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## FORMAL SAFETY ASSESSMENT

### Revisions to the FSA Guidelines

### Submitted by Germany and IACS

#### SUMMARY

*Executive summary:* This document proposes revisions of the FSA Guidelines in response to the invitation by MSC 108 to submit concrete text proposals in order to improve the text of the Guidelines.

*Strategic direction,  
if applicable:* 2

*Output:* 2.21

*Action to be taken:* Paragraph 35

*Related documents:* MSC 108/11 and MSC 108/20

## BACKGROUND

1 The 108th session of the Maritime Safety Committee invited relevant submissions with concrete text proposals in order to improve the text of the *Revised guidelines for Formal Safety Assessment (FSA) for use in the IMO rule-making process* (MSC-MEPC.2/Circ.12/Rev.2) (hereafter referred to as "the FSA Guidelines") (MSC 108/20, paragraph 11.4.3).

## DISCUSSION AND PROPOSALS

2 This document provides proposals for the revision of the FSA Guidelines, with a view to their improvement, as outlined below.

### Clarification regarding the FSA

3 It is proposed to add a new paragraph 1.1.5 to the FSA Guidelines, with a view to dispelling common misconceptions that the FSA is a risk assessment tool or technique, as follows:

"1.1.5 It may be noted that the FSA is a methodology which utilizes risk assessment for the development of regulations by IMO; however, it should also be kept in view that the FSA by itself is not a risk assessment technique."

## Definitions of "sensitivity analysis" and "uncertainty analysis"

4 It will be pertinent, as well as useful, to include the definitions of "sensitivity analysis" and "uncertainty analysis" in section 2 on Basic Terminology (it may be noted that these items are defined in the later parts of the FSA Guidelines in the appendices). The following additional definitions are proposed to be added to section 2 on Basic Terminology after the definition of Risk evaluation criteria:

"Sensitivity analysis: [Option 1] Study of how the variability in the output of a model (numerical or otherwise) can be apportioned to different sources of variability in the model input. This analysis aims to identify the variables whose uncertainty has the greatest influence on the uncertainty of the result.

[Option 2]: Study of how the uncertainty in the output of a model (numerical or otherwise) can be apportioned to different sources of uncertainty in the model input. This analysis aims to identify the variables whose uncertainty significantly influences the uncertainty of the result.", and;

"Uncertainty analysis: Investigation of the uncertainty(ies) of variables that are used in decision-making problems in which observations and models represent the knowledge base. In other words, uncertainty analysis aims to make a technical contribution to decision-making through the quantification of uncertainties in the relevant variables and results."

## Information and data

5 It is proposed to revise paragraph 3.2.4 to better elaborate the term "recent changes", as shown below:\*

"3.2.4 Equally, consideration should also be given to cases where the introduction of recent changes (e.g. regulatory, design, operation, construction/manufacturing) may have affected the validity of historic data for assessing current risk."

## Expert judgement

6 It is proposed to revise paragraph 3.3.1 of the FSA Guidelines in order to better elaborate the purpose and process of expert judgement, as follows:

"3.3.1 The use of expert judgement is considered to be an important element within the FSA methodology. It not only contributes to the proactive nature of the methodology but is also essential in cases where there is a lack of historical data. ~~Further historical data may be evaluated by the use of expert judgement by which the quality of the historical data may be improved.~~ In such cases, data can be enhanced or completed by further consideration of information/data and the use of expert judgement by which the quality of the original historical data may be improved. The subsequent improvements support quantitatively the whole FSA process. The assumptions and rationale used for arriving at the expert judgement should be documented."

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\* Here and elsewhere, tracked changes are indicated using "grey shading" to highlight new insertions and "strikethrough" to highlight deletion of the text.

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## Problem definition

7 It is proposed to revise section 4.1 of the FSA Guidelines pertaining to preparation for the FSA study. The revisions aim to clarify that the FSA can address the risks from all accident categories or focus on a specific accident category (e.g. fire). The text of the proposal is as follows:

"4.1 Preparation for the study

An FSA may address risks posed by all accident categories or focus only on a specific accident category. The purpose of problem definition is to carefully define the problem under analysis 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: ..."

8 Further, it is proposed to relocate the word "routeing" in the parentheses in paragraph 4.1.4 to paragraph 4.1.3, as it will be more appropriate.

