

MARINE GUIDANCE NOTE

MGN 664 (M+F)

Certification Process for Vessels using Innovative Technology

Notice to all port authorities, shipyards, shipowners, vessel designers, operators, surveyors, certifying authorities, recognised organisations and interested stakeholders.

Summary

This document provides guidance on how to process an application for the certification of UK vessels wherever they may be, or other vessels operating in UK waters that use Innovative Technology¹ or where a risk-based approach is used. This process supplements prescriptive regulations that may not cover all aspects of the Innovative Technology, and supports goal-based regulations and established survey, inspection, and certification processes. To aid understanding and consistency, the approach is informed by the guidelines for approval of alternatives and equivalents described in MSC.1/Circ.1455.²

1. Intent

- 1.1. The intent of this document is to ensure a robust certification process for vessels using Innovative Technology or where a risk-based approach is used to address safety, environmental and/or security aspects of the technology.
- This process supplements prescriptive regulations that do not cover all aspects of the technology, and it supports goal-based regulations and established survey, inspection, and certification processes.
- Although this guidance is intended to be generally applicable to the certification of vessels using Innovative Technology, some of the steps and documental requirements may be not relevant due to the specific technology or low risk profile of

¹ The definition of Innovative Technology is given at Annex C.

² MSC.1/Circ.1455 - Guidelines for the Approval of Alternative and Equivalents as Provided for in Various IMO Instruments.

- the operation. Therefore, the details of the certification process and related documentation should be confirmed with the MCA at the beginning of the application.
- 1.4. This guidance is intended as a dynamic document and will be updated in due course, as the MCA's understanding of good practice with respects to regulation of Innovative Technology evolves. Where appropriate, the MCA may publish separate, supplemental guidance that is aimed at managing the risks associated with a specific Innovative Technology.
- 1.5. Certification of vessels that use Innovative Technology requires extensive effort from both the applicant and the MCA to define the Approval Basis and to generate the evidence needed to demonstrate compliance.

2. Scope

- 2.1. This document provides guidance on how to process an application for the certification of UK vessels or other vessels operating in UK waters that use Innovative Technology or where a risk-based approach is used.
- 2.2. This guidance does not replace the existing activities for certification of vessels but is intended to support existing certification activities for instances where Innovative Technology is involved.
- 2.3. When the vessel falls within the scope of the International Convention for the Safety of Life at Sea (SOLAS), SOLAS regulations II-1/55 and II-2/17 on Alternative Design and Arrangements, they should be considered together alongside related IMO Guidelines such as MSC.1/Circ.1455.

3. **Definitions**

3.1 Definitions of the terms used in this guidance are provided in Annex C.

4. General

- 4.1. The detail of certification is dependent upon factors including vessel size, type, gross tonnage (GT), type of cargo and whether they are on a domestic or international voyage.
- 4.2. The overall process for certification of vessels can be found in the relevant regulations applicable to the vessel type and operation. Further guidance is available from Local Marine Offices³ or Survey Operations.
- 4.3. All commercial vessels must comply with the applicable statutory requirements although a vessel may not have survey and certification requirements (e.g., the majority of cargo vessels not "going to sea" i.e. remaining within UK Categorised Waters, as defined in MSN 1837⁴). MCA have the power to inspect these vessels. If the vessel does not comply with statutory requirements, or there is reason to believe that its condition or manner of operation is dangerously unsafe, the vessel is liable for detention.

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³ https://www.gov.uk/government/publications/locations-of-mca-marine-offices

⁴ MSN 1837 (M) Amendment 2. categorisation of waters

5. Stakeholders

- 5.1. The applicant is the person or organisation seeking certification from the MCA and is responsible for providing the required evidence as stated in each stage of the certification process.
- 5.2. Stages of the certification process may be supported by work undertaken to meet thirdparty certification requirements of a Classification Society and the applicant may
 present relevant certification issued by class to support the MCA certification. A
 Classification Society may also support stages of the certification process in a
 consultancy manner. To ensure impartiality, such 'consultancy' can only be provided by
 individuals with no role in, or influence on, certification of the design. In either case, the
 MCA should be informed of classification support and its scope as early as possible.
- 5.3. Throughout the certification process, in agreement with the applicant, the MCA may authorise a Recognised Organisation (RO) to undertake statutory surveys, design appraisal, risk assessment appraisal and certification on its behalf which fall outside the scope of the RO general agreements. Should the RO be part of an organisation which is also undertaking consultancy support, the RO function should be clearly distinguishable and independent with no conflict of interest. The UK authorises Classification Societies to act as an RO for the survey and inspection of UK ships.⁵
- 5.4. Where an RO is to complete work on behalf of the MCA, a vessel specific written appointment is required where it is not covered under the general agreements with the RO. This should be arranged at the initial stage in consultation with the MCA lead.
- 5.5. Certifying Authorities (CA) are authorised by the MCA to examine and certificate small (under 24m) commercial vessels in accordance with the Codes of Practice as detailed in their CA agreements. Certifying Authorities can also undertake the work described above but are unable to survey or certificate under Load Line regulations. More information on Certifying Authorities can be found in MIN 538.6
- 5.6. The RO/CA role and responsibility, scope and method of work should be clarified at the beginning of the process together with a list of activities reserved to the MCA.
- 5.7. The operation of vessels on inland waters may come under the jurisdiction of a Harbour Authority, a Local Authority, or a Navigation Authority and the vessels are subject to their requirements. Depending by the area of operation of the vessel, early engagement with such authorities in co-ordination with the MCA is recommended to seek an advanced agreement on the requirements.

