INTERIM GUIDELINES FOR THE APPLICATION OF FORMAL SAFETY ASSESSMENT (FSA) TO THE IMO RULE-MAKING PROCESS

The Maritime Safety Committee, at its sixty-eighth session (28 May to 6 June, 1997), and the Marine Environment Protection Committee, at its fortieth session (18 to 23 and 25 September, 1997), approved Interim Guidelines for the Application of Formal Safety Assessment (FSA) to the IMO Rule-Making Process as set out in annex 1.

FSA is a rational and systematic process for assessing the risks associated with shipping activity and for evaluating the costs and benefits of IMO's options for reducing these risks. The use of FSA is consistent with, and should provide support to, the IMO decision-making process. It provides a basis for making decisions in accordance with resolutions A.500(XII) "Objectives of the Organization in the 1980's" and A.777(18) "Work Methods and Organization of Work in Committees and their Subsidiary Bodies".

Application of FSA may be particularly relevant to proposals for regulatory measures which have far reaching implications in terms of costs to the maritime industry or the administrative or legislative burdens which may result. This is achieved by providing a clear justification for proposed regulatory measures and allowing comparison of different options of such measures to be made. This is in line with the basic philosophy of FSA in that it can be used as a tool to facilitate a transparent decision-making process. In addition, it provides a means of being proactive, enabling potential hazards to be considered before a serious accident occurs.

These Guidelines are intended to facilitate trial applications of the FSA process and they should remain interim as long as it is necessary to gain experience. Such trial applications will lead to a greater understanding of FSA by all parties, irrespective of their previous expertise in the application of risk assessment techniques.

Member Governments and non-governmental organizations are invited to carry out trial applications of FSA in accordance with the annexed Guidelines and to submit the results thereof to the Organization in accordance with the Standard Format for Reporting Trial Applications shown at annex 2.
ANNEX 1

INTERIM GUIDELINES FOR THE APPLICATION OF FORMAL SAFETY ASSESSMENT (FSA) TO THE IMO RULE-MAKING PROCESS

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INTERIM GUIDELINES FOR THE APPLICATION OF FORMAL SAFETY ASSESSMENT (FSA) TO THE IMO RULE-MAKING PROCESS

1 INTRODUCTION

1.1 Purpose of FSA

1.1.1 Formal Safety Assessment (FSA) is a structured and systematic methodology, aimed at enhancing maritime safety, including protection of life, health, the marine environment and property, by using risk and cost/benefit assessments.

1.1.2 FSA can be used as a tool to help in the evaluation of new safety regulations or making a comparison between existing and possibly improved regulations, with a view to achieving a balance between the various technical and operational issues, including the human element, and between safety and costs.

1.1.3 FSA is consistent with the current IMO decision-making process and provides a basis for making decisions in accordance with resolutions A.500(XII) "Objectives of the Organization in the 1980's", and A.777(18) "Work Methods and Organization of Work in Committees and their Subsidiary Bodies".

1.1.4 The decision makers at IMO, through FSA, will be able to appreciate the effect of proposed regulatory changes in terms of benefits (e.g. expected reduction of lives lost or of pollution) and related costs incurred for the industry as a whole and for individual parties affected by the decision. FSA should facilitate development of regulatory changes equitable to the various parties thus aiding the achievement of consensus.

1.2 Scope of the Guidelines

1.2.1 These Guidelines are intended to outline the FSA methodology as a tool which may be applied in the IMO rule-making process. In order that FSA can be consistently applied by different parties, it is important that the process is clearly documented and formally recorded in a uniform and systematic manner. This will ensure that the FSA process is transparent and can be understood by all parties irrespective of their experience in the application of risk assessment and related techniques.

1.2.2 In the interim period, these Guidelines provide the basis for interested parties to perform trial applications aimed at demonstrating the potential of FSA within the IMO rule-making process.

1.3 Application

1.3.1 The FSA methodology can be applied by:

- an individual Administration or an organization having a consultative status with IMO when proposing amendments to safety and pollution prevention and response-related IMO instruments in order to analyse the implications of such proposals; or

- by the Committee, or an instructed subsidiary body, to review the overall framework of safety and environmental regulations, for instance for a particular ship type or hazard, aiming at identifying priorities or areas of concern of the current regulations.
1.3.2 It is not intended that FSA should be applied in all circumstances, but its application would be particularly relevant to proposals which may have far-reaching implications in terms of either costs (to society or the maritime industry), or the legislative and administrative burdens which may result. In these circumstances, FSA will enable the benefits of proposed changes to be properly established, so as to give Member Governments a clearer perception of the scope of the proposals and an improved basis on which to take decisions.