## Generic model

9 It is proposed to revise paragraph 4.2.3 of the FSA Guidelines to clarify the consideration of the generic model which may be based upon a particular theme/aspect (e.g. ship size), as follows:

"4.2.3 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 aspects which fulfil the defined functions. The functions and systems should be broken down to an appropriate level of detail. Aspects of the interaction of functions and systems and the extent of their variability should be addressed in order to consider all influences characterizing the problem under consideration, for instance ship size or different system designs."

## Hazard identification

10 It is proposed to clarify the identification of hazards in relation to catastrophic events which may occur very remotely. It is proposed to insert the following new paragraph 5.2.1.2 in this regard and to renumber the subsequent paragraphs:

"5.2.1.2 Special attention should be paid to catastrophic events that are expected to occur with a very low frequency (extremely remote) and for which no historical data is available. The actual occurrence of an extremely remote event requires either larger samples or longer observation periods both of which are often not available. Such catastrophic events should not be discarded due to their low frequency, but should be properly assessed in the ranking."

11 It is proposed to insert a new paragraph 5.2.1.4 to clarify that the hazard identification sessions may be used to develop a preliminary list of risk control measures (RCMs), as follows:

"5.2.1.4 The hazard identification sessions and correspondence can also take advantage of the availability of the experts and be used to elaborate a preliminary list of risk control measures that could be investigated further in step 3 based on the step 2 quantitative assessment."

## Ranking of hazards

12 It is proposed to revise section 5.2.2 pertaining to ranking of hazards to reflect that ranking of hazards may not be necessary provided that all identified hazards relevant to the problem definition are addressed in step 2 of the FSA. The proposed text is as follows:

### "5.2.2 Ranking

The identified hazards ... for ranking purposes.

Notwithstanding the above, ranking of hazards may not be necessary during FSA step 1, if all the identified hazards relevant to the problem definition are included in the risk analysis step 2."

## Methods for risk analysis

13 It is proposed to revise section 6.2 of the FSA Guidelines to clarify that the accuracy of the developed risk model should be evaluated to the extent practicable. Therefore, it is suggested to insert the following new text for paragraph 6.2.3 and to renumber subsequent paragraphs:

"6.2.3 Notwithstanding the accurate selection of input data, it is recommended to verify the accuracy of the risk model output against other available information to avoid erroneous overestimation or underestimation of risk. To consider the issue of underreporting within historical data, typical risk models should overestimate the risk calculated by means of historical data."

## Identification of potential risk control measures

14 It is proposed to revise section 7.2.2 with regard to identification of risk control measures, so as to consider potential advances or development of technologies. Therefore, it is proposed to insert a new paragraph 7.2.2.6, as follows:

"7.2.2.6 Identification of RCMs may also take into account anticipated advances or ongoing developments in technologies."

## Cost-benefit assessment

15 It is proposed to revise section 8.1 on the scope of the cost-benefit assessment to clarify the evaluation of costs, benefits and the uncertainties associated therein. Therefore, it is proposed to delete the existing paragraph 8.1.2 and to replace it with the following paragraphs 8.1.2 to 8.1.4:

