1. The Maritime Safety Committee, at its 100th session (3 to 7 December 2018), approved the *Interim guidelines for development and application of IMO goal-based standards safety level approach*, as set out in the annex.

2. The Interim Guidelines serve to outline the process for the development and justification of IMO provisions in accordance with the goal-based standards safety level approach (GBS-SLA). The Maritime Safety Committee, at its ninetieth session (16 to 25 May 2012), agreed that SLA was an application of risk-based methods in order to determine, respectively, the safety level of regulations, with a view to developing or changing international regulations.

3. The GBS-SLA asks for the structured usage of risk-based methods for the development of goals, functional requirements and related regulations and is considered as an alternative to the traditional deterministic approach. Therefore, the annexed Interim Guidelines acknowledge and embrace the IMO risk-based Formal Safety Assessment by making ample reference to the *Revised guidelines for Formal Safety Assessment (FSA) for use in the IMO rule-making process* (MSC-MEPC.2/Circ.12/Rev.2).

4. The Interim Guidelines are applicable to the development of new regulations or recommendations as well as the revision/amendment of existing ones.

5. Member States are invited to use the annexed Interim Guidelines and to bring them to the attention of all parties concerned.

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ANNEX

INTERIM GUIDELINES FOR DEVELOPMENT AND APPLICATION OF
IMO GOAL-BASED STANDARDS SAFETY LEVEL APPROACH

1 Preamble

1.1 Goal-based standards (GBS) are goals and functional requirements that should be
met through regulations, rules and standards.

1.2 Goal-based standards safety level approach (GBS-SLA) aims to apply risk-based
methods to develop functional requirements and verify/justify compliance of regulations and
rules with the safety goals and functional requirements.

2 Purpose

These Guidelines describe the framework of GBS-SLA and specify the process for the
application of the safety level approach under the goal-based standards framework in the IMO
rule-making process, as applicable:

.1 Goal-based standards provide a framework considering goals that set broad,
overarching safety, environmental and/or security standards and functional
requirements in a way specific enough in order not to be open to differing
interpretations. The structure of the GBS framework provides the basis for a
clear structuring of regulations and rules.

.2 The safety level approach ensures that the required safety levels are
established and achieved.

.3 The safety level approach should be applied to achieve safety goals.
Compliance of regulations/rules (Tier IV and V) with these safety goals
should be verified by means of quantitative risk analysis.

3 Definitions

3.1 Goal-based standards are goals and functional requirements that should be met
through regulations, rules and standards. A GBS framework specifies the underlying concept
of goal-based standards and consists of goal-based standards and the associated detailed
requirements of rules and regulations for ships (see figure 1).

3.2 Safety level approach is the structured application of risk-based methodologies for
the IMO rule-making process.

3.3 Safety is the absence of unacceptable levels of risk.

3.4 Safety level is a measure of exposure to risk.

3.5 Required safety level means the maximum exposure to risk as acceptable to the
Organization.
4 Principles

4.1 The accomplishment of the mission of IMO by adopting the highest practicable safety levels is the guiding principle of GBS-SLA. The development of regulations according to GBS-SLA should apply this principle through the formulation of goals and functional requirements in a concise and at the same time holistic way.

4.2 The safety level approach should be applied to achieve explicit required safety levels. The quantitative and rational safety levels of goals and functional requirements should be systematically realized by the associated rules/regulations in a verifiable way.

4.3 The data, risk models and assumptions used in the application of the safety level approach should be transparent and accessible to all the stakeholders involved. The result of risk analysis should be measurable and repeatable.

5 Framework

5.1 The GBS framework describes the structure of IMO GBS and the relation between the different elements. It consists of five major elements, namely Tier I to Tier V (see also figure 1), as follows:

.1 Tier I Goals;
.2 Tier II Functional requirements;
.3 Tier III Verification of conformity;
.4 Tier IV Rules and regulations; and
.5 Tier V Industry practices and standards.