6. Summary of the Activities to Support the Certification of Innovative Technology

6.1. The MCA will provide certification when it is satisfied the safety, environmental and security risks are managed to acceptable levels through the identification and satisfaction of appropriate requirements. These requirements need to be identified by the applicant and agreed by the MCA in a document summarising the basis for approval (Approval Basis). The requirements may be:

⁶ https://www.gov.uk/government/publications/min-538-m-amendment-3-authorisation-of-certifying-authorities

⁵ <u>https://www.gov.uk/guidance/uk-authorised-recognised-organisations-ros</u>

- a) Taken from applicable regulations, codes, and/or standards.
- b) Parts taken from alternative references such as codes, standards, or good practice.
- c) Control measures derived from activities (e.g., analysis, risk assessment) that are necessary to reduce safety, environmental or security risks to acceptable levels.
- 6.2. As far as practicable, certification for the design and operation of vessels that utilise Innovative technology should demonstrate compliance with existing UK maritime regulation, MCA acceptable codes of practice and/or standards. Reliance on alternative references or requirements derived from analyses instead of MCA acceptable codes of practice and/or standards should, as far as is practicable, be kept to a minimum.
- 6.3. Where the applicant intends to address the Innovative Technology though the application of alternative references such as codes, standards, or good practice, the use of these references should be discussed with the MCA. The applicant should propose a comprehensive set of requirements to address the specific application including the scope and justification for the use of each reference.
- 6.4. Where the applicant intends to address the Innovative Technology though activities such as analysis, risk assessment, etc., these activities should be identified and included in the plan of activities to support certification (Certification Plan). The findings of these activities can be used to further develop or demonstrate compliance with the requirements agreed in the Approval Basis.
- 6.5. The activities described in this guidance may derive additional design requirements which should be considered when the drawings of the design are submitted for approval. Also, additional requirements related to the initial / in-service survey, may be identified to verify a specific innovative component or system.
- 6.6. Table 1 summarises the different stages of the process with the related activities to support certification. This table also includes references to MSC.1/Circ.1455 to facilitate a mapping analysis between this document and the IMO circular.
- 6.7. These activities are grouped using a staged approach with specific review points to allow for continued confidence building as the required documents are developed. This is essentially an iterative "Plan-Do-Check-Act" approach.
- 6.8. Table 2 summarises the documents submission for each stage. All submitted documents should have a number and issue date. The various issues of a document should be controlled. It is acknowledged that not all versions may be complete or final.
- 6.9. Annex A and B cover respectively the detail of the activities to be undertaken and the detail of the documents to be submitted.
- 6.10. It is recognised that the applicant may already have completed certification or assurance activities involving 3rd party organisations (e.g., Approval in Principle issued by a Class Society). In this case, the MCA may agree to start the certification process at a later stage, however there is no guarantee the MCA will recognise or accept previous assurance activities.
- 6.11. To ensure that this process does not impose procedural requirements that are disproportionate to the risk presented by the proposed Innovative Technology and its

usage, where justified the MCA may agree to waive specific activity or documents. In any case, certification will only be granted where the applicant has demonstrated that safety, environmental and security risks, as appropriate, have been eliminated or mitigated to the satisfaction of the MCA.

Applicant activities MCA activities 1 - Early Engagement Refer to IMO MSC.1/Circ.1455 Annex par. 4.5 Share concept Design Documents. Preview the information and confirm the b) Share high-level Hazard Log*. innovative aspects. Confirm intention to start the certification. b) Discuss other stakeholders' involvement (e.g., local authority, class societies). c) Confirm the Initial Meeting can take place. 2 - Preliminary Stage of Certification Refer to IMO MSC.1/Circ.1455 Annex par. 4.6 to par. 4.10 **Initial Meeting Initial Meeting** a) Attend the Initial Meeting, fill the MCA a) Attend the Initial Meeting. forms and create the Action Register*. Approval Basis (preliminary) Approval Basis (preliminary) b) Review the Regulatory Gap Analysis and b) Submit the Regulatory Gap Analysis, preliminary documentation. c) Submit preliminary documentation: Design c) Agree the preliminary Approval Basis. Documents, Approval Basis, Certification **Activity and Reporting** d) Preview the ToR and may observe the activity. **Activity and Reporting** e) Review the activity report. d) Submit the Terms of Reference (ToR) of the f) May issue preliminary feedback. activity. e) Submit the activity report. 3 - Final Stage of Certification Refer to IMO MSC.1/Circ.1455 - Annex par. 4.11 to par. 4.18 Approval Basis (final) Approval Basis (final) a) Submit final documentation: Design a) Review final documentation. Documents, Approval Basis, Certification b) Agree the final Approval Basis. Plan. **Activity and Reporting Activity and Reporting** c) Preview the ToR and may observe the activity. b) Submit the ToR of the activity. d) Review and agree the Summary of c) Submit the Summary of Justifications and Justifications and related evidence (e.g., related evidence (e.g., reports, drawings). reports, drawings). d) Submit in-service documentation. e) Review in-service documentation. Initial Survey and Certification** Initial Survey and Certification** e) Assist the initial survey of the vessel. f) Complete the initial survey of the vessel, and issue certification including exemptions/equivalences and conditions. 4 - Operation Refer to IMO MSC.1/Circ.1455 - Annex par. 4.18 Operate in accordance with operating a) In-service survey & inspection of the vessel as requirements, certificate conditions, and any for certification.

Table 1 – Summary of the certification stages and related activities

applicable Safety Management System

*Note: These registers should be maintained and submitted throughout the process.

**Note: Depending on the type of technology and particular application, verification & validation activities other than the Initial Survey may be part of the final stage and included in the Certification Plan.

