *Risk evaluation criteria* are formally recognized objective criteria defining the acceptable risk.

2.18 *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.

2.19 *Risk control measure* is a means of controlling a single element or risk; typically, risk control is achieved by reducing either the consequences or the frequencies; sometimes it could be a combination of the two.

2.20 *Risk control option (RCO)* is a combination of risk control measures.

2.21 *Safety* is the absence of unacceptable levels of risk to life, limb and health (from non-wilful acts).

2.22 *Safety critical*. Containing an element of risk. Necessary to prevent a hazard.

2.23 *Final design*. Elaboration of the preliminary design. The final design complies with the results of the preliminary analysis, e.g. with respect to risk control options already identified, and the requirements of the Administration. The final design is developed on the basis of the statement by the Administration.

2.24 *Submitter* is an entity seeking approval of an alternative design and/or equivalent from the Administration, responsible for communicating with the administration for the submission and follow-up of the approval process.

3 QUALIFICATION REQUIREMENTS

This section of the Guidelines addresses requirements for key personnel involved in the different stages of the alternative and/or equivalent design approval process.

3.1 Stakeholders and target groups

The various main stakeholders and their involvement are indicated in the involvement map in figure 1. In this section, the anticipated need for qualifications of stakeholders, in order to accommodate risk-based approaches in ship design, construction, operation and approval, are based on the involvement of the different target groups.

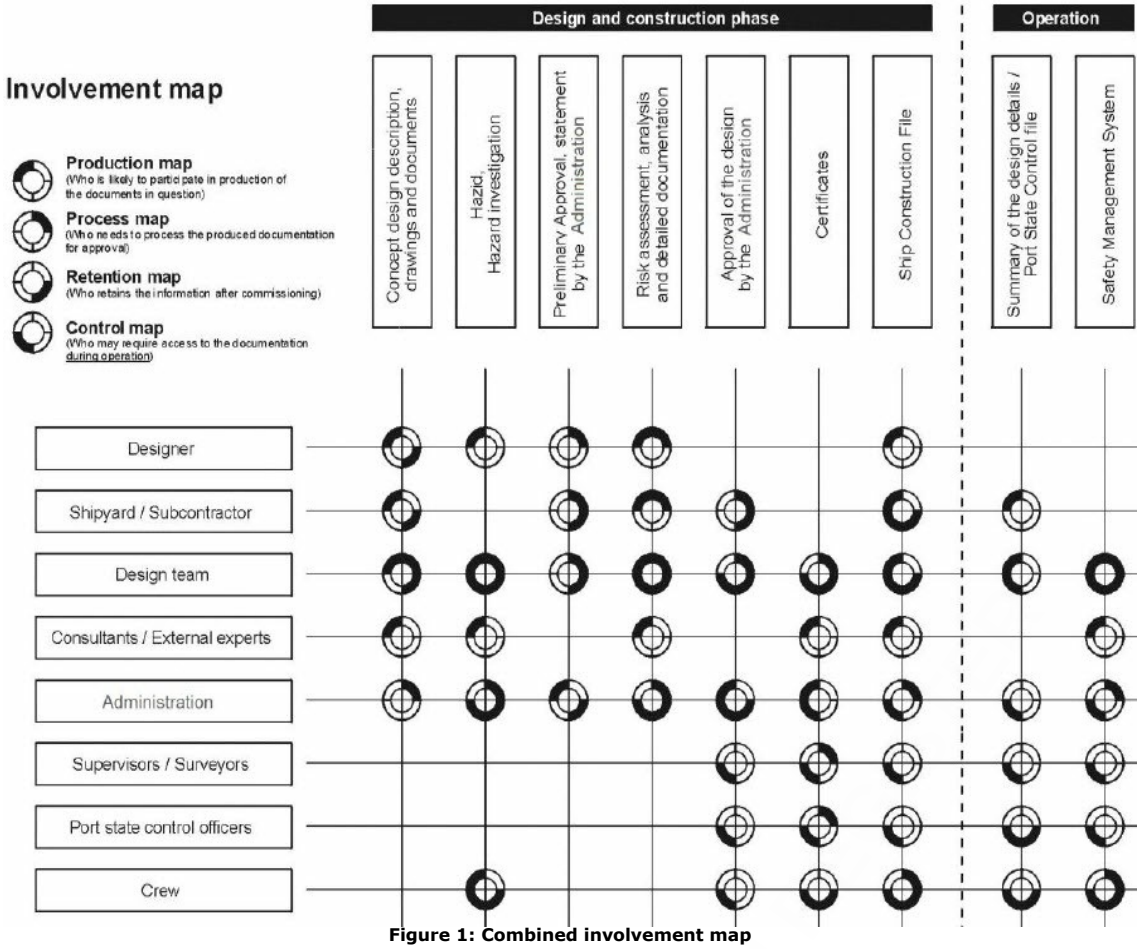

Figure 1: Combined involvement map

3.2 Design team

The design team is the entity (e.g. yard, supplier, owner and operator) that carries out the design development and analyses for the alternative and/or equivalent design. They need to be in a position to assess safety and environmental protection holistically and will also be responsible for the education of operations personnel, documentation on board and integration with the safety management system. Operational and technical experts in the relevant field or from similar operations should be involved and assist the design team in the review of hazards as well as supply expertise to the initial risk assessment sessions. Hence a high level of understanding of the concepts is required or will have to be drawn upon from external sources.

3.3 Designer

The designer is the developer of the design seeking approval. The designer should be familiar with alternative and/or equivalent design approaches in order to utilize them.

3.4 Yard or subcontractors

3.4.1 The yard/subcontractor's is part of the Submitter and provides information for the analyses carried out in order to achieve the approval by the Approval Authority.

3.4.2 The yard/subcontractor's main concern will be to have concise information at an early stage. Depending on the contract, an alternative and/or equivalent design 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 optimize 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.

3.5 Consultants and external experts

3.5.1 Consultants, organizations 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.

3.5.2 Having a central verification task, they are anticipated to have expert level knowledge in their respective fields, and the organization, lab or enterprise they belong to should be able to provide references from similar operations for the personnel involved in a project.

3.6 Administrations

3.6.1 The Administration reviews the delivered documentation; states further requirements for documentation if necessary, can request verification of achieved results and eventually grants approval.

3.6.2 This means that the 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 should have sufficient knowledge of the subject to evaluate the adequacy of the delivered information and the assumptions made. The Administration should make the final decision for applying these Guidelines to approve alternative and/or equivalent design, and the final responsibility of design approval rests with the Administration.

3.7 Supervisors and surveyors

3.7.1 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 an alternative and/or equivalency.

3.7.2 Supervisors and surveyors will require an introduction to alternative and/or equivalent design 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.

3.8 Port State control officers

3.8.1 Port State control officers perform compliance review throughout the operational life of an alternative and/or equivalency 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.

3.8.2 Port State control officers need at least an introduction to the 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.

3.9 Crew

3.9.1 The crew operating an alternative and/or equivalent design performs operational tasks, maintenance and inspection in accordance with the prevalent requirements, as stated in the management system on board.

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

4 PROCESS

4.1 The following process, illustrated in figure 2, is intended to describe the procedure for obtaining and maintaining approval of an alternative and/or equivalency taking into account the Submitter and the Administration. Even though the diagram in figure 2 may suggest a strictly linear or sequential process, this is not the intention, and it is important to note that each phase may be a series of iterations in a loop. As seen from figure 2, the process, which covers concept development through operation, includes the following milestones:

.1 development of a preliminary design;

.2 approval of preliminary design;

.3 development of final design;

.4 final design testing and analyses; and

.5 approval.