2 BASIC TERMINOLOGY

2.1 The following definitions apply in the context of these guidelines:

**Accident**: An unintended event involving fatality, injury, ship loss or damage, other property loss or damage, or environmental damage

**Accident category**: A designation of accidents reported in statistical tables according to their nature, e.g. fire, collision, grounding, etc.

**Consequence**: The outcome of an accident

**Frequency**: The number of occurrences per unit time (e.g. per year)

**Hazard**: A potential to threaten human life, health, property or the environment

**Initiating event**: The first of a sequence of events leading to a hazardous situation or accident

**Risk**: The combination of the frequency and the severity of the consequence

**Risk control measure**: A means of controlling a single element of risk

3 METHODOLOGY

3.1 Process

3.1.1 FSA should comprise the following steps:

1 identification of hazards;
\[\]
2 risk assessment;
\[\]
3 risk control options;
\[\]
4 cost benefit assessment; and
\[\]
5 recommendations for decision making.

3.1.2 Figure 1 is a flow chart of the FSA methodology. The process begins with the decision makers defining the problem to be assessed along with any relevant boundary conditions or constraints. These are presented to the group who will carry out the FSA and provide results to the decision makers for use in their resolutions. In cases where decision makers require additional work to be conducted, they would
revise the problem statement or boundary conditions or constraints, and resubmit this to the group and repeat the process as necessary. Within the FSA methodology, step 5 interacts with each of the other steps in arriving at decision making recommendations. The group carrying out the FSA process should comprise suitably qualified and experienced people to reflect the range of influences and the nature of the "event" being addressed.

3.1.3 The depth or extent of application of the methodology should be commensurate with the nature and significance of the problem. However, before starting the detailed application, a coarse application is suggested for the relevant ship type or hazard category, in order to include all aspects of the problem under consideration. Whenever there are uncertainties, e.g. in respect of data or expert judgement, the significance of these uncertainties should be assessed.

3.1.4 Characterization of hazards and risks should be both qualitative and quantitative, that is both descriptive and mathematical, consistent with the available data, and it should be broad enough to include a comprehensive range of options to reduce risks.

3.2 Problem definition

3.2.1 The problem under analysis and its boundaries should be carefully defined, in relation to the regulations under review or to be developed. The definition of the problem should be consistent with operational experience and current requirements, by taking into account all relevant aspects. Those which may be considered relevant when addressing ships (not necessarily in order of importance) are:

.1 ship category (e.g. type, length or gross tonnage range, new or existing, type of cargo);
.2 ship systems or functions (e.g. layout, subdivision, type of propulsion);
.3 ship operation (e.g. operations in port and/or during navigation);
.4 external influences on the ship (e.g. Vessel Traffic System, weather forecasts, reporting, routeing);
.5 accident category (e.g. collision, explosion, fire); and
.6 risks associated with consequences such as injuries and/or fatalities to passengers and crew, environmental impact, damage to the ship or port facilities, or commercial impact.

3.3 Generic model

3.3.1 In general, the problem under consideration should be characterized by a number of functions. Where the problem relates for instance to a type of ship, these functions include carriage of payload, communication, emergency response, manoeuvrability, etc. Alternatively, where the problem relates to a type of hazard, for instance fire, the functions include prevention, detection, alarm, containment, escape, suppression, etc.

3.3.2 For application of FSA, a generic model should therefore be defined to describe the functions, features, characteristics and attributes which are common to all ships of the type, or relevant to the problem under concern.
3.3.3 The generic model should not be viewed as an individual ship in isolation, but rather as a collection of systems, including organizational, management, operational, human, electronic, and hardware, which fulfill the defined functions. The functions and systems should be broken down to an appropriate level of detail. Aspects such as the interaction of functions and systems, and the extent of their variability, should be addressed.

3.3.4 A comprehensive view, such as the one shown in figure 2, should be taken, recognizing that the ship "hardware" (i.e. the technical and engineering system), which is governed by physical laws, is in the centre of an integrated system. The "hardware" is integrally related to the "software" (i.e. the passengers and crew), which is a function of human behaviour. The "software" interacts with the organizational and management infrastructure and those personnel involved in ship and fleet operations, maintenance and management. These systems are related to the outer environmental context, which is governed by pressures and influences of all parties interested in shipping and the public. Each of these systems is dynamically affected by the others.

3.4 Information and data

3.4.1 The availability of suitable data necessary for each step of the FSA process is very important. When data are not available, expert judgement, physical models, simulations and analytical models may be used to achieve valuable results. Consideration should be given to those data which are already available at IMO (e.g. casualty and deficiency statistics), and to potential improvements in those data in anticipation of an FSA implementation (e.g. a better specification for recording relevant data including the primary causes, underlying factors and latent factors associated with a casualty).