	1. Early Engagement	2.Preliminary Stage Initial Meeting		3. Final Stage	4. Operation
Design Documents	~		✓	✓	
Hazard Log	* *	~	~	✓	
Actions Register		✓	~	✓	
Regulatory Gap Analysis			4		
Certification Plan			✓	✓	
Approval Basis			~	✓	
ToR of the Activity			✓	✓	
Report of the Activity			✓	✓	
Summary of Justifications				✓	
In Service Documentation				✓	

Table 2 – Outline of the certification stages and summary of the submissions

^{*}Note: the hazard log would be a high-level initial summary of hazards at the early engagement.

^{**}Note: In-service Documentation, Hazard Log, and a Change Management system should be maintained during the operation of the vessel. The validity of the assumptions and the findings of the risk assessments made during the certification should be monitored during the life cycle of the vessel. Changes to the design or use of the vessel may require a review of the certification depending on the impact of these changes.

Annex A – Detail of the Activities

A.1. Early Engagement

- A.1.1. When certification is required for a vessel design involving Innovative Technology, engagement with the MCA at an early stage in the design lifecycle is recommended. Commencing certification activities after the design is completed or operating arrangements are already fixed may increase the risk of rejection of the application, or redesign and restrictions being placed on operations.
- A.1.2. Although the MCA may provide early advice to facilitate the process for certification, formal engagement with the MCA begins once an "Initial Meeting" (see later stage) has been established and an MCA Lead assigned as first point of contact.
- A.1.3. The objective of the Early Engagement stage is to develop a common level of understanding of the proposed design; confirm if the proposed design is potentially innovative; and identify any issues which might preclude certification. This engagement will facilitate the subsequent stages of the certification process.
- A.1.4. It is recognised that, at this early stage, the design or proposed operation may still be a concept and the information available may be limited in detail.
- A.1.5. During the Early Engagement stage, the applicant should provide the following documents or information to the MCA (refer to ANNEX B for the documents detail):
 - a) Design Documents (concept).
 - b) High-level Hazard Log: at this stage this will be a summary of the principal safety, environmental and security hazards which will later evolve into the Hazard Log.
 - c) Intention to start certification and general project expectations.
- A.1.6. During the Early Engagement stage, the MCA will:
 - a) Preview the information provided to confirm the innovative technology aspects and provide high level guidance on the certification process.
 - b) Discuss other stakeholders' involvement (e.g., local authority, class societies, RO/CA).
 - c) Preview the documents to confirm that the formal Initial Meeting between the applicant and MCA can take place and arrange the meeting with the relevant persons.

A.2. Preliminary Stage

A.2.1 The Preliminary stage provides the opportunity for the applicant to develop and agree with the MCA the preliminary basis for approval, and for the MCA to review and ask for any clarifications on the preliminary plan of activities, design documentation and report/s of the activity undertaken.

Initial Meeting

- A.2.2 The Preliminary stage is formally initiated by a meeting, or a series of meetings, between the applicant and the MCA. This "Initial Meeting(s)" represents the commencement of engagement with the MCA's regulatory function UK Maritime Services (UKMS).
- A.2.3 The Initial Meeting provides the forum to preview the design, discuss the concept, relevant regulations, codes and standards as well as the stages of the certification process and identify aspects of the design requiring special attention.
- A.2.4 The roles, responsibilities of the parties involved should be clarified at the Initial Meeting. When an RO or CA is involved, the scope and method of work of should be agreed and formalised.
- A.2.5 The parties will have an initial discussion on the activities necessary to achieve certification and the need to document these activities in a Certification Plan.
- A.2.6 The applicant should create an Actions Register to capture all actions and recommendations from the certification process (e.g., actions from meetings, risk assessment workshops) and a Hazard Log to act as single repository of all identified hazards (from the various studies and hazard identification and analyses). These registers should be maintained and submitted throughout the process or at the MCA request.
- A.2.7 The applicant should complete form MSF 5100 "MCA Application for Survey and Inspection of Ships and Fishing Vessels" to enable the project to progress past the Initial Meeting stage.
- A.2.8 At the Initial Meeting, the applicant should: (refer to ANNEX B for the documents detail):
 - a) Present the design and provide Design Documentation.
 - b) Present an outline of the proposed activities to support certification.
 - c) Create and maintain the Actions Register.
- A.2.9 At the Initial Meeting, the MCA will:
 - a) Provide guidance on completing a plan of activities to support the certification (Certification Plan).

Certification Plan

- A.2.10 The applicant should define and implement a coherent approach to management of all safety, security, and environmental activities, associated with innovative and traditional technologies necessary to achieve certification and document their approach in a Certification Plan.
- A.2.11 Given the evolutionary nature of the development of innovative aspects, it is likely that the Certification Plan will need to be updated as the project progresses.
- A.2.12 The applicant should gain MCA agreement on initial and subsequent issues of the Certification Plan. Where not already included in the Certification Plan, the applicant should submit the Terms of Reference (ToR) for specific certification activities (e.g., HAZID workshop, tests, etc.) with adequate notice before the activity is undertaken to allow for MCA review, comment and, if appropriate, participation as an observer.

Approval Basis (Preliminary)

- A.2.13 The applicant should discuss with the MCA the basis of approval (Approval Basis) for the certification of innovative technologies before the design is finalised. Given the evolutionary nature of the design and analysis process, the Approval Basis will be updated as the project progresses, as the understanding of the risks and required control measures evolves.
- A.2.14 A preliminary Approval Basis will need to be defined and agreed with the MCA. This document will be later updated following the findings of the activities of the Certification Plan.
- A.2.15 The Applicant should submit the following preliminary documentations (refer to ANNEX B for the documents detail):
 - a) Design Documents, e.g., design description, functional description, concept of operations, etc.
 - b) Regulatory Gap Analysis to identify instances of regulations that are directly or partially applicable or challenged by the Innovative Technology.
 - c) Approval Basis. This will be a preliminary document which may not include detailed requirements but refers to planned activities of the Certification Plan for further development.
 - d) Certification Plan. Proposing the activities to develop the preliminary Approval Basis.