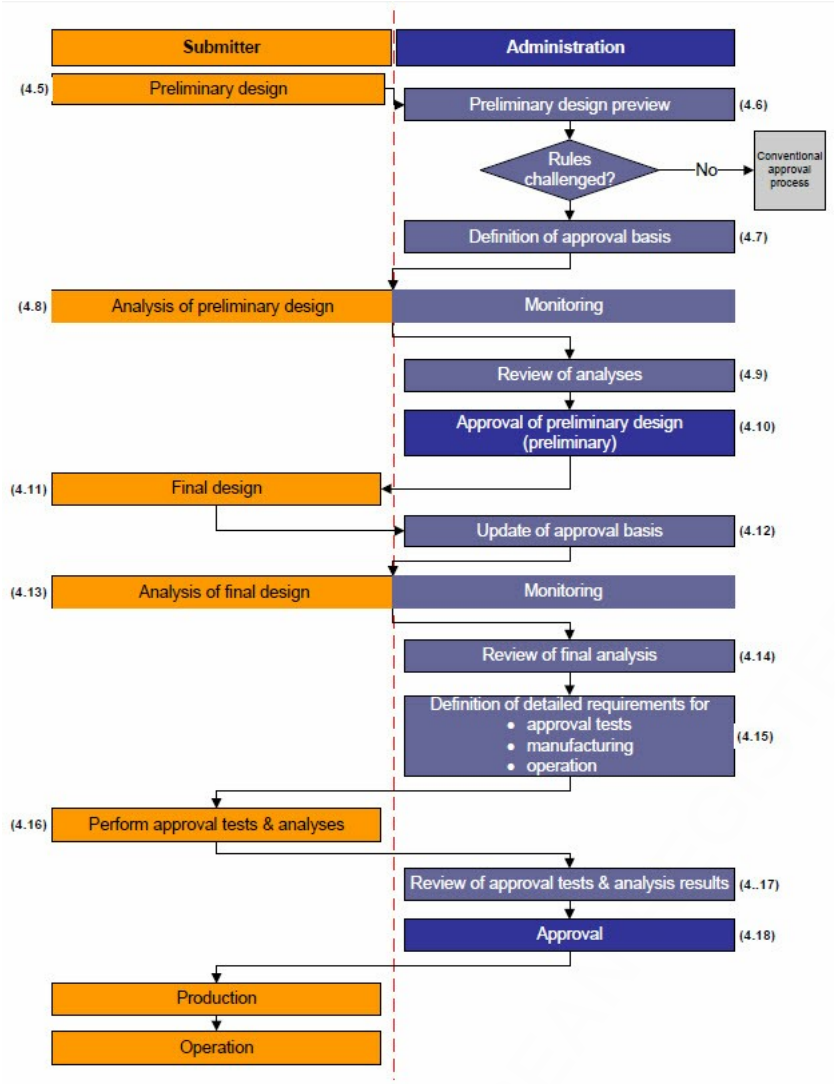

Figure 2: Design and Approval Process

4.2 The Submitter should approach the Administration early in the process in order to seek input from experts and specialist opinions on the use of an alternative and/or equivalency design – with the motivation of obtaining approval by the Administration. The details performed in each phase of the process shown in figure 2 may vary on a case by case basis depending on the design being considered or whether the Submitter is applying for preliminary or final approval. However, the basic process outlined in this document should be generally applicable to the approval of most alternatives and/or equivalencies.

4.3 When a recognized organization acts on behalf of the Administration:

.1 Administration's authorization requested by SOLAS regulation XI-1/1 should include the list of activities reserved to the Administration, such as:

.1 acceptance of, or exemption from, risk analysis (see paragraph 4.6.3);

.2 agreement on evaluation criteria (see paragraph 4.7.1);

.3 termination of the process because the evaluation criteria were not met (see paragraph 4.9.3); and

.4 final approval (see paragraph 4.19.1); and

.2 approvals should only be valid for the ships that were flagged by the Administration at the time the approval was issued.

4.4 Phases in the process

4.4.1 The submission and approval process for an alternative and/or equivalency design should be clear, transparent and well described in order to avoid misinterpretations. In the following sections, the phases of the process outlined in figure 2 are described taking into account the roles of the Administration and the Submitter.

4.4.2 The details of the process for an alternative and/or equivalency design depend also on the design process of the Submitter. The process shown in figure 2 was based on a design process covering preliminary and final design, both consecutively analyzed in the approval process. However, the Submitter may wish to carry out the approval process using a final design, i.e. without an analysis of a preliminary design. In such cases both parties may agree to skip the analysis of the Preliminary Design and adjust accordingly the approval process including the documentation of analyses. Independent of such details the approval process should consider among others the definition of the approval basis, the hazard identification, review of approval basis after HazId and quantitative risk assessment.

4.4.3 Documentation and the exchange of documents between the Administration and the Submitter are highlighted in the description of each phase. Results of assessments need to be fully documented in a manner readily accessible to a third party. A description of the documentation requirements for the submission and approval process is provided in section 6 of this document.

4.5 Preliminary Design Development Phase

4.5.1 In the first phase of the alternative and/or equivalency process the Preliminary design is carried out by the Submitter. A draft of the alternative and/or equivalent under consideration 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.

4.5.2 The objective of this phase is to develop a common level of understanding of the proposed alternative and/or equivalent design to enable the subsequent tasks of the submission and approval process to be properly defined and carried out. Those rules, standards and/or regulations that are being challenged should be identified and thoroughly explained by the Submitter. 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.

4.5.3 The Submitter submits the Preliminary design description addressing the above-mentioned aspects to the Administration.

4.6 Preliminary Design Preview Phase

4.6.1 In this phase, the Submitter organizes a Preliminary design preview meeting with the Administration in order to discuss the concept, relevant rules/guides/codes/standards as well as the further phases involved in the approval process.

4.6.2 The purpose of this meeting is to identify and describe items requiring special attention and to plan how these items are handled by the Administration and Submitter with respect to approval.

4.6.3 The aim of the Preliminary preview phase is also to decide whether the alternative and/or equivalency challenge any prescriptive rules, regulations or standards to such an extent that a risk analysis is required. The safety and environmental aspects of the alternative and/or equivalency design are crucial for this decision. If the Administration comes to the conclusion that there is no need of a risk analysis, the Submitter can follow a conventional approval process, to be determined by the Administration.

4.6.4 The decision whether the alternative and/or equivalency requires a risk-based analysis demonstrating that an equivalent level of safety may be reached by using table 1 to determine the degree of novelty. This decision needs to be transparently documented by the Administration (for the purpose of objectivity). 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 categorization is to establish whether or not the alternative and/or equivalency 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 of new technology

		Technology status		
		Proven	Limited field history	New or unproven
Application Area		1	2	3
Known	0	1	2	3
New	1	2	3	4

4.6.5 The Preliminary design preview meeting should include relevant people from the Submitter and professionals from the different disciplines including risk assessment within or contracted by the Administration.

4.6.6 Ideally, the representatives of the Administration who take part in the initial Preliminary design preview meetings should also take part in the definition of the approval basis, monitor the subsequent analyses and follow the project until final approval in order to take advantage of the learning process that occurs throughout entire approval process.

4.6.7 During the Preliminary design preview phase, the Submitter may be required to submit the following documents:

.1 general description of alternative and/or equivalency;

.2 functional description of alternative and/or equivalency;

.3 identification of interfaces between alternative and/or equivalency and other systems/operations;

.4 preliminary general arrangement drawings;

.5 preliminary detail drawings, if required;

.6 list of codes and standards applied;

.7 risk assessment plans; and

.8 further design basis documents, if necessary.

4.7 Definition of Approval Basis Phase

4.7.1 Following the Preliminary design preview phase, the next phase is for the Administration to define the approval basis with respect to scope of analysis and evaluation criteria. In order to accomplish this, the Administration and the Submitter may have to meet one or several times to discuss the alternative and/or equivalency, its purpose and objectives, 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 alternative and/or equivalency will have to be well understood.

4.7.2 The Submitter and the Administration may also discuss plans for hazard identification, risk assessments and plans for testing and analyses. The scope and extent of the analysis (either qualitative or quantitative analysis or both) to be performed in the Analysis of Preliminary design phase (see paragraph 4.5) is agreed between the Submitter and the Administration considering the requirements of the Submitter with respect to the soundness of the preliminary approval.

4.7.3 A risk assessment plan should be developed to identify appropriate types of assessment techniques by Submitter. The plan should clearly state the proposed evaluation criteria and the basis for the criteria.

4.7.4 A testing and analysis plan should be developed to identify appropriate types of test and engineering analyses by Submitter. This plan is only a preliminary plan, as it will most likely be revised following the results of the analysis for the preliminary design phase.

4.7.5 The work performed within this phase will result in a document issued by the Administration describing the requirements and the formal process for achieving preliminary approval.

4.8 Analysis of Preliminary Design Phase

4.8.1 The scope of this phase is to conduct an analysis of the Preliminary design that has been specified in the previous phases of the process. The Submitter is responsible for facilitating all analyses agreed with the Administration. It is highly recommended to invite Administration representatives to attend the meetings to provide a close dialogue between the Administration and the Submitter in order to ensure that all relevant issues are taken into consideration. However, careful consideration should be given to ensuring that their independence from the design team is maintained. The analysis of the preliminary design is a stepwise process monitored by the Administration that may be terminated in case so-called showstoppers are identified.

4.8.2 At a minimum, a HazId should be required in order to request for preliminary approval of the preliminary design. The Submitter will be required to arrange a HazId workshop, 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 Administration representatives to discuss the alternative and/or equivalency and its associated hazards.

4.8.3 The benefits of including Administration representatives are:

.1 the Administration representatives will be able to point to issues relevant for approval that may be discussed;

.2 the Administration representatives may have expertise within certain areas of the design under consideration and therefore may be able to contribute by drawing attention to issues that may unintentionally have been left out of discussions; and

.3 the amount of questions and misunderstandings will be reduced during the review of the HazId and in the overall approval process.

4.8.4 Typically, results of the HazId will include the following:

.1 identified hazards associated with the alternative and/or equivalency design; and

.2 identified potential safeguards already included in the design.

4.8.5 The results of the HazId should be documented (HazId Report) by the Submitter and submitted to the Administration. A list of the participants in the HazId and their expertise and experience should be submitted to the Administration as well.

4.8.6 Depending on the scope defined by the Submitter and the Administration, the Preliminary design analysis may include a risk assessment. If so, a coarse risk model should be developed based on the HazId. The scope of the evaluation of risk control options depends on the outcome of the risk evaluation.

