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**GUIDANCE ON THE USE OF HUMAN ELEMENT ANALYSING PROCESS (HEAP)
AND FORMAL SAFETY ASSESSMENT (FSA) IN THE IMO RULE MAKING
PROCESS**

1 The Maritime Safety Committee, at its sixty-ninth session (11 to 20 May 1998) and the Marine Environment Protection Committee, at its forty-second session (2 to 6 November 1998), approved the interim guidelines for the application of Human Element Analysing Process (HEAP) to the IMO rule making process (MSC/Circ.878-MEPC/Circ.346)

2 The Maritime Safety Committee, at its seventy-fourth session (30 May to 8 June 2001) and the Marine Environment Protection Committee, at its forty-seventh session (4 to 8 March 2002) approved the Guidelines for Formal Safety Assessment (FSA) for use in the IMO rule-making process (MSC/Circ.1023/MEPC/Circ.392).

3 Member Governments are invited to:

- .1 bring the information on the difference between HEAP and FSA to the attention of all relevant government bodies and maritime industry organizations (annex 1);
- .2 note the example of the use of the Human Element Analysing Process (HEAP) to the IMO rule making process (annex 2); and
- .3 note the guidance on the application of FSA in the IMO rule making process (annex 3).

ANNEX 1

THE DIFFERENCE BETWEEN HEAP AND FSA

Human Element Analysing Process (HEAP)

1 The HEAP is a practical tool, designed to address the human element, to be used for consideration of maritime safety and environmental protection issues at IMO. The flowchart is provided in accordance with Assembly resolution A.850(20) "Human Element Vision, Principles and Goals" goal (a) which states: "to have in place a structured approach for proper consideration of human element issues for use in the development of regulations and guidelines by all Committees and Sub-Committees". The steps outlined in the flowchart list a series of questions that should be considered to appropriately address the human element in the regulatory development process.

2 This is a method developed in IMO for the use of IMO and should be seen as a practical and non-scientific checklist to assist regulators in ensuring that human element aspects related to the ship and its equipment, the master and crew, training, management ashore and on board, and work environment conditions have been taken into consideration when introducing or amending IMO instruments.

3 HEAP is broad in application and not to be seen as any kind of replacement for an FSA study.

Formal Safety Assessment (FSA)

4 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.

5 FSA can be used as a tool to help in the evaluation of new regulations for maritime safety and protection of marine environment 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 maritime safety or protection of marine environment and costs.

6 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", A.777(18) "Work Methods and Organization of Work in Committees and their Subsidiary Bodies" and A.900(21) "Objectives of the Organization in the 2000s".

7 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.

8 This is a risk based approach developed scientifically and used in many industries. A large number of scientific papers on risk based approaches are published regularly.

9 Within FSA the human element is addressed both by the requirement of inclusion of human element experts during hazard identification, and during the execution of the risk assessment, where a set of scientific methods, known under the heading Human Reliability Analysis (HRA), is applied. HEAP is not one of these HRA methods.

ANNEX 2

AN EXAMPLE OF UTILISING HEAP IN THE IMO RULE MAKING PROCESS

1 The Sub-Committee on Fire Protection, while undertaking development of SOLAS new chapter II-2, used HEAP for determining the contents of regulation II-2/14 “Operational readiness and maintenance”, II-2/15 “Instructions, on-board training and drills” and II-2/16 “Operations” and found that HEAP was an useful tool to identify areas which should be taken into account on operation and maintenance of fire safety systems and fire drills.

2 HEAP was used within the correspondence group of comprehensive review on SOLAS chapter II-2.

3 Regulations 4 to 13 of SOLAS new chapter II-2 require fire safety construction, arrangement and equipment on board ship based upon the following basis:

- .1 prevention of fire;
- .2 detection of fire;
- .3 suppression and control of fire; and
- .4 escape from fire.