A.2.16 The MCA will:

- a) Review the preliminary documentation, seeking clarification as necessary.
- b) Provide feedback on the preliminary documentation, highlighting key areas to be addressed in subsequent stages (noting this may result in updates to the Certification Plan).
- c) If satisfied, agree the preliminary Approval Basis.

A.2.17 The applicant should initiate form MSF 1261 "Assessment of Equivalence / Exemptions / Alternative Design Arrangement (ADA) from Statutory Requirements" for any areas identified.

Activities and Reporting (Preliminary)

- A.2.18 Following the agreement on the preliminary Approval Basis, the applicant undertakes the relevant activity/s, engaging with and providing reports to the MCA as defined in the Certification Plan. At the end of the activity the applicant develops and submits a:
 - a) Report of the activity/s undertaken.

A.2.19 The MCA will:

- a) Review the report of activity undertaken and ask for any needed clarification.
- A.2.20 At the end of the Preliminary Stage, if satisfied, the MCA may issue preliminary feedback of the design which would confirm that the preliminary stage meets the MCA expectations. This feedback would not assure the final acceptance and issue of certification being this based on the outcome of the final stage.

A.3. Final Stage

A.3.1. Following the conclusion of the preliminary stage, the applicant will agree with the MCA the updated Approval Basis and undertake the final activities as for Certification Plan. Following completion of these activities, the applicant will submit a Summary of Justifications to support the certification of Innovative Technology. The MCA, if satisfied that all relevant requirements have been met, will provide appropriate certification for the vessel.

Approval Basis (final)

- A.3.2. The applicant should update and finalise the Approval Basis to reflect the final design of the Innovative Technology, considering the outputs from the activities set out in the Certification Plan.
- A.3.3. The applicant should submit the following documentation to facilitate MCA review and agreement of the updated Approval Basis (refer to ANNEX B for the documents detail):
 - a) Design Documents (final).
 - b) Approval Basis (final) summarising:
 - List of applicable regulations, codes and/or standards and how these are affected by design deviations or regulatory gaps.
 - Aspects addressed by direct compliance with regulations, codes, standards.
 - Aspects to be addressed/addressed by the Certification Plan activities and related evaluation/acceptance criteria (e.g., risk assessment, tests, etc.).
 - Operational requirements such as training, maintenance, and survey relating to the Innovative Technology under consideration.
 - Conditions of approval, if any.
 - c) Certification Plan (final).

A.3.4. The MCA:

- a) Review the final Design Documents and Certification Plan seeking clarification as necessary.
- b) If satisfied, agree the final Approval Basis.

Final Activities and Compliance with the Approval Basis

A.3.5. Before the initial survey of the vessel, the applicant should carry out the analysis, tests, and other activities of the Certification Plan, and provides a collection of the evidence produced (Compliance Documentation) to demonstrate the requirements in the Approval Basis have been met. This evidence would typically include the final Design Documents and the reports of activities undertaken including a link to the

- related item of the Certification Plan. It is accepted that, at this stage, as the survey has yet to be undertaken, it will not be possible to produce a complete set of compliance documentation.
- A.3.6. The Applicant should provide a summary of the safety, environmental and security justifications for acceptance of the innovative technology (Summary of Justifications). This summary should articulate the approach taken to demonstrating compliance with the Approval Basis and include the applicant statement that compliance with the Approval Basis has been demonstrated (refer to ANNEX B for the documents detail).
- A.3.7. The applicant should propose any survey requirements associated with the innovative technology. The operational requirements (e.g., training, maintenance) to address the innovative technology aspects should also be included in the In-Service Documentation.

A.3.8. The applicant submits:

- a) The Summary of Justifications: a summary of the safety, environmental and security justification for acceptance of the Innovative Technology.
- b) Compliance Documentation: collection of the evidence generated: e.g., design documents, reports of individual activities, etc.
- c) Proposed survey requirements associated with the Innovative Technology.
- d) In-service Documentation.

A.3.9. The MCA will:

- a) Review the documents submitted and ask for any clarification.
- b) Review and, if satisfied, agree the Summary of Justifications and proposed survey requirements associated with the Innovative Technology aspects.

Survey

A.3.10. The applicant should arrange for an initial survey at an appropriate time in agreement with the MCA. The initial survey should include any specific survey items to address the Innovative Technology aspects.

Certification

- A.3.11. On completion of assessments and survey of both traditional and innovative aspects, if satisfied that all relevant requirements have been met, the MCA will provide appropriate certification for the vessel.
- A.3.12. Certification may include specific conditions to address the Innovative Technology related to the operation and in-service survey of the vessel. Conditions may also include monitoring and reporting of the Innovative Technology performance.

A.4. Operation

- A.4.1. At this stage the vessel has achieved certification and is operating in service, subject to the conditions of its certification. The responsibility is with the owner/operator to ensure that the vessel remains fully complaint and request necessary surveys and/or audits where required. Any modifications to the vessel or its equipment, scheduled area of operations, therefore need to be brought to the attention of the certificating body and MCA where appropriate as this may affect the validity of the certification issued.
- A.4.2. Should a vessel intend to change its area of operation or commence operation from a non-UK port the requirements of the Port State/Local Authority/etc., should also be complied with.
- A.4.3. The vessel should carry on board the relevant documentation such as, in-service documentation and the hazard log.
- A.4.4. The applicant should operate the vessel in accordance with operating requirements, defined limitations, and operating Safety Management System as applicable.