5.2 Additionally, monitoring of completeness, appropriateness and effectiveness of the GBS Tiers are part of this framework.
Figure 1: Goal-based standards framework
6 Structure of IMO GBS-SLA instruments

The development of IMO instruments under the GBS-SLA approach should follow the structure shown in figure 3. Goals and functional requirements would be contained in IMO Conventions such as SOLAS and MARPOL, while the more detailed requirements under Tier IV would be contained in related Codes and other instruments (e.g. national regulation, class rules).
7  Goals (Tier I)

7.1 Goals are high-level objectives to be met. They should address issue(s) of concern and reflect the required safety level. The required safety level can be specified explicitly by a quantitative safety level or implicitly by a process to be used for achieving the highest practicable safety level, e.g. ALARP principle as defined in the Revised guidelines for Formal Safety Assessment (FSA) for use in the IMO rule-making process (FSA Guidelines) (MSC-MEPC.2/Circ.12/Rev.2).

7.2 The required safety level reflected in the goals should address as a minimum:

.1 safety of life at sea including occupational health;
.2 safety of the ship; and
.3 prevention and control of pollution from the ship.

7.3 The goal(s) should be set at the level of subject areas and provide the anchor points of the Codes within the GBS-SLA framework, e.g. as shown in figure 3. Examples of subject areas that could be addressed include:

.1 construction – structure, subdivision and stability, machinery and electrical installations;
.2 construction – fire protection, fire detection and fire extinction;
.3 life-saving appliances and arrangements;
.4 radio communications; and
.5 safety of navigation.

7.4 Goals are established by the Maritime Safety Committee.

8  Functional requirements (Tier II)

8.1 Functional requirements provide the criteria to be satisfied in order to meet the goals. Once a goal has been set, functional requirements can be defined.

8.2 Functional requirements are established by IMO, at the responsible Committee level.

8.3 In order to fulfil the basic objectives of goal-based standards, functional requirements should comply with the following:

.1 cover all areas necessary to meet the goal;
.2 address all relevant hazards. Methods for hazard identification as well as ranking are described in the FSA Guidelines;
.3 provide the criteria for compliance, i.e. the criteria against which regulations and rules are justified/verified by Tier III. The criteria for compliance can be ship-type dependent;
.4 be independent of specific technologies, in order to allow for further technological development; and
.5 clearly describe what function has to be achieved.

8.4 In order to comply with paragraphs 8.3.1 and 8.3.2, the functional requirements should be based on identification and ranking of hazards for the area under consideration.

8.5 Functional requirements should be formulated considering the following three elements:

.1 description: a specific and short explanation of the required function;
.2 rationale: assignment of hazards to be mitigated by the function under consideration; and
.3 expected performance: description of the function in quantitative terms. This description should cover all aspects necessary in order to verify compliance and the conditions under which the requirements have to be reached.

9 Verification of conformity (Tier III)

9.1 Verification of conformity provides the instruments necessary for demonstrating and verifying that the associated rules and regulations for ships conform to the goals and functional requirements. The goals and functional requirements and corresponding clear description of the process for achievement of the related safety level should be submitted to the Maritime Safety Committee. The verification of conformity should be carried out under the Committee's instruction by following the procedures in the Generic guidelines for developing IMO goal-based standards (MSC.1/Circ.1394/Rev.1). Conformity should be demonstrated by means of risk-based methods. Conformity means that associated rules and regulations at a minimum meet the required safety levels specified by goals and functional requirements. The process of risk analysis is described in the FSA Guidelines.

9.2 The verification process should be transparent and result in a consistent outcome irrespective of the evaluator.

9.3 Verification of conformity should consider the following elements:

.1 extent to which the rules/regulations cover the functional requirements and contribute towards meeting the goal(s); and
.2 compliance with the safety level specified by the relevant functional requirements.

10 Rules and regulations (Tier IV)

Rules and regulations for ships are the detailed requirements developed by the Maritime Safety Committee, national Administrations and/or classification societies and applied by national Administrations and/or classification societies acting as recognized organizations in order to meet the goals and functional requirements. These detailed requirements become a part of the implementation framework of GBS-SLA when they have been verified as conforming to the required safety level.
11 Industry practices and standards (Tier V)

Industry standards, codes of practice and safety and quality systems for shipbuilding, ship operation, maintenance, training, manning, etc. may be referenced in the rules/regulations. The responsibility for justifying the suitability of such industry standards and practices, when referenced in a rule set, rests with the rule/regulation submitter. This justification should be provided during the verification of conformity process.