Then, these regulations were screened using HEAP to determine which actions were to be taken by crew and management. Through the process of paragraph 4 “Human element Checklist” of HEAP, details of the following measures relating to fire safety constructions, arrangement and equipment were identified:

- .1 operational readiness;
- .2 maintenance;
- .3 instructions; and
- .4 training and drills on board.

4 The results were reviewed in the correspondence group and drafted regulations 14, 15 and 16 of SOLAS chapter II-2.

5 The Sub-Committee reviewed and endorsed the outcome.

ANNEX 3

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

Introduction

- 1 The Guidelines identify two areas of application:
 - .1 by a Member State or an organisation having a consultative status with the IMO (hereinafter called Member), when proposing amendments to maritime safety and pollution prevention instruments, to support or analyse the implications of such proposals; or
 - .2 by a Committee or instructed subsidiary body, to provide a balanced view of a framework of regulations, so as to identify priorities and areas of concern, and to analyse the benefits and implications of proposed changes.
- 2 Recommendations resulting from an FSA study should aim to be used by decision makers at all levels and in a variety of contexts at the IMO, without a requirement of specialist expertise. For this purpose, an FSA study should be open and transparent for review by all interested Member States and non-governmental organisations which have not participated in the conduct of the FSA study.
- 3 FSA studies submitted to the Organization in accordance with the guidelines for formal safety assessment (FSA), for use in IMO rule-making process for consideration, when introducing or amending IMO instruments should be considered as one source but not the only source of valuable information to support IMO decision making.

Application of FSA by a Member

- 4 A Member Government or an organization having a consultative status with IMO, or a pool of Members, may decide to carry out an FSA and submit its results for consideration by a Committee or instructed subsidiary body. The scope of the FSA definition of the problem and its boundaries should be decided by the Member(s) conducting the study, in the context of the submitted proposal. The costs involved in carrying out the study should be covered by the Member(s) conducting the study, who will also co-ordinate and keep responsibility for the work of subcontractors, if any.
- 5 The Member(s) carrying out the FSA study should make its/their best efforts to ensure that the report is presented in accordance with the Standard Format for Reporting FSA Applications, given in appendix 8 of the FSA Guidelines. It is important that the FSA report includes the names and credentials of the experts who have carried out or have been involved in the FSA.

Review of a FSA study carried out by a Member

6 The Committee or an instructed subsidiary body should consider the submission of an FSA study and decide, on a case by case basis, the most appropriate course of action. When the subject is sufficiently clear, the Committee can form an opinion about the FSA study and its relevant proposals, and decide accordingly. In other circumstances, the Committee may decide that a review is necessary to validate the FSA study and its findings.

7 The review process should be carried out within the Organisation, e.g. by an intersessional correspondence group and/or working group established by the Committee for that purpose.

8 The terms of reference of such a review should be established by the Committee or an instructed subsidiary body, based on the matter under consideration. For instance, the terms of reference may include:

- .1 evaluation of the methodology applied and verification that it is in accordance with the FSA Interim Guidelines;
- .2 evaluation of the appropriateness of the scenarios applied, assumptions made and limitations of the FSA study with regard to the significance of the findings;
- .3 evaluation of whether the risks and risk control options have been evaluated in an appropriate manner; and
- .4 presentation of the results of the review, in clear and comprehensive terms, including any recommendations for the IMO rule-making process.

9 Participation in the review will be voluntary and open to all Member States and non-governmental organizations. All fields of expertise necessary for carrying out the review should be properly covered and the review should be as wide as possible.

10 The Members having carried out the FSA study should provide timely and open access to relevant supporting documents, and any reasonable opportunity to take into consideration the comments received.

11 The results of the review should be presented to the Committee or instructed subsidiary body, as appropriate.

Application of FSA by a Committee or an instructed sub-committee

12 The Committee may decide to carry out an FSA study following:

- .1 a proposal by a Member;
- .2 a proposal from a subsidiary body; or
- .3 discussion in the Committee of an agenda item.