Annex B - Detail of the Documents

This annex provides the detail of the documentation supporting the certification of Innovative Technology.

It is appreciated that for some cases it may be unjustified to impose procedural requirements that are disproportionate to the risk presented, hence the MCA may consider high-level documentation or agree to waive specific documents.

This Annex contains the details of the following items:

- **B.1.Design Documents:**
 - **B.1.1.Design Description**
 - B.1.2.Functional Description / Concept of Operations (CONOPS)
 - B.1.3.Identification if the interfaces between innovative and traditional aspects.
 - B.1.4.Drawings of general arrangement and subsystems
 - B.1.5.List of codes and standards applied
- B.2.Hazard Log
- **B.3.**Actions Register
- B.4.Regulatory Gap Analysis
- **B.5.Approval Basis**
- **B.6.Certification Plan**
- B.7.Terms of Reference (ToR) of the activity
- B.8.Report of the activity
- **B.9.Summary of Justifications**
- B.10.In-service Documentation

B.1. Design Documents

B.1.1 Design Description

The Design Description comprises the material available on the design, including any safety features. The design description should cover all the Innovative Technology aspects and their integration onto the vessel/system.

The applicant should provide a Design Description that is complete and of sufficient detail to facilitate a comprehensive identification and analysis of safety, environmental and security risks.

The Design Description should include:

- Vessel particulars (vessel type, main dimensions, speed, capacity, etc.).
- Area of operation (e.g., categories of waters where the vessel will operate).
- Definition of the design basis comprising various environmental conditions, the intended goal (objectives) of the design.
- Definition of the system and boundaries (physical boundaries, components, and/or subsystems, which are all drivers for determining where interfaces exist) between:
 - Major internal elements of the innovative technology.
 - o The innovative and conventional aspects within the vessel/system.
 - The innovate aspects and external entities

B.1.2 Use Case/Functional Description/CONOPS

To fully understand the potential risks associated with the operation of the vessel/system, a documented Use Case/Functional Description/Concept of Operations (CONOPS) should be provided by the applicant. This should define the operation and support of the vessel/system to a sufficient degree of detail so as to support identification and analysis of safety, security, and environmental risks.

The document should include:

- Overview of safety, security, and environmental systems functionality (e.g., safe behaviours in an event of detected discrepancies such as automatic shutdown on leak detection and vessel reverting to a safe state in the event of command signal loss or security verification such as passwords and encryption protection).
- Overview of operational modes including stages of operation (e.g., launch, recovery, towed, transit).
- Overview of personnel carried (crew and/or passengers).
- Overview of whether the vessel intends to carry dangerous goods.
- Presumed maintenance and operating requirements.
- List of functions and any planned inherent safety features where applicable (e.g., redundancy, fail safe, etc.).

B.1.3 Identification if the Interfaces between innovative and traditional aspects

This document is an identification of interfaces between the innovative aspects and vessel/system, including:

- Identification of the interfaces (e.g., physical, electrical, mechanical, electronic, human) that cross the boundaries between:
 - Major internal elements of the Innovative Technology.
 - The innovative and conventional aspects within the vessel/system.
 - The innovate aspects and external entities.
- List of inputs received, and outputs provided across each of these boundaries.

B.1.4 Drawings of general arrangement and subsystems

The list of drawings would typically include the general arrangement of the vessel, process flow diagrams and detailed drawings of subsystems.

B.1.5 List of Codes and standards applied

This is a list of regulations, codes and standards, applied to the design.

B.2. Hazard Log

B.2.1. To inform the activities necessary to develop the Approval Basis, it is necessary to have an understanding the potential safety, environmental and security hazards associated with the operation of the vessel/system and their contribution to risks. A high-level Hazard log limited to the summary of the identified hazards (Summary of Hazards) should be initially created and later developed in a detailed Hazard Log which will consider the findings of any risk assessment or other activities undertaken during the certification process. The Hazard Log should be maintained during the life cycle of the vessel and support the change management.

Summary of Hazards

- B.2.2. The outputs of a systematic, identification of hazards and analysis of their contribution to risks should be recorded in a report listing all reasonably foreseeable hazards associated with the whole vessel/system and its operation.
- B.2.3. The report should consider potential:
 - Physical hazards.
 - Hazards arising from data anomalies.
 - Human factors and misuse hazards.
 - Hazards arising from intended functionality.
 - Hazards arising from deviation from the intended functionality (e.g., due to functional failures or deviations that emerge from the interactions between systems).
 - Hazards arising from threats to cyber-security.
- B.2.4. The summary should be of sufficient detail to be able to determine the most suitable approach to manage the identified risks, either through:

- The application of maritime regulations, codes, standards; or,
- Through derivation of safety requirements based on risk assessments or other activities.

