SafePASS

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D7.2 SafePASS regulatory, ethical, and GDPR compliance framework

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[1] **R**=Document, report; **DEM**=Demonstrator, pilot, prototype; **DEC**=website, patent fillings, videos, etc.; **OTHER**=other

[2] **PU**=Public, **CO**=Confidential, only for members of the consortium (including the Commission Services), **CI**=Classified, as referred to in Commission Decision 2001/844/EC

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Acronyms and Abbreviations

AD&D	Alternative Design and Arrangements
VR	Virtual Reality
AR	Augmented Reality
IMO	International Maritime Organisation
SOLAS	International Convention for the Safety of Life at Sea
ISM Code	International Management Code for the Safe Operation of Ships and for Pollution Prevention
FSS Code	International Code for Fire Safety Systems
STCW	International Convention on Standards of Training, Certification and Watchkeeping for Seafarers
ILO	International Labour Organisation
LSA	Life Saving Appliances
SRtP	Safe Return to Port
LLL	Low Location Lighting
SSE	Sub-Committee on Ship Systems and Equipment
IACS	International Association of Classification Societies
MVZ	Main Vertical Zone
MES	Marine Evacuation System
GDPR	General Data Protection Regulation
RO	Recognised Organisation
CSSF	Cruise Ship Safety Forum
IT	Information technology
OT	Operational Technology
MSC	Maritime Safety Committee
PST	Polar Service Temperature
MARPOL	International Convention for the Prevention of Pollution from Ships
GBS	Goal Based Standard

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Executive Summary

This deliverable reports on the first work conducted in the context of Task 7.2 (Regulatory, ethical and GDPR compliance framework). The scope of T7.2 is to produce a framework to support the SafePASS solutions in meeting their overall regulatory, ethical and GDPR obligations.

The IMO regulatory framework for LSA and ship evacuation with its well-known gaps and restrictions has been carefully considered from the preparation stage of SafePASS project. One of the project's main objectives is to support the ongoing work in IMO on an enhanced regulatory framework on ship evacuation. However, considering the plethora of new systems proposed in SafePASS, and the strict rules that govern ship design, operation, and maintenance, many issues concerning the integration of the new systems onboard may arise.

In this context, D7.2 starts with a mapping of the relevant, to the project's scope, specific SOLAS areas and identifies possible challenges and implications. Challenges identified due to the prescriptive nature of FSS Code and LSA Code, which do not match with the SafePASS novel evacuation approach. This is further evidenced in Section 3 where the current compliance options in the context of the AD&A and the ship evacuation analysis frameworks are discussed.

The Safe Return to Port is another SOLAS area which will be challenged. This is because SRtP is relevant to the design, while the new systems proposed in SafePASS are also considering operational scenarios. This different approach may further evidence the need for harmonization in the regulations, as well as an update of the current SRtP Explanatory Notes.

Possible integration difficulties for SafePASS components (including components of the smart environment) may arise from the safety management system as enforced by the ISM Code. Integration difficulties refer mainly to the reliability assessment options (i.e. redundancy, functional tests, maintenance routines and possible replacement) for the systems onboard, as required in the maintenance and emergency preparedness elements of the ISM Code. This Code has recently added requirements for cybersecurity management including measures such as network segregation and separation between OT and IT networks, that must be also considered.

SafePASS could challenge STCW as well. The effective use of the SafePASS solutions may require additional competencies from crew members that should be compared with the current competencies listed in the STCW Code.

Integrating ethics in SafePASS project life cycle, as well as disclosing, embedding and organizing ethics in the design process have been formulated, and personal data protection regulation, as well as personal data management and privacy by design principles have been defined.

The second deliverable on the same topic (in month 36), will examine the SafePASS integrated system in order to identify explicit areas challenged in the maritime regulatory framework and support the recommendations to address these challenges that are going to be produced in WP9.

1. Introduction

1.1 Purpose and scope

The purpose of Task 7.2 is to produce a framework to support the SafePASS solutions in meeting their overall regulatory, ethical and GDPR obligations. In this context, two public deliverables will be produced. The current deliverable (D7.2) is the first of the two, which reports on the maritime regulatory, ethical and GDPR compliance framework that the SafePASS overall solution will need to comply with and presents a mapping of possible challenged areas.

1.2 Intended readership

This is a public report intended for any reader interested. Its purpose is to map the maritime regulatory, ethical and GDPR framework that the SafePASS project needs to consider. With respect to the maritime regulatory part, the work forms the basis for the evaluation of the possible implications brought forward by SafePASS solutions and proposes possible pathways for overcoming these.

1.3 Document Structure

The document structure further to this section is as follows:

Section 2 makes the mapping of the specific maritime regulatory framework of international shipping that the SafePASS project needs to consider.