4.8.7 The scope related to the risk assessments at this phase will depend on the degree of novelty of the alternative and/or equivalency and the risk assessment plans defined during the Definition of Approval Basis Phase (see paragraph 4.1.3). Typically, the risk assessments will include the following (which is also documented and submitted to the Administration):

.1 ranking of hazards (identification of frequencies and consequences) and selection of hazards for risk model;

.2 development of a coarse risk model in order to perform quantitative analyses;

.3 description of data analysis, assumptions, uncertainties and sensitivities;

.4 assessment of the alternative and/or equivalency design by means of reference design;

.5 identification of issues, such as design casualty scenarios, that may require further analyses and testing; and

.6 identification of issues that may require special attention with respect to operations, accessibility and inspections.

4.8.8 The risk model may be developed using one of the well-established methods such as 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 Phase (see paragraph 4.1.3).

4.8.9 The work performed related to risk assessments will be documented by the Submitter and submitted to the Administration. The risk assessment will be included as the basis for approval, if required.

4.9 Review of Analysis for Preliminary Design Phase

4.9.1 During this phase the HazId performed in the previous phase will be formally reviewed by the Administration to ensure that:

.1 the HazId team was composed of qualified members;

.2 appropriate procedures for a HazId were followed; and

.3 all hazards are identified.

4.9.2 The HazId will further increase the understanding of the alternative and/or equivalency, and the list of requirements will be revised based on the findings from the HazId.

4.9.3 The risk model and the results of the evaluation, if considered in this phase, will be formally reviewed by the Administration. If the 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.

4.9.4 Any risk control measures that may have been considered in the Preliminary design will be formally reviewed by the Administration.

4.10 Preliminary Approval Phase

4.10.1 The Submitter should seek approval of the Preliminary design from the Administration. The purpose of this is to verify that the alternative and/or equivalency is feasible and sound. The preliminary approval may therefore not be granted until all hazards and failure modes related to the design are identified and until control options (or plans for how to achieve control) of these hazards and failure modes are described. The following conditions should be satisfied prior to granting preliminary approval:

.1 no "showstoppers" were identified, otherwise a re-evaluation of the Preliminary Design phase and possibly improvements should be carried out; and

.2 the alternative and/or equivalency was found feasible and suitable for its expected application.

4.10.2 Such a preliminary approval may be useful with respect to project partners, financial institutions and additional regulatory agencies. The preliminary approval may also assist the Submitter in staying focused on the most important issues.

4.10.3 It should be noted that the issue of a preliminary approval statement by the Administration 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. A preliminary approval statement can facilitate the formal clarification of these aspects.

4.10.4 The basis for preliminary approval may consist of:

.1 a description of the alternative and/or equivalency, its specifications, its functional requirements, its operation and maintenance, health, safety and environmental issues, its interface with other systems, etc.;

.2 preliminary drawings;

.3 specifications of codes and standards applied (including specification of the applicable classification rules or part of rules);

.4 specification of the applicable administration requirements;

.5 hazard identification results;

.6 risk assessment plans or results of risk assessment for preliminary design, including evaluation method, evaluation metrics and evaluation criteria;

.7 design casualty scenarios;

.8 testing and analyses plans;

.9 special requirements for the project; and

.10 description of the approval process.

4.10.5 The preliminary approval should be issued with a set of conditions outlining the requirements and necessary steps the Submitter needs to satisfy and a list of documents that will be required in order to achieve final approval.

4.11 Final Design Phase

4.11.1 Following the preliminary approval, the Submitter will advance into the next phase of the project, this involves the Final design and subsequently required risk assessments, testing and analyses. These phases are more detailed versions of the phases prior to preliminary approval. It will result in an increased understanding of the alternative and/or equivalency design features, and both the Submitter and the Administration will gain confidence in the design as the level of accuracy increases.

4.11.2 The objective of this phase is to elaborate the preliminary design to a corresponding Final design. This Final design complies with the results of the preliminary analysis with respect to risk control options already identified and the requirements of the Administration. The final design is developed on the basis of the statement by the Administration.

4.12 Update of Approval Basis Phase

As previously discussed, the preliminary approval is issued with a set of conditions outlining the requirements and necessary steps the Submitter should satisfy in order to achieve final approval. Following the risk assessment, if done for the preliminary design and subsequent final design phase, the Submitter's Final design phase and the risk assessment of the preliminary design, the level of understanding of the alternative and/or equivalency has increased. The preliminary approval conditions may be revised as a result. That is, the requirements to be met in order to achieve final approval will be described in more detail. In addition, as the Submitter is in the process of selecting testing and analysis methods, the Administration will have an opportunity to guide and potentially specify explicit requirements for this selection.

4.13 Analysis of Final Design Phase

4.13.1 The tasks to be performed in this phase are similar to the analysis of the Preliminary design. In a first sub-phase, a review of the analysis of the preliminary design is performed to determine the difference between Preliminary design and Final 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.

4.13.2 The requirements related to the risk assessment of the final design will be based on the novelty of the design, the risk assessment plans defined for the previous phase and the differences between the preliminary and the final design. Typically, the risk assessment will address the following:

.1 identified hazards associated with the alternative and/or equivalency (update of preliminary analysis);

.2 identified potential safeguards already considered in the design;

.3 identification of frequencies and consequences associated with the hazards, and the resulting risks;

.4 a precise risk model in order to perform quantitative analyses;

.5 description of data references, assumptions, uncertainties and sensitivities;

.6 comparison of risk levels with evaluation criteria;

.7 identification of potential risk reducing measures;

.8 cost-benefit assessments in order to select the most appropriate risk reducing measures;

.9 description of selected risk reducing measures;

.10 re-evaluation of risk taking into account the additional risk reducing measures and comparison with evaluation criteria;

.11 identification of issues that may require further analyses and testing; and

.12 identification of issues that may require special attention with respect to operations, accessibility and inspections.

4.13.3 The work performed related to risk assessments should be documented and submitted in a timely manner to the Administration in order for them to stay informed of the processes and to provide feedback, if necessary. The results of the risk assessments shall be the basis for consideration of final approval, if required.

4.14 Review of Analysis for Final Design Phase

All results of the analyses for the Final design will be reviewed by the Administration.

4.15 Definition of Detailed Requirements Phase

Detailed requirements will be defined for the alternative and/or equivalency design by the Administration and the Submitter jointly on the basis of the results of the quantitative risk analyses in order to achieve approval. These requirements address the following topics:

.1 approval tests: testing and analysis methods required to confirm assumptions used for the quantitative risk analysis;

.2 approval numerical calculations/simulations: numerical results required to demonstrate quantitative performance;

.3 manufacturing: level of quality control during manufacturing and installation; and

.4 operation: operational limits and maintenance, including definition of operation and maintenance procedures, as well as data acquisition and assessment during operation.

4.16 Perform Approval Tests and Analyses Phase

4.16.1 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 alternative and/or equivalency will meet expectations from a functional and safety point of view, including environmental protection. The engineering analyses are performed by the Submitter. Models used for the analyses, input data and results are documented and submitted to the Administration for review.

4.16.2 The types and extent of the analyses and tests required depend on the level of novelty, 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. 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. The Administration should oversee these tests with experts in relevant areas.

4.16.3 Submittals required with respect to the analyses and tests include:

.1 statements of relevant codes and standards applied and deviations made to their application;

.2 selection of appropriate evaluation criteria used to assess the design;

.3 design calculations;

.4 analyses reports (including objectives, scope, assumptions, results, conclusions and recommendations);

.5 test/simulation reports, including descriptions of modelling/test set-up, as well as objectives, scope, results, analyses, conclusions and recommendations; and

.6 error and uncertainty assessments.

4.17 Review of Approval Tests and Analyses Phase

The Administration 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. The attendance of an Administration representative at appropriate stages in the testing process is recommended and should be planned for and agreed as part of the definition of detailed requirements as described in paragraph 4.15.

4.18 Final Approval

4.18.1 The Final 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.

4.18.2 At the time of approval, all potential hazards and failure modes for the alternative and/or equivalency will have been assessed versus evaluation criteria, to a level of confidence necessary to grant final approval.

4.18.3 In most cases, approval of the alternative and/or equivalency will involve conditions related to in-service surveys, inspections, monitoring, and possibly testing. In most cases, the conditions will be fixed already during the design phase. As experience accumulates and confidence in the alternative and/or equivalency is gained, these additional conditions and requirements may be relaxed.

4.18.4 Following final approval, in the construction and in-service phase the Administration needs assurance that knowledge related to the alternative and/or equivalency 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.