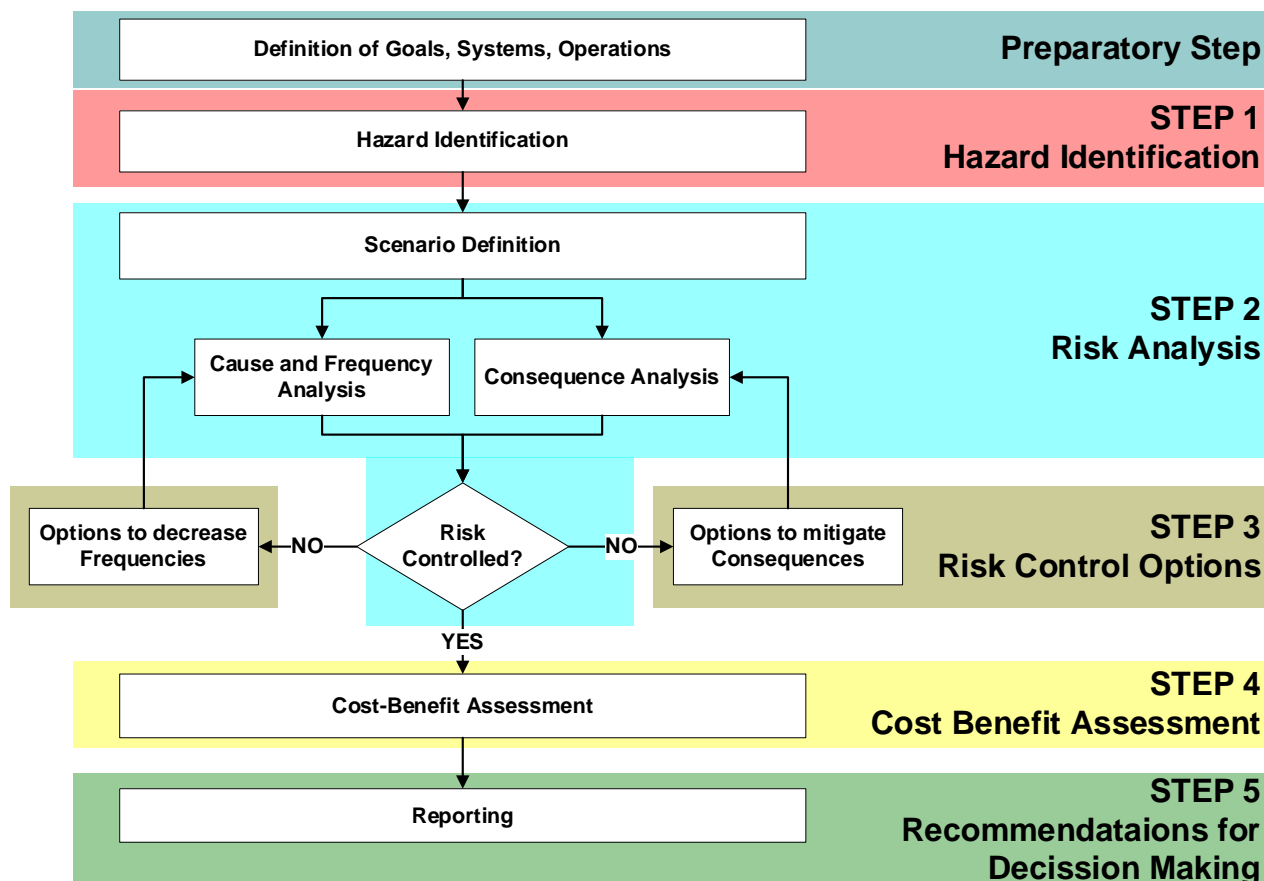
8.1.2 Costs of the RCOs should be expressed in terms of life cycle costs and may include initial, operating, training, inspection, certification, decommission, etc. as far as practicable.

8.1.3 Benefits of the RCOs may include reductions in fatalities, injuries, environmental damage and clean-up, third-party economic impact (tourism, fishery), loss/damage of cargo, loss of ship or ship repair.

8.1.4 It should be noted that due consideration should be given to the estimation of costs and benefits and related uncertainty because of the importance of both parameters for demonstrating cost-effectiveness."

### Application and review process

16 It is proposed to replace figure 1 with the depiction as shown below, as this provides a better understanding of the FSA process.



17 The footnote to figure 2 is proposed to be replaced with the text as shown below to reflect the latest reference:

"\* DALY = Disabled Adjusted Life Years (World Health Organization (WHO) Statistics; <https://www.who.int/data/gho/data/themes/mortality-and-global-health-estimates/global-health-estimates-leading-causes-of-dalys>)"

### Revisions of appendix 1

18 It is proposed to revise paragraph 5.2.2 of appendix 1 of the FSA Guidelines, as follows:

"5.2.2 At this stage it is not necessary to generate a lot of detail. The aim is to identify those key human interactions and/or human-machine interactions which require further attention. Therefore ..."

### Revisions of appendix 3

19 With regard to paragraph 5.7 of appendix 3 of the FSA Guidelines, it is proposed to delete the hyperlink as follows, since this appears to be inactive:

"5.7 SWIFT (Structured What If Technique) is one example of a What If Analysis Technique. (<http://www.dnv.nl/Syscert/training&consultancy.htm>)."

20 In regard to section 9 of appendix 3 of the FSA Guidelines, it is proposed to ensure that the paragraphs on "sensitivity analysis" and "uncertainty analysis" are consistent with those proposed to be included in the definitions (see paragraph 4 above). Alternatively, these paragraphs may be deleted.