Hazard Log

- B.2.5. The Hazard Log develops from the Summary of Hazards using the findings of further analysis. Within their defined scope, hazard identification activities should:
 - Identify all reasonably foreseeable hazards and associated potential accidents, from all reasonably foreseeable causes.
 - Cover all technologies, applicable to the vessel/system, and is carried out through the design breakdown to a sufficient level of detail to address all causes of hazards, accidents or failure modes that contribute to a hazard or accident.
 - Consider human factors where they may be a contributory cause of a hazard.
 - Consider cyber-security where security breaches may be a contributory cause of a hazard.
 - Consider both systematic and random failures where they may be a contributory cause of a hazard.
 - Consider the undesired impact of the intended functionality; this is especially important for applicants carrying out systems integration.
 - Consider the potential for data anomalies where they may be a contributory cause of a hazard (e.g., where the vessel/system relies on data from external sources to perform safety related functions).
- B.2.6. The Hazard Log is the primary mechanism for recording all causes, hazards, accidents, controls, etc. identified. It is a live database or document, updated with the results of risk assessment activities throughout the design lifecycle. The Hazard Log should clearly show the linkage between causes, hazards, accidents, and control measures.
- B.2.7. The Hazard Log should maintain an up-to-date record of the implementation status of control measures throughout the design lifecycle.
- B.2.8. The applicant should update the Hazard Log throughout the design lifecycle to ensure that it accurately reflects the status of the design, hazard analysis, study findings and safety engineering activities.
- B.2.9. The applicant should ensure that the Hazard Log is issued to the MCA at appropriate intervals as defined in the Certification Plan.

B.3. Actions Register

- B.3.1. The Actions Register is a continually updated record of the actions associated with the application for certification.
- B.3.2. The applicant should maintain an Actions Register as appropriate throughout the application process.
- B.3.3. This Actions Register should, as a minimum, record:

- Actions agreed by the applicant and MCA.
- Actions derived by the certification activities (e.g., HAZID recommendations)
- The status of each action.
- The individual/organisation expected to carry out each action and due date.
- A brief description of action progress and outcomes.
- B.3.4. The applicant should provide an updated version of the Actions Register at the conclusion of each stage or when requested by the MCA.

B.4. Regulatory Gap Analysis

- B.4.1. This is a screening of the design against potentially applicable regulations, codes, and standards to identify:
 - Requirements (prescriptive or goal-based) that are directly applicable (including reference and scope).
 - Requirements that are challenged (e.g., deviation from a prescriptive requirement).
 - Regulatory gaps where Innovative Technology contributions to the safety, environmental or security risks are not addressed by existing requirements.
 - Potential requirements for type approval of components or subsystems.
- B.4.2. The applicant should provide the MCA with a report which contains the findings of the gap analysis along with the underpinning rationale.
- B.4.3. The analysis should be of sufficient detail to support the development of the Approval Basis and to justify the approach to manage the identified deviations/gaps, either through:
 - The application of regulations, codes, standards.
 - The application of alternative references such as codes, standards, or good practice.
 - Through derivation of requirements based on analysis, risk assessments, studies, etc.

B.5. Approval Basis

- B.5.1. The applicant should develop and provide the MCA with a preliminary issue and subsequent versions of the Approval Basis.
- B.5.2. Given the evolutionary nature of the design and analysis process, the Approval Basis will be updated as the project progresses, as the understanding of the risks and required control measures evolves.

- B.5.3. A preliminary Approval Basis will need to be defined and agreed with the MCA on a case-by-case basis. This document will be later updated following the findings of the activities of the Certification Plan.
- B.5.4. The final Approval Basis is an agreed set of requirements including justifications that must be satisfied for the vessel/system to be issued an approval or certification. The requirements may be:
 - Taken from applicable regulations, codes, and/or standards (most likely to manage the risks associated with the conventional aspects of the design).
 - Parts taken from alternative references such as codes, standards, or good practice (most likely to manage the risks associated with innovative aspects of the design where existing maritime regulations, codes, standards or good practice are considered insufficient).
 - Control measures derived from analysis/ risk assessment that are necessary to reduce safety, environmental or security risks to acceptable levels (most likely to manage the risks associated with innovative aspects of the design where existing maritime regulations, codes, standards, or good practice are considered insufficient).

B.5.5. The document should summarise:

- List of applicable regulations, codes and/or standards and how these are affected by design deviations or regulatory gaps.
- Aspects addressed by direct compliance with regulations, codes, standards.
- Aspects to be addressed/addressed by the Certification Plan activities and related evaluation/acceptance criteria (e.g., analysis, risk assessment, tests, etc.).
- Operational requirements such as training, maintenance, and survey.
- Conditions of approval, if any.

Approach and Inherently Safer Design

- B.5.6. The Approval Basis should include the approach taken to justify the certification of Innovative Technology.
- B.5.7. When the equivalency approach is used, the Approval Basis should include the evaluation criteria to demonstrate an equivalent level of safety based on the goal of the regulation and available functional requirements or referring to the benchmark provided by a similar design but without Innovative Technology (traditional design).
- B.5.8. It is recognised that in some cases it may be impracticable to use the above approach due to lack of functional requirements or absence of a representative traditional design for comparison. An alternative approach is the assessment of the risk and application of recognised risk criteria.
- B.5.9. The applicant should seek MCA agreement on the criteria used in risk assessments to assist transparent and consistent judgements on risk.

- B.5.10. The applicant should apply the principles for an inherently safer design to the Innovative Technology and its integration into the vessel/system.
- B.5.11. The applicant should identify and record in the Approval Basis mitigation strategies to minimise safety, security, and environmental risks.