3.4.2 Data concerning incident reports, near misses and operational failures may be very important for the purposes of making more balanced, proactive and cost-effective legislation. A judgement on the value of data which can be collected should be carried out in order to identify uncertainties and limitations, and to assess the degree of reliance which should be placed on the available data.

4 FSA STEP 1 - IDENTIFICATION OF HAZARDS

4.1 Scope

4.1.1 The purpose of step 1 is to identify and generate a prioritized list of hazards, specific to the problem under review. This purpose is achieved by the use of standard techniques to identify hazards which can contribute to accidents, and by screening these hazards using a combination of available data and judgement. The hazard identification exercise should be undertaken in the context of the functions and systems generic to the ship type or problem being considered, which were established in paragraph 3.3, by reviewing the generic model.

4.2 Methods for hazard identification

4.2.1 The approach used for hazard identification generally comprises a combination of both creative and analytical techniques, the aim being to identify as many relevant hazards as possible. The creative element is to ensure that the process is proactive, and not confined only to hazards that have materialized in the past. It typically consists of structured group reviews aiming at identifying the causes and effects of accidents and relevant hazards. Consideration of functional failure may assist in this process. The group carrying out such structured reviews should include experts in the various appropriate aspects, such as ship design and
operations and specialists to assist in the hazard identification process and incorporation of the human element. A structured group review session may last over a number of days. The analytical element ensures that previous experience is properly taken into account, and typically makes use of background information (for example applicable regulations and codes, available statistical data on accident categories and lists of hazards to personnel, hazardous substances, ignition sources, etc.). Examples of hazards relevant to shipboard operations are shown in appendix 1.

4.2.2 A coarse analysis of possible causes and outcomes of each accident category should be made by using standard techniques (such as fault and event trees, HAZOPs, FMEAs, etc. as described in appendix 2), to be chosen according to the problem under concern.

4.3 Incorporation of the human element

4.3.1 The human element is one of the most important contributory aspects to the causation and avoidance of accidents. Human element issues throughout the integrated system shown in figure 2 should be systematically treated within the FSA framework, associating them directly with the occurrence of accidents, underlying causes or influences. Appropriate techniques for incorporating human factors should be used.

4.4 Ranking of identified hazards

4.4.1 The identified hazards relevant to the problem being considered, and established at an earlier stage of step 1, should be screened to prioritize them and to discard scenarios judged to be of minor significance. Screening is undertaken using available data, supported by judgement, on the frequency of different outcomes of accident categories. A risk matrix, as shown in figure 3, may be used.

4.5 Results

4.5.1 The output from step 1 comprises:

.1 a prioritized list of hazards; and

.2 preliminary description of the development of hazards to final outcomes.

5 FSA STEP 2 - RISK ASSESSMENT

5.1 Scope

5.1.1 The purpose of step 2 is to identify the distribution of risk, thus allowing attention to be focused upon high risk areas, and to identify and evaluate the factors which influence the level of risk. Step 2 aims to establish the relationship between the regulatory regime at the IMO and the occurrence and consequence of accidents. This enables appropriate regulatory changes to be introduced to reduce risks.
5.1.2 Different types of risk (i.e. risks to people, the environment or property) should be addressed as appropriate to the problem under consideration, together with the units in which they are expressed, as described in appendix 3.

5.1.3 This purpose can be achieved by first constructing and quantifying a diagram (in this context called a risk contribution tree) to display the distribution of risk, as indicated in figure 4. This is determined principally from accident data, failure data or other sources of information. Then, for each high risk area, further diagrams (in this context called regulatory impact diagrams) can be constructed to represent the network of influences linking the regulatory regime to the occurrence of events, as indicated in figure 5. These factors should be quantified using expert judgement to highlight the major influences and hence facilitate effective regulation.

5.2 Risk contribution tree

5.2.1 The risk contribution tree may be used as a mechanism for displaying diagrammatically the distribution of risk amongst different accident categories and sub-categories, as shown in figure 4. Structuring the tree starts with the accident categories, which may be divided into sub-categories to the extent that available data allow and logic dictates, in order to describe the prioritized list of hazards. The preliminary fault and event trees from step 1 can be developed to demonstrate how direct causes initiate and combine to cause accidents (using fault trees), and also how accidents may progress further to result in different magnitudes of loss (using event trees). Whilst the example makes use of fault and event tree techniques, other established methods could be used if appropriate.