Section 3 presents and comments on the compliance options available for SafePASS systems and methods under the current framework.

Section 4 presents the initial list of the possible regulatory implications for SafePASS Systems.

Section 5 presents a first contribution to the improvement of the regulatory framework for ship evacuation.

Section 6 includes the initial report on the Ethical framework of SafePASS.

Section 7 includes the first work on the GDPR framework.

2. Mapping of the relevant Maritime Regulatory Framework

2.1 SOLAS

The International Convention for the Safety of Life at Sea, known as SOLAS 1974 (SOLAS), is the most important international treaty for the safety of merchant ships. SOLAS specifies minimum standards for the construction and operation of ships as well as onboard equipment, compatible with their safety (IMO, 2021).

Currently, SOLAS splits its requirements into fourteen chapters, of which relevant to the SafePASS work are the following:

a) Chapter II-1 (Construction – Subdivision and stability, machinery, and electrical installations)
b) Chapter II-2 (Fire protection, fire detection and fire extinction)
c) Chapter III (Life-saving appliances and arrangements)
d) Chapter IX (Management for the Safe Operation of Ships)
e) Chapter XIV (Safety measures for ships operating in polar waters)

SOLAS chapters are divided into regulations that introduce more specific requirements, and further detailed and amended through relevant Codes, Circulars and Resolutions. Table 1 includes the relevant (to SafePASS) Regulations per Chapter and identifies the relevant IMO instruments (Codes, Circulars and Resolutions) which detail more the regulation's requirements.

It is noted that at this stage of work in SafePASS (month 18), where only the conceptual design of some important components is available, it is not possible to specifically indicate all SOLAS areas that may be concerned. A revision of this table will be provided in D7.3 (in month 36) when the new design solutions, the new (and novel) LSAs and the details of the integrated SafepPASS system will be made available.

Table 1: SOLAS areas relevant to SafePASS

SOLAS	Regulation	Description	Codes Guidelines Resolutions
Chapter II-1	Reg. 3.5	Definitions	Res. MSC.216 (82)
Chapter II-1	Reg. 55	Alternative Design and Arrangements	Res. MSC.216 (82)
Chapter II-2	Reg. 13	Means of Escape	FSS Code (Ch. 13) MSC/Circ.1167, MSC 404(96) Res. A.1116(30)
Chapter II-2	Reg. 21	Casualty Threshold, Safe Return to Port and Safe Areas	MSC.1/Circ1369
Chapter II-2	Reg. 22	Design Criteria for Systems to Remain Operational after a Fire Casualty	MSC.1/Circ1369
Chapter II-2	Reg. 23	Safety Centre on Passenger ships	MSC.1/Circ1368
Chapter III	Reg. 4	Evaluation, Testing and Approval of Life-Saving Appliances and Arrangements	MSC.81(70) MSC.1/Circ. 1628-33

			LSA Code
Chapter III	Reg. 7	Personal Life-Saving Appliances	LSA Code MSC.201(81)
Chapter III	Reg. 8	Muster List and Emergency Instructions	
Chapter III	Reg. 12	Launching Stations	
Chapter III	Reg. 19	Emergency Training and Drills	MSC.1/Circ.1206 Rev.1 MSC.1/Circ.1326 MSC.1/Circ.1578
Chapter III	Reg. 20	Operational Readiness, Maintenance, and Inspections	MSC.402(96)
Chapter III	Reg. 22	Personal Life-Saving Appliances (Passenger Ships)	LSA Code
Chapter III	Reg. 25	Muster Stations (Passenger Ships)	
Chapter III	Reg. 29	Decision Support System for Masters of Passenger Ships	
Chapter III	Reg. 34	Life-Saving Appliances	LSA Code
Chapter III	Reg. 36	Instructions for on-board maintenance	MSC.402(96)
Chapter III	Reg. 37	Muster List and Emergency Instructions	LSA Code MSC.421(98)
Chapter III	Reg. 38	Alternative Design and Arrangements	MSC.1/Circ. 1212 MSC.1/Circ.1455
Chapter IX		Management for the Safe Operation of Ships	ISM Code
Chapter XIV	Reg. 4	Alternative Design and Arrangements	Polar Code (Ch. 8) MSC.1/Circ. 1212

In the following paragraphs, SOLAS areas of interest are elaborated and possible challenges for the SafePASS proposed solutions are identified.

2.1.1 FSS Code

The purpose of the International Code for Fire Safety Systems (FSS Code) is to provide international standards of specific engineering specifications for fire safety systems required by chapter II-2 of SOLAS, further detailing the SOLAS mandatory provisions.