4.18.5 All documents and drawings required to be submitted by the Submitter are verified by the Approval Authority.

4.19 Communication between Administration and the Submitter

4.19.1 Throughout the process, continuous communication between the Administration and the Submitter is important. As seen from the discussions in this section the process requires the Administration and the Submitter to work together on a number of occasions:

.1 design preview: In order to decide whether the alternative and/or equivalency requires observance of the approval process as outlined in this document or whether a conventional process can be followed, the Administration and the Submitter will need to meet and discuss the preliminary design developed by the Submitter;

.2 definition of approval basis: In order to define the approval basis, the Administration and the Submitter 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 utilize) and plans for testing and engineering analyses. The definition of evaluation criteria may require additional meetings with the Administration to discuss and evaluate the selected criteria;

.3 monitoring of analysis of Preliminary design: the Administration may participate in the HazId for all alternative and/or equivalency designs. Furthermore, if a risk assessment and an identification of risk control options are agreed at this stage between the Administration and the Submitter, the Administration may monitor the activities of the Submitter;

.4 review of analysis of Preliminary design: The Administration reviews the results of the analyses for the Preliminary design;

.5 approval of Preliminary design: The preliminary approval will be given with a set of conditions that are to be met to achieve full approval. The Administration and the Submitter need to arrange a meeting to discuss the steps forward in the process;

.6 update of approval basis: In order to consider the results of the analyses performed for the preliminary design and the information provided by the specific design in the further risk analysis process, the approval basis is updated;

.7 review of analysis of Final design: The Administration reviews and eventually evaluates the necessary risk assessments necessary to satisfy the conditions outlined in the approval for the preliminary design;

.8 definition of detailed requirements: There may be a need to arrange a meeting to discuss the final design and results from the risk assessments and to further detail or revise the conditions given together for the approval of the final design;

.9 review of approval tests and analyses: The Submitter submits the required documentation and evidence of the testing and analyses to the Administration. Whether or not a meeting is required depends on the complexity of the testing and analyses; and

.10 final Approval: The approval 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. There should be a meeting between the Administration and the Submitter when issuing the approval certificate. During this phase, there may be a need for additional documents and drawings to be submitted to the Administration.

5 EVALUATION CRITERIA

5.1 General

5.1.1 The expected safety performance of the alternative and/or equivalent design should be quantitatively specified in the form of the evaluation criteria. As stated in section 4, the approval of alternatives and/or equivalencies requires the development, review, and selection of appropriate evaluation criteria. Before evaluation the alternative and/or equivalent design, the Submitter and the Administration need to agree on established evaluation criteria.

5.1.2 Following the design preview phase, the Submitter and the Administration will need to develop the evaluation criteria to be applied and an assessment plan which clearly states the agreed evaluation criteria and its basis.

5.1.3 Safety objectives and functional requirements available in IMO instruments should be taken into consideration when developing the evaluation criteria.

5.2 Evaluation criteria

5.2.1 The basic principle for the evaluation criterion should be "safety equivalence". This means that the alternative and/or equivalent will be designed so that it will perform its intended safety related function(s) in a manner that is equivalent to or better than the prescriptive requirement it is deviating from. The evaluation criterion used for the evaluation of the alternative/equivalent design shall be specified either on basis of prescriptive requirements or an equivalent, regulations compliant design. Therefore, the safety level of the prescriptive requirement should be made explicit to enable a comparison with the safety level of the alternative and/or equivalent design.

5.2.2 Depending on the area to which the approval of the alternative and or equivalent design is being sought, the evaluation criteria could fall into one or more of the following categories:

.1 life safety criteria – These criteria address the survivability of passengers and crew and may represent the effects or flooding, fire, etc.

.2 damage to ship structure and related systems – These criteria address the impact that a casualty might have on a ship structure, mechanical systems, electrical systems, fire protection systems, etc. These criteria may represent physical effects of an accident.

.3 damage to the environment – These criteria address the impact of an accident on the atmosphere and the marine environment.

5.2.3 The evaluation criterion can be also specified by means of performance criteria characterizing the safety level of IMO regulations. In that case the performance criterion should be developed, taking into consideration the intent of the regulations and related mandatory instruments (e.g. mandatory codes and standards), if any.

5.2.4 The purpose of the analyses is to verify that a design with reasonable confidence will perform its intended safety related function(s) when necessary and in a manner equivalent to or better than the prescriptive IMO requirements.

5.2.5 The analysis used to show that the alternative design and arrangements provide the equivalent level of safety to the prescriptive IMO requirements should follow an established approach to safety design. This approach should be based on sound science and engineering practice incorporating widely accepted methods, empirical data, calculations, correlations and computer models as contained in engineering textbooks and technical literature. The general process of analysis is outlined in section 4 of these Guidelines.

5.2.6 For alternative design falling into areas where no appropriate IMO regulations or other relevant industry standard exist the evaluation criteria may be specified by means of risk acceptance and agreed with Administration.

5.2.7 Risk analysis is the calculation of probabilities and consequences for the event examined and the conversion of these into a risk metric (i.e. a measurable value, risk acceptance criterion, evaluation criterion, safety level, etc.) based on which decisions may be taken.

5.2.8 This approach may address 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 to the design of the alternative and/or equivalency in question.

5.2.9 Different risk metrics for each type of risks can be employed and typically the following types of evaluation criteria are used:

.1 individual and societal risk; and

.2 risk to crew, passengers and people ashore, as appropriate.

5.2.10 The above are criteria for total risk (e.g. fatalities from fire, collision, structural damage, etc.) as opposed to criteria for individual hazards or individual risks. For the risk assessment of structural issues of ships, among others, it may be necessary to develop acceptance criteria for individual failure modes (limit states) of ships (e.g. failure due to fatigue of steel plates). This may also be necessary when examining the satisfaction or not of acceptance criteria for individual functional requirements relating to the structure of ships, its global and local strength, etc. Such risk evaluation criteria for individual hazards of ship structures and individual failure modes have not been developed nor established to date.

5.2.11 The risk acceptance criteria should be preferably specified by IMO or by the Administration otherwise.

5.3 Special considerations

5.3.1 In those cases where it may not be possible to define the evaluation criteria during the Preliminary Design phase, the Submitter and Administration should agree on the strategy for defining such criteria.

5.3.2 If the evaluation criteria cannot be fulfilled the approval process should be either terminated or restarted with a modified design.

5.3.3 Submitter and Administration should consider the impact that one particular evaluation criterion might have on other areas that might not be specifically part of the alternative design. For example, the failure of a particular safeguard may not only affect the life safety of passengers and crew in the adjacent space, but it may result in the failure of some system affecting the overall safety of the ship.

5.3.4 The Revised Guidelines for Formal Safety Assessment (FSA) for use in the IMO rule-making process (MSC-MEPC.2/Circ.12) contains information on risk acceptance evaluation criteria.

6 DOCUMENTATION REQUIREMENTS

6.1 Documentation

6.1.1 The approval process for an alternative and/or equivalency is different from a conventional approval process, and therefore the documentation process needs to be clear, transparent and well described to avoid misinterpretations. As illustrated in figure 2, documentation may comprise, but is not limited to, the following:

6.1.1.1 From Submitter to Approval Authority:

.1 design documents:

.1 description of the alternative and/or equivalency design, including design basis;

.2 functional description;

.3 identification of interfaces between the design and other systems/operations (compliant with regulations);

.4 preliminary general arrangement drawings;

.5 preliminary detail drawings of subsystems (if available);

.6 list of codes and standards that are considered to be applied;

.7 risk assessment plans;

.8 testing and analysis plans; and

.9 further design basis documents, as necessary;

.2 analysis reports for assessment of preliminary design:

.1 identified hazards;

.2 safeguards included in the design;

.3 evaluation criteria applied;

.4 issues that may require further analyses and testing;

.5 description of analysis method applied, including the details of workshop conducted; If analysis for preliminary design includes a risk analysis;

.6 frequencies and consequences associated with the hazards and resulting risks;

.7 risk models;

.8 data references, expert judgments, assumptions, uncertainties and sensitivities;

.9 cost-benefit assessments;

.10 selected risk reducing measures;

.11 design casualty scenarios;

.12 issues that may require further analyses and testing; and

.13 information on the participated experts in the analysis;

.3 issues that may require special attention with respect to operations, accessibility and inspections;

.4 description of final design (including revisions to "preliminary design description" submittals);

.5 analysis reports for assessment of final design – including information regarding:

.1 as specified for assessment of preliminary design;

.6 analyses and testing reports – including information regarding:

.1 statements of relevant codes and standards applied, and deviations made to their application;

.2 selection of appropriate evaluation criteria used to assess the design;

.3 design calculations;

.4 analyses reports (including objectives, scope, assumptions, results, conclusions and recommendations);

.5 test reports, including descriptions of modeling/test set-up, as well as test objectives, scope, results, analyses, conclusions and recommendations; and

.6 error and uncertainty assessments; and

.7 design specifications:

.1 underlying analyses, testing and calculations that define the basis for design; and

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

6.1.1.2 From Administration to Submitter:

.1 description of approval requirements and process;

.2 preliminary approval statement with conditions (if analysis of preliminary design is performed);

.3 description of detailed requirements;

.4 statement of approval of design specifications; and

.5 certificate with conditions.