**Appendix 4**

21 Paragraph 3 of appendix 4 of the FSA Guidelines indicates that the table on the severity index is merely an example and users should develop their own table on the severity index as suited to the problem. To emphasize this point and to avoid potential misinterpretation of the table as being a standard table, it is proposed that the word "example" be highlighted (bold and underline) so as to caution users. It is further suggested to include a footnote to the table to consider severity indices greater than 4 in case there is a higher number of fatalities than 100. Finally, a formula is also proposed to evaluate the severity index considering equivalent fatalities, which may not be in terms of exponents of 10. The proposed text is, as follows:

"3 The following table gives an **example** of a logarithmic severity index, scaled for a maritime safety issue. Consideration of environmental issues or of passenger vessels may require additional or different categories.

Alternatively, the severity index (SI) for fatalities can be directly calculated from the equivalent number of fatalities (S) using the below formula

$$SI = 3 + \log (S)$$

Severity index				
SI	SEVERITY	EFFECTS ON HUMAN SAFETY	EFFECTS ON SHIP	S (Equivalent fatalities)
1	Minor	Single or minor injuries	Local equipment damage	0.01
2	Significant	Multiple or severe injuries	Non-severe ship damage	0.1
3	Severe	Single fatality or multiple severe injuries	Severe damage	1
4	Catastrophic	Multiple fatalities	Total loss	10
Severity indices > 4 are suggested to be used for accidents with a higher number of fatalities				

22 Paragraph 4 of appendix 4 of the FSA Guidelines regarding the "frequency index" is similarly proposed to be amended, as follows:

"4 The following table gives an **example** of a logarithmic probability/frequency index.

Alternatively, the frequency index (FI) can be directly calculated from the frequency of occurrence using the below formula

$$FI = 6 + \log (F)$$

Frequency index			
FI	FREQUENCY	DEFINITION	F (per ship year)
7	Frequent	Likely to occur once per month on one ship	10
6	Highly probable	Likely to occur once per year on one ship	1
5	Reasonably probable	Likely to occur once per year in a fleet of 10 ships, i.e. likely to occur a few times during the ship's life	0.1
4	Probable	Likely to occur once per year in a fleet of 100 ships, i.e. likely to occur during the ship's life	10 <sup>-2</sup>
3	Rare	Likely to occur once per year in a fleet of 1,000 ships, i.e. likely to occur in the total life of several similar ships	10 <sup>-3</sup>
2	Remote	Likely to occur once per year in a fleet of 10,000 ships.	10 <sup>-4</sup>
1	Extremely remote	Likely to occur once in the lifetime (20 years) of a world fleet of 5,000 ships	10 <sup>-5</sup>

"

23 Paragraph 5 of appendix 4 of the FSA Guidelines is similarly proposed to be revised, as follows:

"5 The following table gives an **example** of a risk matrix based on the tables above."

### Appendix 5

24 Section 4.2 of appendix 5 of the FSA Guidelines is proposed to be revised, as follows:

"With this approach the amount of risk reduction that can be justified in the ALARP region is determined. Several researchers have proven that most risks in shipping fall into this region. However, it should be noted that this has not yet been verified for all ship types. As such, most of the risk-based decisions will require a CEA. However, it should be noted that this has not yet been verified for all ship types. It should be noted that an assessment and related risk rating is valid for a specific point in time and is therefore subject to change with time. There are several indices which express cost-effectiveness in relation to safety of life such as GCAF and NCAF, as described in appendix 7."

25 A new paragraph 5.3.3 is proposed to be added to appendix 5 as follows:

"5.3.3 In case no global assessment due to an FN diagram is possible (e.g. only a single accident category is considered in the FSA), analysts may simply apply the ALARP principle to look for cost-efficient control measures."

### Appendix 7

26 The co-sponsors agree with the proposal in document MSC 108/11 (Norway) to revise the cost-effectiveness criteria in table 2 of appendix 7 of the FSA Guidelines. In this regard, the co-sponsors propose the following changes to the text of paragraph 1.3.2:

"1.3.2 The proposed values for NCAF and GCAF in table 2 were derived by considering societal indicators (refer to document MSC 72/16, UNDP 1990, Lind 1996). They are provided for illustrative purposes only. The specific values selected as appropriate and used

in an FSA study should be explicitly defined. These criteria given in table 2 are not static but should be updated every year according to the average risk free rate of return (approximately 5%) or by use of the formula based on LQI (Nathwani et al. (1997), Skjong and Ronold (1998, 2002), Rackwitz (2002 a, b)). The values shown in table 2 were determined using 2019 data (Hamann and Cichowicz, 2023)."