Control Measures Derived from Analyses

- B.5.12. For specific requirements that are control measures derived from analyses (e.g., hazards analysis, risk assessment, studies) the Approval Basis should:
 - Clearly identify, record, and track the requirements throughout the development lifecycle.
 - Determine any requirements necessary to ensure design integrity. Note this
 includes integrity requirements for electrical/electronic/programmable
 electronic (software and complex electronic hardware).
 - Record traceability⁷ between each requirement, the source of the requirement including analysis and mitigation for hazards or potential accidents.
 - Define the required verification activities necessary to demonstrate that the requirements are met (typically in the form of a compliance checklist or matrix).
 The proposed means of compliance, may include:
 - o Compliance statement, design review, calculation, analysis, safety assessment, simulation, inspection, or equipment qualification.
 - Factory or sea tests.
 - The compliance documentation or evidence to be presented.
 - o Requirements for instructions for sustaining safety/seaworthiness.
- B.5.13. Given the evolutionary nature of the development of innovative aspects, it is likely that the Approval Basis will be updated as the project progresses, that is, as the understanding of the risks and required control measures evolves. The preliminary Approval Basis may contain requirements to undertake studies or analyses to derive safety requirements which will be captured in subsequent issues of the Approval Basis.

MCA Agreement and Period of Validity

- B.5.14. The applicant should gain MCA agreement on all issues of the Approval Basis.
- B.5.15. Dependant on the UK maritime regulation, MCA acceptable codes of practice and/or standards that the vessel is certified against, the period of validity of the approval basis may be time limited. If certification is not achieved within that timescale, a further review of the Approval Basis may be required.

⁷ Traceability is fundamental, without it, it is not possible to understand how the results of low-level activities contribute to demonstrating satisfaction of requirements. If traceability is lost, then this can seriously undermine the validity of the Hazard Log. Traceability is bi-directional (top-down and bottom-up).

B.6. Certification Plan

- B.6.1 The applicant should define and implement a coherent approach to management of all safety, security, and environmental activities, innovative and traditional necessary to achieve certification and document their approach in a Certification Plan.
- B.6.2 The Certification Plan should cover activities to a level of detail that is reasonably practicable to determine what activities are to be performed, by whom, (e.g., designer, shipyard, shipowner, design consultant, RO, CA), at what time, and with what methods and tools.

General

- B.6.3 The Certification Plan should record or refer to:
 - Key findings from the initial Hazard Log/Summary of Hazards and the Regulatory Gap Analysis.
 - Stakeholders who are responsible, accountable, to be consulted or informed of the activities that support the approval.
 - The proposed MCA level of involvement in certification activities.
 - Arrangements for regular liaison with the MCA throughout the application process.
 - Reports of the activities to be provided to the MCA throughout the application process.
 - If necessary, arrangements to achieve an MCA preliminary feedback of the design.
 - The extent of involvement and activities being undertaken by ROs or CAs. This
 is to include arrangements to ensure that ROs or CAs have appropriate
 approvals in place (for example to undertake activities on behalf of the MCA or
 to make recommendations to the MCA).
 - Arrangements for identifying the requirements from safety, security and environmental-management regulations, codes, standards.
 - Arrangements for ensuring design integrity. This is to include arrangements for ensuring the integrity of electrical/electronic/programmable electronic (software and complex electronic hardware) systems.
 - Arrangements for undertaking hazard identification, analysis and risk assessments or other supporting studies.
 - Arrangements for developing, maintaining, and issuing a Hazard Log, including updates to record the results of hazard identification, analysis and risk assessments or other supporting studies.
 - The process for identifying, recording, and tracking safety, security, and environmental management requirements.
 - Arrangements for information management including:
 - Arrangements to ensure that the information set is kept up to date as the design and analysis evolves.

- Arrangements to maintain consistency between the information set and the configuration of the vessel/system.
- All information provided to the MCA are version controlled.
- Arrangements for assuring the work of all suppliers/sub-contractors.
- Arrangements to ensure that suitably qualified and experience resources are used.
- Arrangements for demonstrating compliance with the Approval Basis (see survey and verification & validation).
- Arrangements for developing, maintaining, and issuing the Summary of Justifications.

Survey, Verification & Validation

- B.6.4 The applicant should include in the Certification Plan, information on the survey, verification & validation activities and proposed means of compliance e.g.:
 - Reference to design data.
 - Design review.
 - Calculations/analysis.
 - Risk assessments.
 - Tests (land based, alongside or at sea).
 - Simulation.
 - Design inspection/audit.
 - Physical survey and inspection (forming a list of items for survey and inspection).
 - The proposed CA/RO and MCA level of involvement in compliance demonstration activities.
 - The proposed breakdown of compliance demonstration activities.
 - Arrangements for the examination and testing of equipment/systems during construction, installation, and commissioning.
 - When the compliance documents or evidence will be available.
 - If required, the need for periodic progress reviews between the MCA, the applicant, and other relevant organisations.
- B.6.5 The plan of these activities can be developed in stages as the required information becomes available.
- B.6.6 The Certification Plan should articulate the arrangements for ensuring that the survey, verification and validation activities are applicable to the configuration, version and build state definition of the Innovative Technology to be certified.
- B.6.7 These activities should be included in the Certification Plan and submitted before compliance demonstration commences and updated as necessary during this process.

B.6.8 The MCA will need to review the activities in the Certification Plan to confirm that the design conforms to the Approval Basis, and to determine any areas where compliance evidence is incomplete. The extent to which the MCA will review evidence will be informed by the extent of the 3rd parties (CA/RO) assurance that the applicant has agreed with the MCA and put in place.

B.7. Terms of Reference of the Activity

- B.7.1 The applicant should develop Terms of Reference (ToR) for each key activity or groups of activities identified in the Certification Plan.
- B.7.2 The ToR should include:
 - The objective and scope of proposed activities.
 - Proposed methodology (along with justification of suitability).
 - Acceptability criteria (along with justification of suitability).
 - Arrangement to ensure adequate, qualified and experienced resources are used.
 - Arrangements for documenting the activities undertaken and their findings.
 - Arrangements for updating the Hazard Log, Approval Basis or Compliance Documentation.
- B.7.3 The applicant should provide to the MCA each ToR of the certification activities in advance of the start of the activity.