12 Monitoring

12.1 Monitoring is a method of evaluating the effectiveness of goals (Tier I), functional requirements (Tier II), rules and regulations (Tier IV) and standards/practices (Tier V) as well as attempting to identify risks not addressed in the initial rules/regulations development. In order to verify that the risk of shipping is kept as low as reasonably practicable, the GBS framework should be continuously monitored and systematically analysed. The degree of detail for the data recording depends on the item to be monitored.

12.2 The process of examination of the effectiveness of a new rule/regulation using the risk-based approach is described in the FSA Guidelines.

12.3 As illustrated by figure 1 of these Guidelines, two monitoring processes are distinguished:

.1 the monitoring of the effectiveness of rules/regulations; and
.2 the monitoring of the effectiveness of the goals (Tier I) and the functional requirements (Tier II).

12.4 The monitoring system to be established should address (list without any prioritization):

.1 safety of all persons on board, including occupational safety and health;
.2 matters related to society;
.3 safety of ship;
.4 protection of environment; and
.5 protection of cargo.

12.5 For both processes, monitoring should consider, but not be limited to, historical data, such as casualty reports, in-service experience, accident investigation, incident reports, near miss reports, new scientific research results as published in the industry, as well as risk analysis.

12.6 Monitoring responsibilities should be assigned with respect to monitoring tasks as follows:

.1 Tier I:
   .1 Monitoring (including data collection): Committee
   .2 Analysis: Committee
   .3 Evaluation: Committee
.2 Tier II:

.1 Monitoring (including data collection): Sub-Committees

.2 Analysis: Sub-Committees

.3 Evaluation: Sub-Committees

.3 Tier IV:

.1 Rules: monitoring (including data collection) and analysis by rule maker, evaluation by rule maker, supervision by IMO

.2 Requirements: monitoring and analysis by IMO/Sub-Committees, evaluation by IMO/Sub-Committees

12.7 The organization(s) responsible for the monitoring and analysis is (are) also responsible for the development and update of the reporting format.

13 Application of the safety-level approach to the IMO rule-making process using the FSA Guidelines

The application of the safety-level approach to the IMO rule-making process is described in table 1 with the corresponding linkage to the applicable FSA steps. This approach can be utilized for:

.1 the development of new instruments using the GBS-SLA framework;

.2 the revision of existing instruments not based on the GBS-SLA framework; and

.3 the revision of existing instruments which have been developed using the GBS-SLA framework.
### Table 1
Application of SLA to the IMO rule-making process

<table>
<thead>
<tr>
<th>Stage</th>
<th>Description</th>
<th>FSA step(s)/ references within the FSA Guidelines</th>
<th>Output for GBS SLA</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Decide the scope for the new regulation or review/update the scope for existing regulations.</td>
<td>Paragraph 4</td>
<td>Preamble for Tiers 1 and 2</td>
</tr>
</tbody>
</table>
| 2     | For development of new regulations, identify and prioritize hazards. For revision of existing regulations in accordance with the framework of GBS-SLA:  
  • Identify and prioritize hazards (if this step was performed earlier, then it may be skipped).  
  • Update the hazard list (applicable for revision of existing regulation developed in GBS-SLA framework). | Step 1 | Basis for Tiers 1 and 2 |
| 3     | Estimate the current safety level(s). | Step 2 | Basis for Tiers 1 and 2 |
| 4     | Decide the goals and required safety level(s) to be used for the development of new regulations, based on the outcome under stage 3 and in accordance with the FSA Guidelines. | Required safety level(s) to be agreed by the Committee | Tier 1 Goals  
  Basis for Tier 3 |
| 5     | 1 Perform FSA in accordance with the FSA Guidelines to derive the risk control options (RCOs).  
  2 Formulate the Functional requirements with their expected performances using the RCOs. | Steps 2,3,4,5 | Tier 2 FRs  
  Tier 3 Verification criteria |
| 6     | Develop new rules/regulations or reformulate existing rules/regulations based upon the functional requirements with their expected performances derived in Stage 5. | Tier 4 Rules/Regulations |