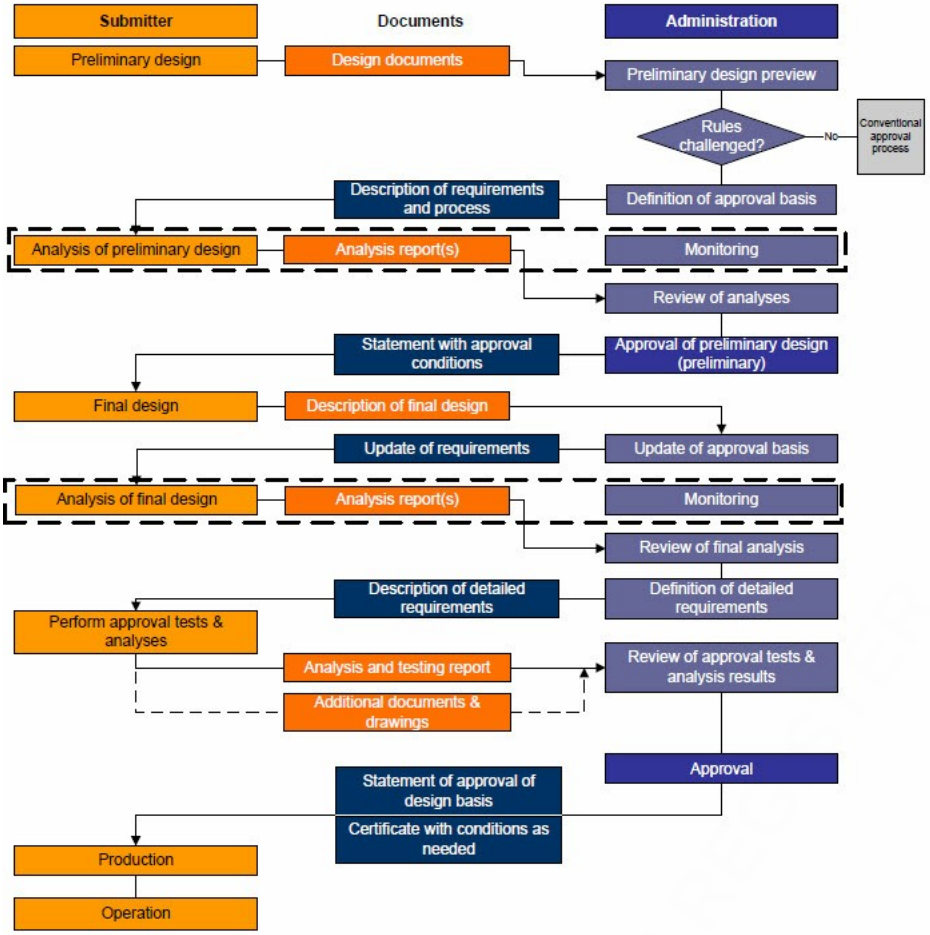

Figure 3: Documentation flowchart for the approval procedure

6.1.1.3 Documentation that is required to be exchanged between the Administration and the Submitter in the approval process is summarized in figure 3, and this chapter of the Guidelines outlines requirements pertaining to this documentation.

6.1.1.4 The document requirements described in this section are considered as minimum. According to the complexity and features of subjected design development, slight modifications of the requirements could be required. In this case, the modifications should be conducted on the basis of the agreement between the Administration and the Submitter.

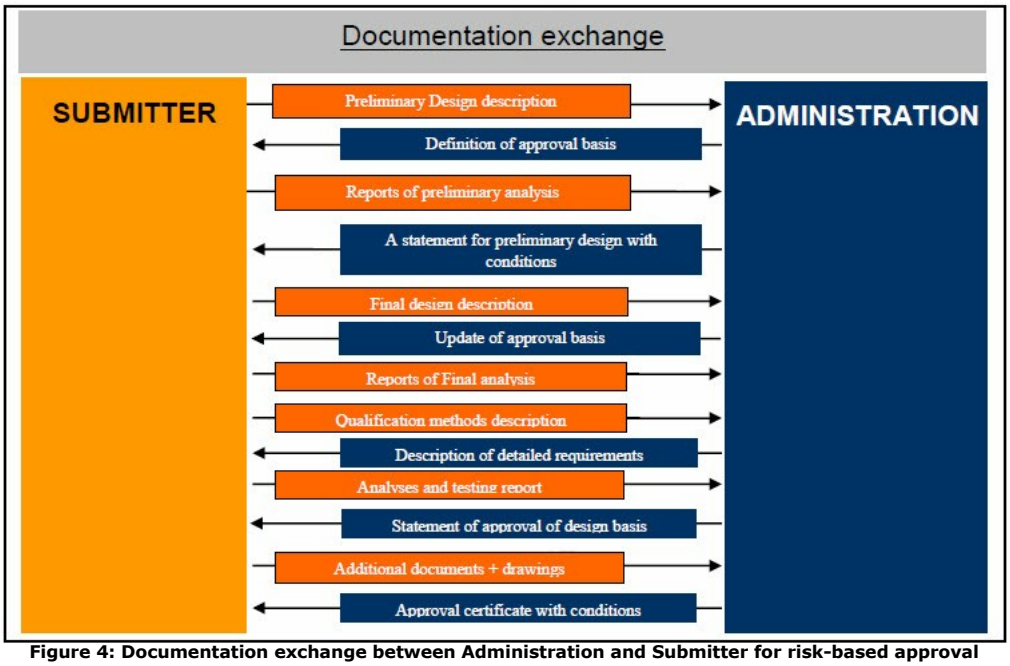

Figure 4: Documentation exchange between Administration and Submitter for risk-based approval

6.2 Approval guidance

6.2.1 A matrix as shown in table 2 may be applied for guidance to the Submitter 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 using table 1 from section 4. The following paragraphs are explanatory notes to the approval matrix.

6.2.2 *Header row: Project category*

In order to rank the novelty of a design, the categorization from table 1 from section 4 may be used.

6.2.3 ***Row A: Basic risk assessment (HazId)***

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 may be ranked in qualitative terms or semi quantitative terms.

6.2.4 ***Row B: Further analysis requirements***

6.2.4.1 Due to the difference in complexity in each of the various designs, differentiation in the documentation requirements is:

.1 semi-quantitative risk assessment: A qualitative or quantitative estimates (range categories) of frequencies and consequences of an activity or operation. Scenarios are described and categorized according to their probability and impact;

.2 quantitative risk assessment: A numerical description of frequency and consequence of defined hazards 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.

6.2.4.2 If a semi-quantitative risk assessment describes and suggests reduction of risks to a satisfactory level, then requirements for quantitative assessments may be redundant.

6.2.5 ***Row C: Qualifications of analysts***

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

6.2.6 ***Row D: Applied rules and guidance***

This element reflects the various sources of potentially applicable regulations and guidance on specific requirements in each case.

6.2.7 ***Row E: Potential additional tests, surveys and compliance control***

This addresses anticipated follow-up activities after construction.

6.2.8 ***Row F: Review by third party***

This addresses the review of the alternative design or equivalency study by independent expert peers. The higher the degree of novelty and/or risk level, the more detailed the review should be.

6.3 General considerations

6.3.1 In the following, general issues and procedural considerations are dealt with. Prevalently, the responsibility for ensuring documentation quality rests with the Submitter. A party wishing to enter into the approval process may therefore preferably have safety and quality management systems in place for their own processes as well as for 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 and document title
- responsible person(s), including company and contact information
- scope statement/project description
- project identification number
- distribution list
- authorization signatures
- date
- revision number/letter
- other controlling documents/processes, if necessary

Project Category Requirements	Known application of proven technology (conventional process) (1)	Known application of a technology with a limited field history/New application of proven technology (2)	New application of a technology with a limited field history/Known application of a new or unproven technology (3)	New application of novel or unproven technology (4)	Activity performed by: Requirements
A) Basic risk assessment	Not required	Required (unless rule challenge deemed insignificant or of negligible impact on safety and nvironment)	Required	Required	Submitter (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 semi-quantified 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)	Submitter in cooperation with the Administration

C) 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
D) 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
E) 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 risk-based features, if deemed necessary	Continuous monitoring and review subject to reporting to the Administration until a sufficient level of experience is gained	Submitter (operator)
F) Review by third party	Considered	Considered	Considered	Recommended	N/A

Table 2 – THE APPROVAL MATRIX

6.3.2 ***Drawings and layouts***

6.3.2.1 Any design detail deviating from conventional best practice should be described comprehensively to facilitate a full understanding of the extent of the novel type equipment or detail with intended design basis including environmental conditions and operational scheme.

6.3.2.2 Safety critical details have to be documented.

6.3.3 ***Design parameters***

All parameters applied in 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.

6.3.4 ***Requirements for risk control measures***

6.3.4.1 For alternative designs the acceptable risk level will typically be set by a regulation compliant reference design (see sections 4 and 5).

6.3.4.2 In the absence of a regulation compliant reference design to compare with, the evaluation criteria may be specified by means of risk analysis. Identified risk levels will usually be categorized to belong to three categories: intolerable risks which should be reduced, negligible risks which do not require any action, and risks in the ALARP area which should be reduced to as low as reasonably practicable.

6.3.4.3 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 efficient.

6.3.4.4 If risk control measures are operational, then their implementation into management systems should be documented, to ensure that the crew is fully informed and familiar of such special measures.