13 There are different options which may be followed by the Committee for undertaking the FSA study. In some circumstances, for instance when a proposal has far reaching implications and requires a balanced view between all relevant issues, the Committee may decide that the FSA study should be carried out by an instructed Sub-Committee, as described in paragraphs 15 to 24 below.

14 Further options for undertaking an FSA study may also be appropriate, one of which could be to invite a Member, or a pool of Members, to carry out the FSA study and report its results for consideration by the Committee. The Member(s) accepting this proposal could proceed according to the steps given in paragraphs 4 to 11 above.

15 In cases where the Committee decides that the study should be carried out by instructed sub-committee(s) the FSA study may be conducted in accordance with the flow chart shown in figure 1, as described below.

16 The Committee may decide to establish a working group, instructed to:

- .1 develop the terms of reference for undertaking FSA;
- .2 propose a list of required competencies;
- .3 develop and execute a project management plan;
- .4 co-ordinate the conduct of FSA;
- .5 validate FSA, when necessary; and
- .6 report the results of FSA to the Committee, for information and approval.

17 The terms of reference of FSA may include, *inter alia*:

- .1 the definition of the problem under consideration and its boundaries (chapter 4 of the Guidelines);
- .2 characterization of the problem under consideration, for example in terms or features, characteristics and attributes which are relevant to the problem concerned (section 4.2 of the Guidelines);
- .3 the organization and tasks proposed for carrying out the 5 steps of the FSA process, including instructions to the relevant subsidiary bodies; and
- .4 the list of competencies required for carrying out each step of FSA.

18 The Committee should examine the draft terms of reference developed by the working group, including in particular the necessary competencies, for approval. On the basis of the approved terms of reference, the Committee will:

- .1 instruct the sub-committee(s) to undertake FSA (for instance a sub-committee or several sub-committees);

- .2 endorse the list of competencies for carrying out each step of FSA; and
- .3 invite Members willing to participate in the conduct of the FSA study to provide persons with the required competencies.

19 Members interested in participating in FSA should provide the Committee with a list of persons proposed to participate in the sub-committees instructed to carry out the FSA study, together with details of their relevant competencies. The working group should determine that such a list, when completed, covers the competencies deemed necessary for carrying out each step of the FSA study, and report to the Committee to decide as appropriate.

20 Each instructed subsidiary body should carry out the parts of the FSA study assigned to them. Any progress reports that the Committee may require, and, on completion of the FSA study, the final report should be submitted to the Committee. This final report should be in accordance with the Standard Reporting Format, given in annex 2 of the FSA Guidelines.

21 Interim reports may be submitted to the working group for the purposes of providing inputs to other parts of the process and enabling the working group to facilitate and monitor progress according to the project plan. The working group should review these reports and inform the Committee whether the FSA study proceeds in accordance with the approved project management plan. The working group should also propose necessary corrective actions, if any.

22 In addition to the final report submitted to the Committee by the sub-committees undertaking the FSA study, the working group should, at the completion of the FSA study, present to the Committee a summary report, which may include, *inter alia*:

- .1 an evaluation that the methodology applied is in accordance with the Interim Guidelines;
- .2 any proposals for improvement of the Interim Guidelines;
- .3 deviations, if any, from the terms of reference approved by the Committee, and reasons therefore; and
- .4 a list of recommendations resulting from the FSA study for a decision by the Committee.

23 The Committee should receive the recommendations made by the working group and decide as appropriate.

Review of a FSA study carried out by the Committee or an instructed sub-committee

24 Based on the discussion of the FSA final and summary reports, the Committee may decide to carry out a review of FSA, similar to the guidelines given in paragraphs 6 to 11 above.

Participation of experts in an FSA Study

25 The participation of experts in the various fields is an essential part for the success of an FSA application. The team carrying out the FSA study should be selected in accordance with the area of interest of the study and related problems. A number of other experts should be involved to gather expert views and judgements throughout the 5 steps of the FSA process.