5.2.2 Quantifying the contribution to risks is typically undertaken in three stages using available accident statistics:

1. the categories and sub-categories of accident are quantified in terms of the frequency of accidents;

2. the magnitude of accident outcomes is quantified in risk terms; and

3. the distribution of outcome magnitudes across all the sub-categories of accident is determined in risk terms, so as to display which categories contribute how much risk.

5.3 Regulatory impact diagram

5.3.1 In general, the structure of a regulatory impact diagram, such as the one shown in figure 5, reflects influences at various levels, including direct causes, their underlying factors and regulatory policy. The regulatory impact diagram can represent, respectively, the influences affecting the "likelihood" of an accident occurring, the "escalation" of an accident and "mitigation" aspects, such as the evacuation of people from a stricken ship, containment of oil pollution, clean-up, etc. (the latter would include consideration of emergency preparedness).

5.3.2 Regulatory impact diagrams can be used in a comparative (i.e. not absolute) way. Where there is uncertainty in the risk contribution tree (e.g. inadequate data to determine with confidence the frequency of a particular sub-category of accident) sensitivity studies may be carried out.
5.4 Results

5.4.1 The output from step 2 comprises:

.1 an identification of the high risk areas needing to be addressed;

.2 an identification of the principal influences within the overall regulatory regime that affect the level of risk; and

.3 a re-evaluation of risk for each risk control option identified in step 3.

6 FSA STEP 3 - RISK CONTROL OPTIONS

6.1 Scope

6.1.1 The purpose of step 3 is to propose effective and practical risk control options, comprising the following three principal stages:

.1 focusing on areas of risk needing control;

.2 identifying potential risk control measures; and

.3 grouping risk control measures into practical regulatory options.

6.1.2 Step 3 aims to create risk control options that address both existing risks and risks introduced by new technology or new methods of operation. Both historical risks and newly identified risks (from steps 1 and 2) should be considered, producing a wide range of risk control measures. Techniques designed to address both specific risks and underlying causes should be used.

6.2 Areas Needing Control

6.2.1 The purpose of focusing is to screen the output of step 2 so that effort is focused on the areas most needing risk control. The main aspects to making this assessment are to review:

.1 risk levels, by considering frequency of occurrence together with the severity of outcomes. Accidents with an unacceptable risk level become the primary focus;

.2 probability, identifying the areas of the risk contribution tree that have the highest probability of occurrence. These should be addressed irrespective of the severity of the outcome;

.3 severity, identifying the areas of the risk contribution tree that contribute to high severity outcomes. These should be addressed irrespective of their probability; and

.4 confidence, identifying areas where the risk contribution tree has considerable uncertainty either in risk, severity or probability.
6.3 Potential Risk Control Measures

6.3.1 Structured review techniques are typically used to identify new risk control measures for risks that are not sufficiently controlled by existing measures. These techniques may encourage the development of appropriate measures and include risk attributes and causal chains. Risk attributes relate to how a measure might control a risk, and causal chains relate to where, in the "initiating event to fatality" sequence, risk control can be introduced.

6.3.2 Risk control measures (and subsequently risk control options) have a range of attributes. These attributes may be categorized according to the examples given in appendix 4.

6.3.3 The prime purpose of assigning attributes is to facilitate a structured thought process to understand how a risk control measure works, how it is applied and how it would operate. Attributes can also be considered to provide guidance on the different types of risk control that could be applied. Many risks will be the result of complex chains of events and a diversity of causes. For such risks the identification of risk control measures can be assisted by developing causal chains which might be expressed as follows:

\[
\text{causal factors} \rightarrow \text{failure} \rightarrow \text{circumstance} \rightarrow \text{accident} \rightarrow \text{consequences}
\]

6.3.4 Risk control measures should in general be aimed at one or more of the following:

.1 reducing the frequency of failures through better design, procedures, organizational polices, training, etc;

.2 mitigating the effect of failures, in order to prevent accidents;

.3 alleviating the circumstances in which failures may occur; and

.4 mitigating the consequences of accidents.

6.4 Risk control options

6.4.1 The purpose of this stage is to group risk control measures into a limited number of well thought out practical regulatory options. There is a range of possible approaches to grouping individual measures into options. The following two approaches, related to likelihood and escalation, can be considered:

.1 "general approach" which provides risk control by controlling the likelihood of initiation of accidents, and may be effective in preventing several different accident sequences; and

.2 "distributed approach" which provides control of escalation of accidents, together with the possibility of influencing the later stages of escalation of other, perhaps unrelated, accidents.

6.4.2 In generating the risk control options, the interested entities, who may be affected by the combinations of measures proposed, should be identified.
6.5 Results

6.5.1 The output from step 3 comprises:

1. a range of risk control options, which are assessed for their effectiveness in reducing risk by re-evaluating step 2; and

2. a list of entities affected by the identified risk control options.