6.3.5 ***Reporting format***

6.3.5.1 The documentation of the project prerequisites, any assumptions and exclusions made, the HazId, the risk assessment, (if any), recommendations and conclusions as per the approval process may take several forms, all with their own advantages and drawbacks, such as:

.1 PC based work sheets and documents;

.2 technical reports; and

.3 programs tailored to the purpose.

6.3.5.2 Regardless of the format, the content should be verifiable. 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.

6.3.6 *Calculation/analysis requirements*

6.3.6.1 When making decisions based on analysis techniques, care should 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/regulation challenge is variable and, depending hereon, the most suitable methodologies may also vary.

6.3.6.2 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 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 acceptable by the Approval Authority;

.4 ensure that the applied model reflects the as built and operated ship or system as accurately as possible. If necessary, the process should be conducted iteratively, as the design process progresses, to ensure all safety critical aspects are covered;

.5 apply assumptions on a sound basis and perform 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;

.8 include normal operational modes as well as states of emergency in the analysis; and

.9 include sensitivity analysis, uncertainty analysis and importance measures.

6.3.7 *Errors and uncertainties*

6.3.7.1 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.

6.3.7.2 Uncertainty reflects either lack of knowledge about the actual value of a variable (epistemic uncertainty) or variability intrinsic to the parameter (aleatory uncertainty). In standard risk assessment methods, however, uncertainties involved can be accounted for within the method (e.g. conservative assumptions).

6.3.7.3 Although uncertainty on variables may be considerable, expected values can be estimated. Therefore, it may be sensible to choose a reasonable estimate reference. Choosing values implying the worst conceivable case could result in an exaggerated picture of the risks involved.

6.3.7.4 To examine the impact of specific variables on the final results, a sensitivity analysis should be carried out, where the effect of for example doubling the value of a variable may be examined to decide whether the originally selected values are conservative enough or if they deserve a more precise/detailed analysis or not.

6.3.7.5 Hence the following issues which may require investigation at any given stage require consideration:

.1 variation in the input data;

.2 the impact of simplifications/assumptions of problems;

.3 the effects of various characteristics of the scenarios; and

.4 the reliability of systems.

6.3.7.6 Variables which are found to have a major impact in the sensitivity analysis may justify a more conservative or precise approach than variables of lesser importance. The sensitivity analysis may indicate the variables of major impact and how uncertainties of such variables are handled.

6.4 Preliminary design description

6.4.1 A design description comprises the material available on the design, including any risk-based features, describing the project to the extent possible in this phase, as follows. Such a description comprises many elements which are of importance in relation to the understanding of the approval procedure. This section provides guidance on documentation to be submitted as well as considerations by the Administration upon receipt.

6.4.2 *Procedural intent, initial considerations*

6.4.2.1 *Description of the alternative and/or equivalency design*

High-level description of the design submitted for approval, including the documentation quoted in the documentation section. Definition of the design basis comprising various environmental conditions, intended goal (objectives) of the design and operational scheme (including operational limitations) should be clarified.

6.4.2.2 *Functional description*

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

6.4.2.3 *Identification of interfaces between the alternative and/or equivalency and other systems/operations*

This applies only to project categories 2-4, table 2.

6.4.2.4 *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.

6.4.2.5 *Preliminary general arrangement drawing*

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

6.4.2.6 *Preliminary detail drawing of subsystems*

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

6.4.2.7 *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.

6.4.2.8 *Risk assessment plans*

This applies only to project categories 2-4, table 2. This describes risk assessment as deemed necessary by the Submitter. This allows the Administration to evaluate whether the detail level contemplated is sufficient. The effort applied and the detail of assessment and analysis depend on experience with the design (or similar designs) in the intended application.

6.4.2.9 *Testing and analysis plan*

This applies to project categories 1 to 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.

6.4.2.10 *High-level conclusion*

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

6.4.3 *Documentation to be delivered*

Description of the alternative and/or equivalency design

6.4.3.1 The Submitter supplies (the examples below refer to risk-based ship design):

.1 preliminary main dimensions, preliminary overall shape and configuration, calculations of weights, hydrostatics, stability calculations, etc.;

.2 speed, capacity and any further relevant particulars;

.3 material data sheets for materials planned for use during construction, particularly where restrictions on the application of such materials exist; and

.4 a list of regulations challenged at this stage, if any, to the best knowledge of the Submitter.

6.4.3.2 The Administration previews to provide verification of the documentation on:

.1 whether the description supplied is sufficient information to commence the process; and

.2 whether agreement exists on the identified list of regulations challenged.

Functional description

6.4.3.3 The Submitter supplies:

.1 description of modes of operation and intended area of service;

.2 specific operational parameters, including estimates of limitations bearing in mind any novel characteristics;

.3 function statements and planned inherent safety features (electric/hydraulic, power packs, redundancies, overload switches), main pressures and voltages where applicable; and

.4 drawings, wiring diagrams and piping plans as well as presumed maintenance and operating requirements.

6.4.3.4 The Administration previews to provide verification of the documentation on whether all safety critical functions and processes have been included and described concisely.

Identification of interfaces between alternatives and/or equivalencies and other operations

6.4.3.5 The Submitter supplies a description of the items where alternative design features are deemed to interact with conventional features.

6.4.3.6 The Administration previews to provide verification of the documentation on:

.1 whether all potential items of interaction are included and described to a comprehensive level of detail; and

.2 whether all identified rules challenged as shown in the list are addressed and the potential impacts described.

Design approval basis documents

6.4.3.7 The Submitter supplies:

.1 identification of the design parameters, addressing the nature of operational requirements;

.2 the principles underlying the design; and

.3 calculations and descriptions of assumptions made, including limitations.

6.4.3.8 The Administration previews to provide verification of the documentation on:

.1 whether the design approval basis documents are considered to be complete;

.2 whether safety has been considered and included as a design parameter;

.3 whether simplifications applied when analysing the design provide an adequate level of accuracy; and

.4 whether tools applied in the process are approved or subject to approval.

6.4.3.9 Preliminary general arrangement drawings: identical to conventional approval process.

6.4.3.10 Preliminary detail drawing of subsystems: identical to conventional approval process.

List of Codes and standards applied

6.4.3.11 The Submitter supplies:

.1 codes or standards adhered to;

.2 scope of codes and standards adhered to;

.3 requirements challenged in the alternative and/or equivalency ship design;

.4 type approvals achieved for components or subsystems, if any; and

.5 documentation of applicability of any code or standard, as well as any exemption, deviation or non-compliance.

6.4.3.12 The Administration previews to provide verification of the documentation on:

.1 whether standards complied with are relevant and sufficient;

.2 whether applicability is documented to the satisfaction of the Administration;

.3 whether certificates or statements of compliance are available and up to date; and

.4 whether required examinations are carried out by accredited bodies or labs.

Risk assessment

6.4.3.13 The Submitter supplies:

.1 risk assessment as deemed necessary by the Submitter in accordance with the assessment of deviation from a conventional design;

.2 a description of proposed risk evaluation criteria;

.3 a description of risk assessment with regard hereto, including statement on techniques of choice, the applicability of techniques, tools, and proposed preliminary depth level; and

.4 a list of proposed participants in the risk assessment team and their qualifications.

6.4.3.14 The Administration previews to provide verification of the documentation on:

.1 whether the risk assessment planned by the Submitter would provide an adequate level of assessment and analysis;

.2 whether the evaluation criteria chosen are acceptable;

.3 whether the techniques chosen by the Submitter are adequate for the scope of assessment/analysis; and

.4 whether the aggregate qualifications of the risk assessment team are considered adequate for the task.

Testing and analysis plan

6.4.3.15 The Submitter supplies:

.1 tests and analyses plans to validate the applicability of materials or systems for their intended use; and

.2 statements of methods and details of labs performing tests and analyses to validate materials or systems.

6.4.3.16 The Administration previews to provide verification of the documentation on:

.1 whether all relevant materials and systems will be tested or analysed;

.2 whether methods are acceptable; and

.3 whether the labs performing the tests are recognized and accredited or subject to accreditation within a reasonable time frame.

High-level conclusion

6.4.3.17 The Administration supplies the following to the Submitter:

.1 high-level conclusion of the preview (acceptable/conditionally acceptable/not acceptable);

.2 statement of areas which may contain further challenges;

.3 terms of adherence to intended approval method (viability considerations); and

.4 evaluation of the time frame for approval, if possible.

6.4.3.18 Queries by the Administration, preceding preliminary approval:

.1 Does the design description supply sufficient information to give a broad understanding of the project?

.2 Does the Approval Authority agree with the rules applicable and challenged (potential further rule challenge)?

.3 Is it possible to initiate the process on the basis of the documentation submitted and available?

.4 Have provisions for dealing with any instances yet to be evaluated been considered?

.5 Do these provisions appear adequate?

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

6.5 Definition of approval basis

6.5.1 ***Procedural intent***

6.5.1.1 As a consequence of reviewing the documentation supplied and based on the results from the preview of the documentation, the Administration is in a position to define the approval basis:

.1 if regulation challenges are negligible or their impact minor (subject to exemption by the Administration), the design can be approved by means of a conventional process; and

.2 if regulation challenges or the impact of challenge is significant, an approval process in accordance with this Guideline should be followed.