26 The team carrying out an FSA study should cover the fields of expertise necessary to progress within the 5 steps of the FSA process. The composition of the team depends on the type of problem and level of detail of the assessment. For instance, the team might include:

- .1 experts in risk assessment techniques;
- .2 experts in statistical data gathering and analysing;
- .3 experts involved in casualty investigations;
- .4 experts in the human element;
- .5 experts in the applicable rules and regulations;
- .6 experts from the technical, operational and organizational field, (e.g.: designers, builders and operators);
- .7 experts in consequence assessment (e.g.: SAR, salvage and environment protection);
and
- .8 experts in cost benefit assessment.

27 The team carrying out an FSA study may involve other experts in order to provide additional expert views, technical evaluations and/or judgements. All the experts involved in FSA study should have, as far as possible, a basic knowledge and understanding of the FSA methodology, as set out in the FSA Guidelines.

28 The experts to be involved should cover the widest possible range of knowledge, qualifications and competence relevant to the problem under consideration, including for instance:

- .1 organizational and managerial aspects, e.g. pertinent to shipping companies;
- .2 technical aspects, e.g. design, construction, operation and maintenance;
- .3 legal, finance and insurance matters; and
- .4 matters of concern to flag Administrations and port State controls.

29 The names and expertise of the members of the team carrying out an FSA study and other experts involved should be included in an annex to the report containing the results of the study.

30 Other experts in various fields may be involved when reviewing and discussing the results of the FSA study.

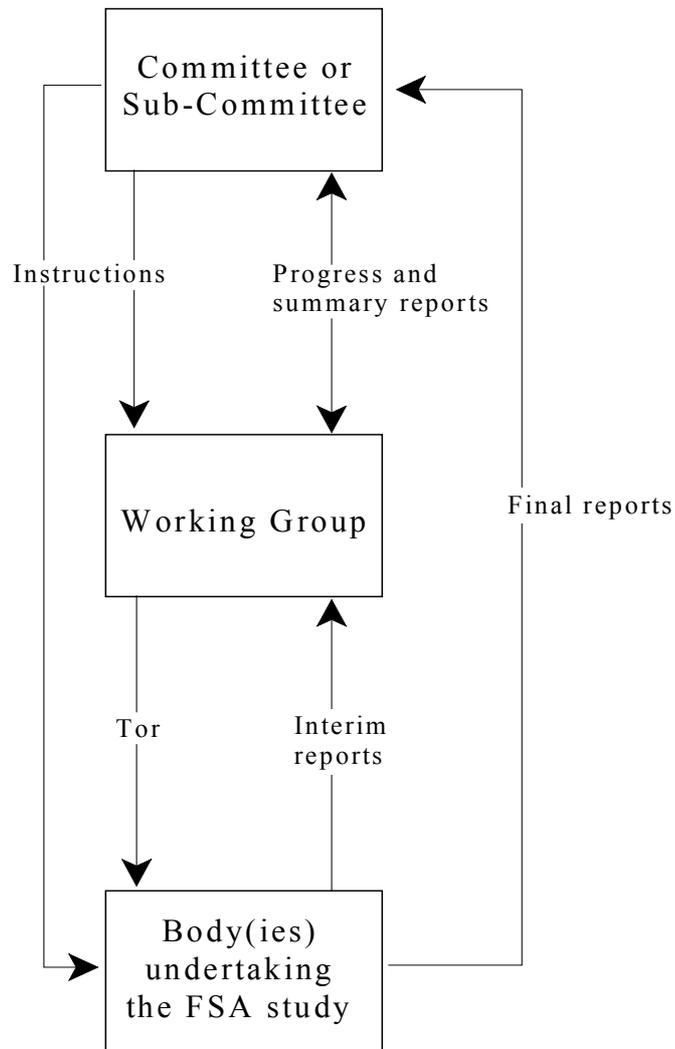


Figure 1.