7 FSA STEP 4 - COST BENEFIT ASSESSMENT

7.1 Scope

7.1.1 The purpose of step 4 is to identify benefits and costs associated with the implementation of each risk control option identified and defined in step 3. A cost benefit assessment may consist of the following stages:

1. consider the risks assessed in step 2, both in terms of frequency and consequence, in order to define the base case in terms of risk levels of the situation under consideration;

2. arrange the risk control options, defined in step 3, in a way to facilitate understanding of the costs and benefits resulting from the adoption of an option;

3. estimate the pertinent costs and benefits for all risk control options;

4. estimate and compare the cost effectiveness of each option, in terms of the cost per unit risk reduction by dividing the net cost by the risk reduction achieved as a result of implementing the option; and

5. rank the risk control options from a cost-benefit perspective in order to facilitate the decision making recommendations in step 5 (e.g. to screen those which are not cost effective or impractical).

7.1.2 Costs should be expressed in terms of life cycle costs, and may include initial, operating, training, inspection, certification, etc. Benefits may include reductions in the costs associated with fatalities, injuries, casualties, environmental damage and clean-up, indemnity of third party liabilities, etc., and an increase in the average life of ships.

7.2 Application

7.2.1 The evaluation of the above costs and benefits could be carried out by using various methods and techniques. Such a process should be conducted for the overall situation and then for those interested entities which are the most influenced by the problem under concern.

7.2.2 In general, an interested entity can be defined as the person, organization, company, coastal State, flag State, etc., who is directly or indirectly affected by an accident, or by the cost effectiveness of the proposed new regulation. In the initial stages of FSA implementation, different interested entities with similar interests can be grouped together for the purposes of applying the FSA methodology and identifying decision making recommendations.
7.3 Results

7.3.1 The output from step 4 comprises:

.1 costs and benefits for each risk control option identified in step 3 from an overview perspective;

.2 costs and benefits for those interested entities which are the most influenced by the problem under concern; and

.3 cost effectiveness expressed in terms of net cost per unit risk reduction.

8 FSA STEP 5 -RECOMMENDATIONS FOR DECISION MAKING

8.1 Scope

8.1.1 The purpose of step 5 is to define the recommendations which should be presented to the relevant decision makers. The recommendations would be based upon the comparison and ranking of hazards and their underlying causes; the comparison and ranking of risk control options as a function of associated costs and benefits; and the identification of those risk control options which keep risks as low as reasonably practicable.

8.1.2 The basis on which these comparisons should be made should take into account that, in ideal terms, all those entities that are significantly influenced in the area under concern should be equitably affected by the introduction of the proposed new regulation. However, taking into consideration the difficulties of this type of assessment, the approach should be, at least in the earliest stages, as simple and practical as possible.

8.2 Results

8.2.1 Output from this step can provide an objective comparison of alternative options, based on potential reduction of risks and cost effectiveness, in areas where legislation or rules should be reviewed or developed. Recommendations should be usable by decision makers at all levels and in a variety of contexts within the IMO, without a requirement for specialist expertise. This step should also provide feedback information to review the results generated in the previous steps.

9 PRESENTATION OF FSA RESULTS

9.1 To facilitate the common understanding and use of FSA at IMO in the rule-making process, each report of an FSA process, the standard format for which is shown at annex 2, should:

.1 provide a clear statement of the final recommendations;

.2 list the principal hazards, risks, costs and benefits identified during the assessment;

.3 explain the basis for significant assumptions, limitations, data models and inferences used or relied upon in the assessment or recommendations;
.4 describe the sources, extent and magnitude of significant uncertainties associated with the assessment or recommendations; and

.5 describe the composition and expertise of the group that performed the FSA process.

9.2 Those submitting the results of an FSA process should provide timely and open access to relevant supporting documents, and a reasonable opportunity for, and a mechanism to incorporate, comments.
FIGURE 1
FLOW CHART OF THE FSA METHODOLOGY

Decision Makers

FSA Methodology

Step 1 Hazard Identification

Step 2 Risk Assessment

Step 3 Risk Control Options

Step 4 Cost Benefit Assessment

Step 5 Decision Making Recommendations
FIGURE 2

Components of the Integrated System

Environmental Context

Organizational/Management Infrastructure

Personnel Subsystem

Technical/Engineering System
FIGURE 3
RISK MATRIX

FREQUENCY

Frequent
Reasonably Probable
Remote
Extremely Remote

Intolerable
ALARP
Negligible

Insignificant  Minor  Major  Catastrophic

CONSEQUENCE

ALARP = As Low As Reasonably Practicable
Note: Risk level boundaries (Negligible/ALARP/Intolerable) are purely illustrative
FIGURE 4
EXAMPLE OF A RISK CONTRIBUTION TREE*