B.8. Report of the Activity / Compliance Documentation

- B.8.1 The report of the activity undertaken as part of the Certification Plan should include a summary of the activity and related findings/recommendations in connection with the Approval Basis.
- B.8.2 When a report of the activity is used as evidence to demonstrate compliance with a requirement, it is referred to as a Compliance Document. Compliance Documentation is the collection of evidence produced by the applicant such as reports of the activities undertaken, drawings, specifications, calculations, analysis etc. The aim is to provide a comprehensive record of how compliance with a requirement/s within the Approval Basis is demonstrated.
- B.8.3 Each compliance document or evidence item should contain:
 - An adequate link to corresponding Certification Plan items.
 - The reference of the Approval Basis requirements addressed by the document.
 - Data demonstrating compliance.
 - A statement declaring that the document provides the proof of compliance for which it has been created.

B.9. Summary of Justification

- B.9.1 This document summarises the justifications of why the vessel using Innovative Technology should be certified by the MCA.
- B.9.2 The summary should:
 - Present a structured rationale supported by evidence justifying that Innovative Technology is compliant with the agreed Approval Basis.
 - Summarise the key elements of the applicant's submission and references to evidence so that, in principle, it would be possible to access the totality of the supporting evidence, starting from the summary report.
 - Where there are shortfalls in the evidence, provide the rationale for certification and the ways of mitigating the residual risk.
 - Contain information on assumptions and limitations regarding the safe use of the Innovative Technology.
- B.9.3 The applicant should consider providing incremental issues of the Summary of Justification to give the MCA visibility of progress.

B.10. In Service Documentation

- B.10.1 The applicant should ensure that all master copies of In-Service Documentation required by the Approval Basis are produced, maintained, and updated by the appropriate vessel/system designer. As a minimum the In-Service Documentation should include:
 - Operation manuals.
 - Training and familiarisation plan and records.
 - Maintenance manuals.
 - Maintenance system, plan and records.
 - Through life process for change management.
- B.10.2 All in service documentation should be available for all operators of the vessel and the contents of the manuals should be validated.

Annex C - Definitions

Action Register

The continually updated record of the actions associated with the application for certification.

Activity

An activity of the Certification Plan to enable the certification of the vessel through the development of the Approval Basis and demonstration of compliance. These certification activities normally involve analysis (e.g., risk assessment, studies) and verification & validation (e.g., simulation, tests, survey).

Activity Report / Report of the Activity

A report of the activity undertaken as part of the Certification Plan including a summary of the activity and related findings/recommendations in connection with the Approval Basis. When an activity report is used as evidence to demonstrate compliance with a requirement, it is referred to as a Compliance Document.

Approval Basis

The basis of approval clarifying the requirements to which the applicant must show compliance to be granted certification.

Certification Plan

A document which defines a coherent approach to management of all safety, security, and environmental activities necessary to address the Innovative Technology and achieve certification of the vessel through the development of the Approval Basis and demonstration of compliance.

Change Management

A systematic method to control modifications to the Innovative Technology of the vessel (e.g., equipment, components).

Concept of Operations (CONOPS)/Use Case Description Document

A document which describes the overall high-level concept of how the system will be used to meet stakeholder expectations, usually in a time-sequenced manner. It describes the system from an operational perspective and helps facilitate an understanding of the system goals. It stimulates the development of the requirements, and architecture related to the user elements of the system.

Design Documents

The collection of design records (description, drawings, list of applied regulations and standards etc.) to support the development of the Approval Basis and to demonstrate compliance.

Design Integrity

The extent to which the design is free from flaws which could give rise to or contribute to hazards or failure modes that contribute to a hazard.

Emission Reduction Technologies

Technologies to enable the reduction of pollution or greenhouse gas from shipping, such as alternative power configurations, energy storage and alternative fuels technologies.

Hazard Log and Hazard Log Report

The continually updated record of the hazards and accidents associated with a system. It includes information documenting risk management for each hazard and accident. The Hazard Log Report is a periodic report of status of the Hazard Log.

Innovative Technology

Innovative Technologies are those emission reduction, autonomy and other forms of 'smart' maritime technology whose contributions to safety, environmental and/or security risks are not sufficiently managed to acceptable levels solely by the application of MCA accepted maritime regulations, codes, standards or good practices.

Operating Environment

The total set of all external natural and induced conditions to which a system is exposed at any given moment, and this can include but is not limited to the design criteria, area categories and other relevant parameters.

Preliminary Feedback

Preliminary feedback is issued by the MCA at the conclusion of the preliminary stage to confirm the proposed preliminary design appears to comply in principle with the intent of the rules, regulations and/or appropriate criteria set in the preliminary Approval Basis even though the design may not be fully evolved. This feedback is subject to a list of conditions that are addressed in the final design stage. This feedback may be used as input for the final approval for MCA certification but would not guarantee itself the MCA approval. This is because there may be technical or regulatory challenges that prevent approval when the details of the design are subjected to full process of MCA certification.

Regulatory Gap Analysis

This is a systematic analysis of the design against applicable regulations, codes, and standards to support the development of the Approval Basis trough the identification of applicable requirements, deviations or gaps in the regulatory framework.

Smart Shipping or Smart Maritime Technology

Technologies which control or influence the operation or security of vessels, through increased use of data, automation and integration with systems both on board and remotely, including all degrees of autonomy.

System

A combination, with defined boundaries, of elements that are used together in a defined operating environment to perform a given task or achieve a specific purpose. The elements may include personnel, procedures, materials, tools, products, facilities, services and/or data as appropriate.

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