6.5.1.2 The sequence takes place based on the outcome from the preview. First, it consists of an evaluation by the Administration 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 Submitter. In principle, this step in the process requires the owner to have selected an Administration, as the design should be subject to the requirements given internationally, regionally and nationally.

6.5.1.3 The Administration 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 imposed 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.

6.5.2 ***Documentation to be delivered***

6.5.2.1 The Administration supplies the following to the Submitter:

.1 Statement from the Administration on those operations which should be evaluated in depth through the risk assessment;

.2 Concise statement from the Administration on intended sets of regulations/standards and processes applicable to the project;

.3 The segments (if any) which may be subject to simple compliance with existing regulations; and

.4 Summary conditions of compliance and approval from the Administration.

6.5.2.2 Queries by the Administration preceding preliminary approval:

.1 Are all operational phases considered, either by standard compliance verification or by evaluation through risk analysis?

.2 Are alternative industry standards, which may have been chosen, relevant and applicable?

.3 Have evaluation criteria been assigned?

6.6 Analysis of preliminary design (including the HazId report)[1]

[1] Consider remarks on process made in section 4.

6.6.1 *Procedural intent*

6.6.1.1 For alternative and/or equivalent designs (unless the regulation challenges are deemed insignificant or of negligible impact in terms of safety), a HazId will always be required, as it fulfills the requirement that the basic risk assessment should address the parameters of the submitted design known to this point and evaluate where further scrutiny is justified and necessary.

6.6.1.2 The Submitter should consider:

.1 statements of main conclusions from initial meetings, including key elements of risk that may be examined further;

.2 description of HazId procedure applied;

.3 documentation in support of any assumptions made;

.4 documentation of existing safeguards and control measures;

.5 plans and means for proposed safeguards and control measures;

.6 levels of agreement within the team and the qualifications and experience of the participated members;

.7 points of discussion and further examination, including further analysis and applicable techniques;

.8 needs for further in-depth examination of historical evidence/expert judgment or calculations; and

.9 sources of information.

6.6.1.3 When receiving the HazId report and monitoring the session(s), the Administration may consider:

.1 whether safety issues have been comprehensively covered (whereas commercial risks in this context are beyond the scope of the Administration);

.2 whether all relevant, conceivable scenarios have been considered, ranked and prioritized;

.3 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;

.4 whether the qualifications and experience of the participants are verifiable upon request;

.5 whether existing and proposed safeguards and control measures are adequate and viable. (The adequate reduction of risk to acceptable level, or plans to perform such reduction in the Final design process, is a condition of preliminary approval.); and

.6 whether identified significant hazards can be adequately analysed and reduced by means of the planned detailed risk analysis processes.

6.6.1.4 The Administration 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 Administration representative may participate to ensure that potential comments from the Administration to the Submitter are covered to the maximum extent possible).

6.6.1.5 The HazId further serves to clarify and rank all identified hazards. As mentioned above, the HazId is a meticulous, formalized brainstorming process, documenting any contributory factors impacting on safety critical elements. The documentation derived from the process is submitted to the Administration.

6.6.1.6 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.

6.6.2 *Documentation to be delivered*

6.6.2.1 The Submitter supplies the following to the Administration:

.1 full HazId report (also see recommendations in the FSA Guidelines), including the following:

.1 prioritized lists of hazards and scenarios (ranking);

.2 causal sequences considered; and

.3 documentation on background information applied (historical data, sources, impacts, effects, relevance);

.2 desired field verifications of measures;

.3 related or equivalent systems or subsystems (can equivalence be applied/documented at any given instance);

.4 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);

.5 details on how and based on which evidence consequences and probabilities have been ranked; and

.6 any supporting documentation which may potentially validate estimates during the HazId.

6.6.2.2 Queries by the Administration preceding preliminary approval:

.1 To what extent are known and standardized techniques applied in the identification of hazards and which techniques have been applied?

.2 Have all relevant areas of expertise contributed to achieve the most comprehensive overview possible?

.3 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)?

.4 To what extent can reliance be placed in the applicability of the data?

.5 Are references made to all applied information sources to enable fact-checking?

.6 Have criteria for individual risk and societal risk been accepted.

6.7 Preliminary approval statement with conditions

6.7.1 *Procedural intent*

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

6.7.1.2 The Administration 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.

6.7.1.3 The report from the HazId is submitted to the Administration 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.

6.7.1.4 Particular requirements prevail with regards to the ensuing risk assessment session, quoted evaluation criteria and further risk assessment.

6.7.1.5 The statement to the Submitter at this point will concern:

.1 the Final design characteristics with requirements for any areas of particular concern identified;

.2 requirements for the Final risk analyses to be performed in the next step of the process (project categories 2-4);

.3 assumptions in the high-level process to be verified through the detailed design sequences;

.4 required test and analysis results; and

.5 required additional general documentation describing the ship as needed prior to final approval (manuals, system specifications, data sheets).

6.7.1.6 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/preliminary level to a specific detailed level of examination.

6.7.2 *Documentation to be delivered*

6.7.2.1 The Administration supplies the following to the Submitter: preliminary approval statement, with any conditions as applicable, including requirements for further risk analyses.

6.7.2.2 Queries by the Administration:

.1 Are the conditions of final approval stated in a manner that adequately explains the need for their fulfillment?

.2 Are the conditions reasonably and rationally argued for?

6.7.2.3 If no medium or high risks have been identified in the basic risk assessment at the preliminary stage, and the Administration 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.

6.7.2.4 If the Administration considers the identified risks to be unacceptable, and/or proposed risk reduction measures are considered impractical, the Administration can refuse supplying a preliminary approval statement, citing appropriate reasons for the rejection.

6.8 Description of Final design, risk assessment report review and qualification method description

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

6.8.1 ***Procedural intent***

6.8.1.1 Upon receipt of the preliminary approval statement, the description of the final design may commence. The final design elements and the scenarios imposed by the operational conditions will at this stage be subject to a risk assessment of all vital/safety critical elements.

6.8.1.2 The risk assessment is to live up to the detail level necessary to examine risks with respect to the evaluation criteria as well as follow acceptable methods (qualification of the methodology should be part of the report submitted).

6.8.1.3 Initially, the required level of detail mainly depends on the novelty impact of the issue addressed. In order to avoid possible conflict of interest, it is recommended that the party setting the requirements to the risk assessment and eventually approving it is not the party performing and delivering it.

6.8.1.4 The Submitter has to consider:

.1 all relevant IMO guidance documents;

.2 further information, plans and drawing details in the course of such information being produced;

.3 documentation on any previously unidentified risks, rendered evident by the increased comprehensiveness of the design, analysis of such risks and, and information on the analysis methods selected;

.4 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 Submitter);

.5 applied evaluation criteria (relative, qualitative or quantitative), examined and explained. If a reference design exists, or equivalent arrangements can be found, then relative criteria should be applied;

.6 a description of sources of frequency and consequence estimates, documenting relevance for the design in question;

.7 statement on assumptions, exclusions, limitations and uncertainties;

.8 a description of further planned tests and analyses of materials and systems; and

.9 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.

6.8.1.5 The Administration has to consider:

.1 whether relevant guidance have been taken into account;

.2 whether the documentation supplied renders a complete picture of the design to the extent known at the given stage;

.3 whether all previously and newly identified risks have been analysed:

.1 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.

.2 by personnel with adequate knowledge and experience. The adequacy of personnel qualifications depends on the required analysis depth level;

.3 at an adequate depth level. The analysis may yield information to support confidence in the safety of the design and document risks being compliant with evaluation criteria agreed at the highest level possible;

.4 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.); and

.5 sequentially and iteratively to ensure that any potential new or altered elements of risk are covered as the design process progresses;

.4 whether agreement prevails on the selected evaluation criteria;

.5 whether assumptions, exclusions and limitations are justified and whether the approach is sufficiently robust to retain confidence in the design;

.6 whether the applied risk control options are considered effective and viable;

.7 whether historical/statistical data is as recent as possible and is relevant for the application;

.8 whether the numerical tools used are fit and validated for purpose; and

.9 whether evidence prevails that intended or planned further tests and analyses will have an acceptable outcome.

6.8.2 ***Documentation to be delivered***

6.8.2.1 The Submitter supplies the following to the Approval Authority:

.1 description of risk model(s), calculations and analyses (methodology, frequency and consequence estimates, sensitivity analysis, limitations of methods, assumptions made, reproducibility/falsification tests applicable);

.2 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));

.3 clear indication where and how expert judgment was applied (where no data is available);

.4 level of agreement in the expert group (concordance, see FSA Guidelines);

.5 applicable risk control options and associated considerations, including the analysis efficiency of proposed options;

.6 error/uncertainty/sensitivity discourse; and

.7 main risk contributory factors.

6.8.2.2 Queries by the Administration preceding approval:

.1 Are the models used of an approvable methodology (recognized risk assessment techniques, adequate for the task)?

.2 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?

.3 Has an acceptable methodology and degree of consensus been achieved when applying expert judgment?

.4 Can the results be reproduced by a third party having knowledge of the case?