* As defined in the context of these Guidelines
EXAMPLE OF A REGULATORY IMPACT DIAGRAM*

* As defined in the context of these guidelines
APPENDIX 1

EXAMPLES OF HAZARDS

1 SHIPBOARD HAZARDS TO PERSONNEL
   - asbestos inhalation
   - burns from caustic liquids and acids
   - electric shock and electrocution
   - falling overboard
   - pilot ladder/pilot hoist operation

2 HAZARDOUS SUBSTANCES ON BOARD SHIP
   Accommodation areas:
   - combustible furnishings
   - cleaning materials in stores
   - oil/fat in galley equipment
   Deck Areas:
   - cargo
   - paint, oils, greases etc. in deck stores
   Machinery spaces:
   - cabling
   - fuel and diesel oil for engines, boilers and incinerators
   - fuel, lubricating and hydraulic oil in bilges, savealls, etc.
   - refrigerants
   - thermal heating fluid systems

3 POTENTIAL SOURCES OF IGNITION
   General
   - electrical arc
   - friction
   - hot surface
   - incendive spark
   - naked flame
   - radio waves
   Accommodation areas (including bridge):
   - electronic navigation equipment
   - laundry facilities - irons, washing machines, tumble driers, etc.
   Deck areas:
   - deck lighting
   - funnel exhaust emissions
   - hot work sparking
   Machinery spaces:
   - air compressor units
   - generator engine exhaust manifold

4 HAZARDS EXTERNAL TO THE SHIP
   - storms
   - lightning
   - uncharted submerged objects
   - other ships
APPENDIX 2

HAZARD IDENTIFICATION TECHNIQUES

1 Fault Tree Analysis

1.1 A Fault Tree is a logic diagram showing the causal relationship between events which singly or in combination occur to cause the occurrence of a higher level event. It is used in Fault Tree Analysis to determine the probability of a top event, which may be a type of accident or unintended hazardous outcome. Fault Tree Analysis can take account of common cause failures in systems with redundant or standby elements. Fault Trees can include failure events or causes related to human factors.

1.2 The development of a Fault Tree is by a top-down approach, systematically considering the causes or events at levels below the top level. If two or more lower events need to occur to cause the next higher event, this is shown by a logic 'and' gate. If any one of two or more lower events can cause the next higher event, this is shown by a logic 'or' gate. The logic gates determine the addition or multiplication of probabilities (assuming independence) to obtain the values for the top event.

2 Event Tree Analysis

2.1 An Event Tree is a logic diagram used to analyse the effects of an accident, a failure or an unintended event. The diagram shows probability or frequency of the accident linked to those safeguard actions required to be taken after occurrence of the event to mitigate or prevent escalation.

2.2 The probabilities of success or failure of these actions are analysed. The success and failure paths lead to various consequences of differing severity or magnitude. Multiplying the likelihood of the accident by the probabilities of failure or success in each path gives the likelihood of each consequence.

3 Failure Mode and Effect Analysis (FMEA)

3.1 FMEA is a technique in which the system to be analysed is defined in terms of functions or hardware. Each item in the system is identified at a required level of analysis. This may be at a replaceable item level. The effects of item failure at that level and at higher levels are analysed to determine their severity on the system as a whole. Any compensating or mitigating provisions in the system are taken account of and recommendations for the reduction of the severity are determined. The analysis indicates single failure modes which may cause system failure.

4 Hazard and Operability Studies (HAZOP)

4.1 These studies are carried out to analyse the hazards in a system at progressive phases of its development from concept to operation. The aim is to eliminate or minimise potential hazards.

4.2 Teams of safety analysts and specialists in the subject system, such as designers, constructors and operators are formally constituted. The team members may change at successive phases depending on the expertise required. In examining designs they systematically consider deviations from the intended functions, looking at causes and effects. They record the findings and recommendations and follow up actions required.
APPENDIX 3

MEASURES AND TOLERABILITY OF RISKS

1 There are two fundamental measures of risk, individual risk and societal risk. It is necessary for the risk to be both tolerable to the individual and tolerable to society. Individual risk can be regarded as the risk to an individual in isolation while societal risk is the risk to society of a major accident. There is a clear perception in society that a single accident that kills 1,000 people is worse than 1,000 accidents that kill a single person. Therefore the tolerable level of societal risk is usually lower than the tolerable level of individual risk.