27 Further, it is proposed to insert the citation for the new reference. The citation should be added to the list of references, as follows:

"Hamann, R, Cichowicz, J. (2023). *Updating the threshold for IMO cost-benefit assessment*. Journal of Ship Technology Research, Vol. 70(3), pp 239 – 248."

28 Consequently, table 2 of appendix 7 of the FSA Guidelines is proposed to be revised as follows:

"

	NCAF [US \$]	GCAF [US \$]
criterion covering risk of fatality, injuries and ill health	3 8.7 million	3 8.7 million
criterion covering only risk of fatality*	1.5 4.35 million	1.5 4.35 million
criterion covering only risk of injuries and ill health*,**	1.5 4.35 million	1.5 4.35 million
<p>* NCAF and GCAF criteria are normally used covering not only fatalities from accidents but implicitly also injuries and/or ill health from them. This is an adequate approach because as was mentioned above, many accidents involve both consequence categories: fatalities and injuries/ill health.</p> <p>However, if accidents are analysed that involve only one of the two consequence categories (fatalities, injuries), the criteria should be adjusted to cover explicitly only the category relevant to the accident under consideration. In MSC 72/16, a proposal was made that the NCAF and GCAF are split equally for the two consequence categories.</p> <p>** refer also to QALY approach</p>		

"

29 It is proposed to revise paragraph 1.3.3.1 of appendix 7 of the FSA Guidelines to clarify the use of GCAF or NCAF, as follows:

".1 GCAF or NCAF:

In principle, either of the two criteria can be used. However, it is recommended to firstly consider GCAF instead of NCAF. The reason is that NCAF also takes into account economic benefits from the RCOs under consideration. This may be misused in some cases for pushing certain RCOs, by considering more economic benefits on preferred RCOs than on other RCOs. The reason is that NCAF adds another source of uncertainty into the evaluation which can be avoided when an RCO is already cost-efficient according to GCAF."



30 It is further proposed to add a new paragraph 1.3.5 in appendix 7 of the FSA Guidelines clarifying the actions which may be contemplated when for an RCO both GCAF and NCAF pass the cost-effectiveness criterion, and to renumber the following paragraph. The proposed text is, as follows:

"1.3.5 Notwithstanding that RCOs can be ranked according to GCAF and NCAF, due consideration should be given to the risk reduction of each RCO because it has been noted that RCOs with low-risk reduction potential are favoured by this method. When clear conclusions cannot be drawn from the initial ranking by GCAF/NCAF, other criteria may be used, e.g. cost-benefit-ratio ( $CBR = \Delta Cost - \Delta Benefit$ )."

31 It is proposed to revise the renumbered paragraph 1.3.6 for evaluation of the QALY. The proposal is to provide the formula only, rather than the actual numerical evaluation existing in the present version. The revision is proposed, as follows:

" $QALY = GCAF$  (covering injuries/ill health) / 35 = US\$42,000"

### ***Environmental risk evaluation criteria***

32 Paragraph 2.1 of appendix 7 of the FSA Guidelines is proposed to be revised to elaborate possible data sources. A proposal in this regard is shown, as follows:

"2.1 Noting that the most appropriate conversion formula to use will depend on the specific scope of each FSA to be performed, a general approach to be followed is outlined in the following suggested example. Possible sources of data for oil spill could include ITOPF data (<https://www.itopf.org/>), IOPC data (<https://iopcfunds.org/>), US data and Norwegian data."

### ***Appendix 8***

33 In appendix 8 of the FSA Guidelines, paragraph 4.1 and sections 2, 3, 4, 5, 6 and 7 of the Standard Reporting Format restrict the maximum number of pages to be utilized for developing various reporting aspects of the FSA. It is proposed that the above-mentioned paragraph and sections be revised to convey that the number of pages is an indicative number in general rather than a firm maximum limit.

34 For the reporting of the results achieved in each step of the FSA (section 6 of the Standard Reporting Format contained in appendix 8 of the FSA Guidelines), the following suggestions are provided:

- .1 for step 2, the results should also include details of expert judgement where utilized; and
- .2 for step 3, the results should include details of the risk control measures identified.

### **Action requested of the Committee**

35 The Committee is invited to consider the proposals for revising the FSA Guidelines as outlined in paragraphs 3 to 34 above and to take action, as appropriate.