.5 Have limitations of the methodologies applied been accounted for?

.6 Have all main risk contributory factors been accounted for and evaluated?

.7 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)?

.8 Have issues of interaction effects or interface issues been considered (among other things aggravating or mitigating conditions)?

6.9 Definition and description of detailed requirements

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

6.9.1 ***Procedural intent***

6.9.1.1 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 Submitter.

6.9.1.2 The Administration has to consider:

.1 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;

.2 conditions of approval are linked to the outcome of tests, reports, detail drawings and achievement of third party approval, where applicable; and

.3 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.

6.9.2 ***Documentation to be delivered***

6.9.2.1 The Administration delivers the following to the Submitter:

.1 concise reference to facilitate the adherence to imposed standards or regulations;

.2 statement of options of compliance (if one exists); and

.3 drawings, measurements, tables, written documentation on equipment specifications.

6.9.2.2 Queries by the Administration preceding approval:

.1 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?

.2 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?

.3 Have any such organizational or operational requirements been sufficiently documented, such as to become part of a safety management system?

.4 Has assessment taken place of effects of novel designs interacting with the equipment and manning needed on board (tools, measuring equipment)?

.5 If general industry standards are applied, are certificates and reports made available?

6.9.2.3 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.

6.10 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 Submitter by the Administration.

6.11 Analysis and testing reports/additional documentation

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

6.11.1 *Procedural intent*

6.11.1.1 The Submitter 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.

6.11.1.2 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.

6.11.2 *Documentation to be delivered*

6.11.2.1 The Submitter delivers the following to the Administration:

.1 test reports;

.2 results of further analyses conducted as a consequence of the detailing of the design and the increased understanding of the design;

.3 detailed drawings of the design, equally as a consequence of detailing;

.4 tabulated values, achieved figures, measurements;

.5 possible errors and uncertainties in the applied methods; and

.6 additional drawings.

6.11.2.2 Queries by the Administration preceding approval:

.1 Has the criticality of any errors or uncertainties (with sensitivity analysis) been considered?

.2 Have any novel processes, materials or methods been documented to an extent granting adequate reliability?

.3 Does all documentation submitted live up to formal requirements (such as readability, comprehensiveness, language, documented audit trail)?

.4 Are test methods of a nature which is trusted or sufficiently documented elsewhere to be relied upon?

6.12 Issuance of Certificate of Approval with conditions

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

6.12.1 *Procedural intent*

6.12.1.1 Provided all outstanding information is submitted as required, the Administration may approve the design.

6.12.1.2 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.

6.12.1.3 At all times both preliminary 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.

6.12.1.4 The approval serves to give the Submitter a statement of compliance with the statutory requirements, 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.

6.12.1.5 Provided the documentation lives up to the given requirements, the design approval process as such is concluded.

6.12.1.6 Unless risks of the subjected design have been demonstrated that they are capable of being controlled within the acceptable risk

level through the proposed risk reduction measures, the Administration can refuse issuing the Certificate of Approval.

6.12.2 ***Remaining documentation to be delivered***

6.12.2.1 The Submitter supplies the following to the Administration:

.1 certificates of process compliance with industry standards (applicability being verifiable). Such certification from other authorities may be deemed acceptable, at the discretion of the Administration;

.2 Safety assurance documentation, including any evaluation criteria with their justification agreed within the company or sector, as applicable;

.3 technical documentation relating to the project in question. Technical documentation submitted for review should contain the following information, as a minimum;

.4 details of application for any system or subsystem operated and requiring approval;

.5 specifications, including limitations, disclaimers and tolerances;

.6 material data sheets and/or manufacture certificates where applicable;

.7 the quality assurance system applied to maintain the conditions prevalent at the time of certification;

.8 any pertinent or historical test or analysis data, if these are to be considered in the survey plan; and

.9 installation manuals, maintenance procedures and operational plans.

6.12.2.2 The Administration delivers the following to the Submitter:

.1 statement of approval of design basis;

.2 certificates of approval with conditions as needed; and

.3 other certificates.

6.12.2.3 Queries by the Administration preceding release into service:

.1 whether provisions to rectify or mitigate any conditions are in place; and

.2 whether inspection of compliance through the construction phase has been adequately planned and documented.

7 OPERATION

7.1 Requirements pertaining to the operation of ships that have approved alternatives and/or equivalencies

7.1.1 This section of the Guidelines considers special requirements that apply to the operation of ships with approved alternatives and/or equivalencies onboard. In particular, the requirements for documentation on board such ships are addressed as well as requirements for change of flag.

7.1.2 Depending on the particular design of the alternative and/or equivalency, conditions for maintaining the safety level intended during the design approval may be imposed on ship operation. 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 assessments undertaken as a part of the process described in these Guidelines, 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 these ships will be performed as on conventional ships. It is therefore important that the features of the alternative and/or equivalent design and possible operational conditions are taken into account and understood by the Administration. Thus, clear documentation on the alternative and/or equivalent design should be kept on board. In the following, the requirements for onboard documentation are outlined.

7.1.5 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 requirements

7.2.1 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 ships with alternatives and/or equivalencies are addressed. This covers both current documentation that will be affected by the alternative and/or equivalency and additional documentation and certificates that need to be developed.

7.2.2 In general, the following documentation should exist:

.1 certificates (see paragraph 6.12.2.2) stating that the ship has an alternative and/or equivalency, including condition of approval, if any; and

.2 information on the alternative and/or equivalent design, comprising of the following:

.1 scope of the analysis or design, including the critical design assumptions and critical design features;

.2 description of the alternative and/or equivalent design and arrangements, including drawings and specifications;

.3 list of IMO regulations affected;

.4 summary of the results of the engineering analysis and basis for approval; and

.5 test, inspection and maintenance requirements.

7.2.3 Where appropriate, the details of onboard documentation are to be consistent with relevant Ship Construction File (SCF) requirements.

7.3 Change of flag

7.3.1 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 from the previous to the new Administration, including any subsequent revisions.

7.3.2 The new Administration will examine the documentation, and will decide if it is acceptable.

7.3.3 The new 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.

7.4 IMO reporting

7.4.1 The Administration that approves an alternative and/or equivalent design should submit detailed relevant information to the IMO, based on the form set out in the appendix, as appropriate, for circulation to the Member Governments. This information should enable Member Governments to trace the basis of the decision but not infringe upon any Intellectual Property Rights and it should comprise, as a minimum:

.1 scope of the analysis or design, including the critical design assumptions and critical design features;

.2 description of the alternative design and arrangements, including drawings and specifications;

.3 list of IMO regulations affected;

.4 summary of the results of the engineering and risk analysis, and basis for approval (including criteria, standard, etc.);

.5 description of any model used in the risk and engineering analysis (including risk models as well as computational software), and the verification procedure used during the model development;

.6 description of any design casualty scenarios and related software simulations, tests and trials made during the approval process;

.7 test, inspection and maintenance requirements for the operational phase; and

.8 condition of approval, if any.

7.4.2 Additional requirements with respect to reporting to IMO may be specified in the regulations permitting the application of alternatives and/or equivalencies.

7.5 Inspections and surveys

7.5.1 Alternative and/or equivalent design approval should specify if survey intervals are coincident with those relevant to prescriptive requirements or if different intervals are needed.

7.5.2 Survey and inspection of a ship which has alternatives and/or equivalencies will be required similar to those for conventionally designed ships, and flag state inspection and port State control need to be performed. Thus, surveyors need an understanding of the alternatives and/or equivalencies, which may be promoted by means of on board documentation and certificates, as relevant. Proper authoritative documentation may provide the surveyor with evidence that the ship has been built and maintained in a satisfactory manner.

7.5.3 A port State control officer, in addition to checking certificates and documentation, may opt to perform a detailed inspection to obtain objective evidence that the ship is in a proper condition. 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 and operation details.

8 REFERENCES AND BIBLIOGRAPHY

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 I 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.

IMO, 2013a. "Revised guidelines for Formal Safety Assessment (FSA) for use in the IMO rule-making process", MSC-MEPC.2/Circ.12, IMO.

IMO, 2013b. "Guidelines for the application of Human Element Analysing Process (HEAP) to the IMO rule-making process", MSC-MEPC.2/Circ.13, 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

Appendix

REPORT ON THE APPROVAL OF ALTERNATIVE DESIGN AND ARRANGEMENTS

FOR

……

The Government of …… has approved on …… an alternative design

and arrangement in accordance with provisions of regulation ……of the

……, as described below:

Name of ship .....

Port of registry .....

Ship type .....

IMO Number .....

.1 scope of the analysis or design, including the critical design assumptions and critical design features;

.2 description of the alternative design and arrangements, including drawings and specifications;

.3 list of IMO regulations affected;

.4 summary of the results of the engineering and risk analysis, and basis for approval (including criteria, standard, etc.);

.5 description of any model used in the risk and engineering analysis (including risk models as well as computational software), and the verification procedure used during the model development;

.6 description of any design casualty scenarios and related software simulations, tests and trials made during the approval process;

.7 test, inspection and maintenance requirements for the operational phase; and

.8 condition of approval, if any.