2 Individual risk is usually assessed by some form of a criticality matrix where the risk is assessed against frequency of occurrence (ranging from extremely remote to frequent) and severity of outcome (ranging from insignificant to catastrophic). Societal risk is usually assessed by a technique such as an FN curve where the acceptable level of frequency of an accident (F) is plotted against the number of people killed by the accident (N).

3 When each risk assessment is made, it will be necessary also to determine which assessment method should be used. Generally, accidents that cause one or two fatalities are best assessed by individual risk considerations, while accidents that cause the loss of a crew or the passengers are best assessed by societal risk considerations.

4 Whichever assessment method is used, the uncertainties of quantitative risk assessment must be balanced against the potential risk reduction. It is necessary to consider the uncertainty in the process in order to avoid premature judgements about the benefits of a particular Risk Control Option.

5 The current best practice is to recognise that there are three levels of risk: Intolerable, As Low As Reasonably Practicable (ALARP) and Negligible.

6 "Intolerable" means that the risk cannot be justified except in extraordinary circumstances, "Negligible" that the risk has been made so small that no further precaution is necessary, and "ALARP" that the risk falls between these two states.

7 The risk when travelling on a ferry should therefore be made "ALARP". There are no exceptional benefits to a passenger to allow an "intolerable" risk and sea travel can clearly never be made so safe that the risk is "negligible" and no precautions need to be made.

8 The extent to which risk exposure is involuntary (as opposed to voluntary) may also be relevant in determining the acceptability of risk. For example, a lower level of risk might be appropriate for people living near a port and unaware of the risks that shipping operations impose upon them, compared with the risks experienced by crew members who choose to continue their employment in a particular shipping trade.
APPENDIX 4

ATTRIBUTES OF RISK CONTROL MEASURES

1 Category A attributes

1.1 Preventive risk control is where the risk control measure reduces the probability of the event.

1.2 Mitigating risk control is where the risk control measure reduces the severity of the outcome of the event or subsequent events, should they occur.

2 Category B attributes

2.1 Engineering risk control involves including safety features (either built in or added on) within a design. Such safety features are safety critical when the absence of the safety feature would result in an unacceptable level of risk.

2.2 Inherent risk control is where at the highest conceptual level in the design process, choices are made that restrict the level of potential risk.

2.3 Procedural risk control is where the operators are relied upon to control the risk by behaving in accordance with defined procedures.

3 Category C attributes

3.1 Diverse risk control is where the control is distributed in different ways across aspects of the system, whereas concentrated risk control is where the risk control is similar across aspects of the system.

3.2 Redundant risk control is where the risk control is robust to failure of risk control, whereas single risk control is where the risk control is vulnerable to failure of risk control.

3.3 Passive risk control is where there is no action required to deliver the risk control measure, whereas active risk control is where the risk control is provided by the action of safety equipment or operators.

3.4 Independent risk control is where the risk control measure has no influence on other elements.

3.5 Dependent risk control is where one risk control measure can influence another element of the risk contribution tree.

3.6 Involved human factors is where human action is required to control the risk but where failure of the human action will not in itself cause an accident or allow an accident sequence to progress. Critical human factors is where human action is vital to control the risk either where failure of the human action will directly cause an accident or will allow an accident sequence to progress.

3.7 Where a critical human factor attribute is assigned, the human action (or critical task) should be clearly defined in the risk control measure.
3.8 Auditable or Not Auditable reflects whether the risk control measure can be audited or not.

3.9 Quantitative or Qualitative reflects whether the risk control measure has been based on a quantitative or qualitative assessment of risk.

3.10 Established or Novel reflects whether the risk control measure is an extension to existing marine technology or operations, whereas novel is where the measure is new. Different grades are possible, for example the measure may be novel to shipping but established in other industries or it is novel to both shipping and other industries.

3.11 Developed or Non-developed reflects whether the technology underlying the risk control measure is developed both in its technical effectiveness and its basic cost. Non-developed is either where the technology is not developed but it can be reasonably expected to develop, or its basic cost can be expected to reduce in a given timescale. The purpose of considering this attribute is to attempt to anticipate development and produce forward looking measures and options.
ANNEX 2

STANDARD FORMAT FOR REPORTING TRIAL APPLICATIONS OF THE FORMAL
SAFETY ASSESSMENT

1. This standard format is intended to facilitate the compilation of the results of trial applications
according to the "Interim Guidelines for the Application of Formal Safety Assessment (FSA) to the IMO
Rule-Making Process" and the consistent presentation of those results to IMO.

2. Interested parties having carried out a trial application of the Interim Guidelines should provide the
significant results of the FSA process in a clear and concise report, which can also be understood by other
parties not having the same experience in the application of risk assessment techniques.

3. The report should contain an executive summary and the following sections: definition of the
problem, background information, method of work, description of the results achieved in each step and
final recommendations arising from the FSA process.

4. The level of detail of the report depends on the problem under consideration. However, to facilitate
the understanding and use of the results of the trial application, the report should not exceed 20 pages,
excluding figures and appendices.

5. Those submitting the results of the FSA trial application should provide the other interested parties
with timely and open access to relevant supporting documentation and source of information or data which
are referred to in the above-mentioned report, as reflected in paragraph 9.2 of the Interim Guidelines.

6. The following paragraph presents the standard format of FSA trial application reports. The subjects
expected to be presented in each section of the report are listed in italic characters and reference is given,
in brackets, to the relevant paragraph(s) of the Interim Guidelines.
STANDARD REPORTING FORMAT

(Ref. MSC/MEPC circular)

1. **TITLE OF THE TRIAL APPLICATION**

2. **SUMMARY** (MAX 1/2 PAGE)

   2.1 Executive summary: scope of the trial application and reference to the paragraph defining the problem assessed and its boundaries.

   2.2 Actions to be taken: type of action requested (e.g., for information or review) and summary of the final recommendations listed in section 7.

   2.3 Related documents: reference to any supporting documentation.

3. **DEFINITION OF THE PROBLEM** (MAX 1 PAGE)

   3.1 Definition of the problem to be assessed in relation to the proposal under consideration by the decision-makers.

   3.2 Reference to the regulation(s) affected by the proposal to be reviewed or developed (in an annex).

   3.3 Definition of the generic model (e.g., functions, features, characteristics or attributes which are relevant to the problem under consideration, common to all ships of the type affected by the proposal).

      (Ref. paragraphs 3.2 and 3.3 of the Interim Guidelines)

4. **BACKGROUND INFORMATION** (MAX 3 PAGES)

   4.1 Lessons learned from recently introduced measures to address similar problems.

   4.2 Casualty statistics concerning the problem under consideration (e.g., ship types or accident category).

   4.3 Any other sources of data and relevant limitations.

      (Ref. paragraph 3.4 of the Interim Guidelines)

5. **METHOD OF WORK** (MAX 3 PAGES)

   5.1 Composition and level of expertise of those having carried out the trial application (name and credentials in an annex).

   5.2 Description on how the assessment has been conducted in terms of number of meetings, organisation of working groups, etc.

   5.3 Start and finish date of the assessment.

      (Ref. paragraph 3.1.2 of the Interim Guidelines)
6 DESCRIPTION OF THE RESULTS ACHIEVED IN EACH STEP

6.1 For each step, describe:

.1 method and techniques used to carry out the assessment;

.2 assumptions or limitations, if any, and the basis for them; and

.3 outcomes of each step of the FSA methodology, including:

STEP 1 - HAZARD IDENTIFICATION: (ref. paragraph 4.5 of the Interim Guidelines)

- prioritised list of hazards.
- identified significant accident scenarios.

STEP 2 - RISK ASSESSMENT: (ref. paragraph 5.4 of the Interim Guidelines)

- types of risk (e.g. individual, societal, environmental, business).
- presentation of the distribution of risks depending on the problem under consideration.
- identified significant risks
- principal influences that affect the risks.
- sources of accident and reliability statistics.

STEP 3 - RISK CONTROL OPTIONS: (ref. paragraph 6.5 of the Interim Guidelines)

- what hazards are covered by current regulations.
- identified risk control options.
- assessment of the control options as a function of their effectiveness against risk reduction.

STEP 4 - COST BENEFIT ASSESSMENT: (ref. paragraph 7.3 of the Interim Guidelines)

- identified types of cost and benefits involved for each risk control option.
- cost-benefit assessment for the entities which are influenced by each option.
- identification of the cost effectiveness expressed in terms of cost per unit risk reduction.
STEP 5 - RECOMMENDATIONS FOR DECISION-MAKING

(ref. paragraph 8.2 of the Interim Guidelines)

- objective comparison of alternative options.
- discussion on how recommendations could be implemented by decision makers.

7 FINAL RECOMMENDATIONS FOR DECISION MAKING (MAX 2 1/2 PAGES)

7.1 List of final recommendations, ranked and justified in an auditable and traceable manner.

(ref. paragraph 8.2 of the Interim Guidelines)

END OF THE REPORT

IT IS RECOMMENDED THAT THE LENGTH OF THE REPORT BE KEPT TO LESS THAN 20 PAGES EXCLUDING FIGURES AND ANNEXES.

ANNEXES (AS NECESSARY)

.1 name and credential of the experts involved in the trial application
.2 list of references
.3 sources of data
.4 accident statistics
.5 technical support material
.6 any further information