The Ch. 11 of the FSS Code includes specifications for low-location lighting (LLL) systems as required in Ch. II-2 of SOLAS. The LLL systems are part of the directional guidance systems assisting passengers in the evacuation process and their compatibility with the dynamic directional signage proposed in SafePASS is subject to verification.

Ch.13 of the FSS Code details the specifications for means of escape as required by Ch. II-2 of the SOLAS Convention that covers the following:

1. Minimum stairway width,
2. A calculation method of stairway width according to passenger's load,
3. Initial Distribution of persons for relevant escape calculation,
4. Details of stairways (inclination, alignment etc)
5. Size of Doorways and corridors,
6. Evacuation routes to the embarkation deck (assembly station, and routes to survival craft and embarkation position,
7. Means of escape plans

a. number of crew and passengers in all occupied spaces;
b. number of crew and passengers expected to escape by a stairway and through doorways, corridors and landings;
c. assembly stations and survival craft embarkation positions;
d. primary and secondary means of escape;
e. width of stairways, doors, corridors, and landing areas.

Means of escape plans shall be accompanied by detailed calculation for determining the width of escape stairways, doors, corridors, and landing areas. An example of assembly stations and embarkation plan of a passenger ship is shown in Figure 1.

Most of these requirements are very prescriptive and may be challenged by the SafePASS systems, to facilitate crowd management in a real emergency scenario.

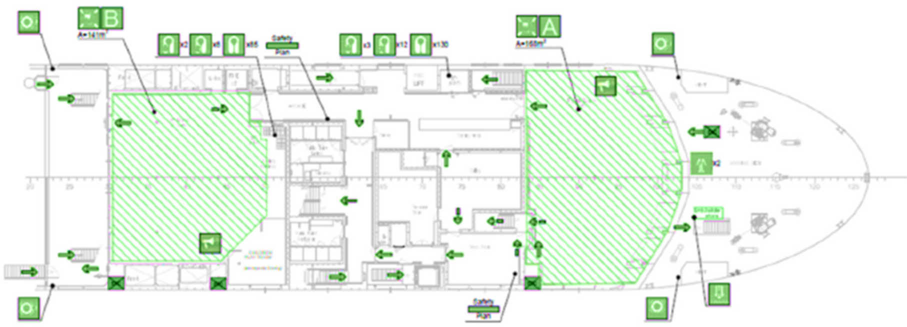

Figure 1: FSS Code, extraction from assembly station and embarkation plan (RINA, 2020)

2.1.2 LSA Code

The International Life-Saving Appliance (LSA) Code contains specific technical requirements for LSAs and is mandatory under Reg. 34 of SOLAS, which states that all life-saving appliances and arrangements shall comply with the applicable requirements of the LSA Code (IMO, 2021).

All types of LSAs are covered in the LSA Code: personal life-saving appliances, visual signals, survival craft, rescue boat, launching and embarkation appliances and other life-saving appliances.

The approval process of a new LSA may follow a prescriptive approach in case SOLAS is not challenged, or an alternative approach in case there are deviations from standard design requirements. In both cases though, this approval is made separately from the vessel which forms a limitation of the regulation since it does not take into consideration the different ship design arrangements and locations onboard to which the LSA has to adapt and perform. This along with other limitations of the current SOLAS framework are reported in other SafePASS work (D3.2 - Report on Emerging Needs and Specification for LSA).

IMO in the "Revised recommendation on testing of life-saving appliances" MSC.81(70), introduced detailed prototype tests for life-saving appliances before production has started (in Part 1) and production and installation tests that should be performed with the presence of the Flag Administration (Part 2).

SOLAS requires the LSA to pass through regular inspection and maintenance intervals by qualified personnel. Updated requirements (included in MSC. 402(96)) are in force since 2020, concerning the maintenance, thorough examination, operational testing, overhaul and repair of lifeboats and rescue boats, launching appliances and release gear (IMO, 2016_2).

In IMO, work is ongoing to revise SOLAS Ch. III and the LSA Code, to remove gaps, inconsistencies, and ambiguities, and to restructure the relevant requirements following the concept of goal-based standards. This work is ongoing in a correspondence group and initial developments will be announced in the 8th meeting of the Sub-Committee on Ship Systems and Equipment (SSE 8) in March 2021.

2.1.3 Safe Return to Port (SRtP)

SOLAS (Ch II-2 Reg 21) provides ship design criteria for a "safe return to port". The regulation adopted in 2006 and applies to passenger ships having their keel laid on or after 1 July 2010, with a length of 120m or more, or having three or more Main Vertical Zones (MVZ). According to this regulation, a passenger ship shall be able to proceed to a safe port under her own power after a fire or a flooding casualty which does not exceed a "casualty threshold" specified by SOLAS.

While the ship is in the SRtP condition, all persons onboard shall be accommodated in a "safe area" where basic services for passengers' health and safety should be available.

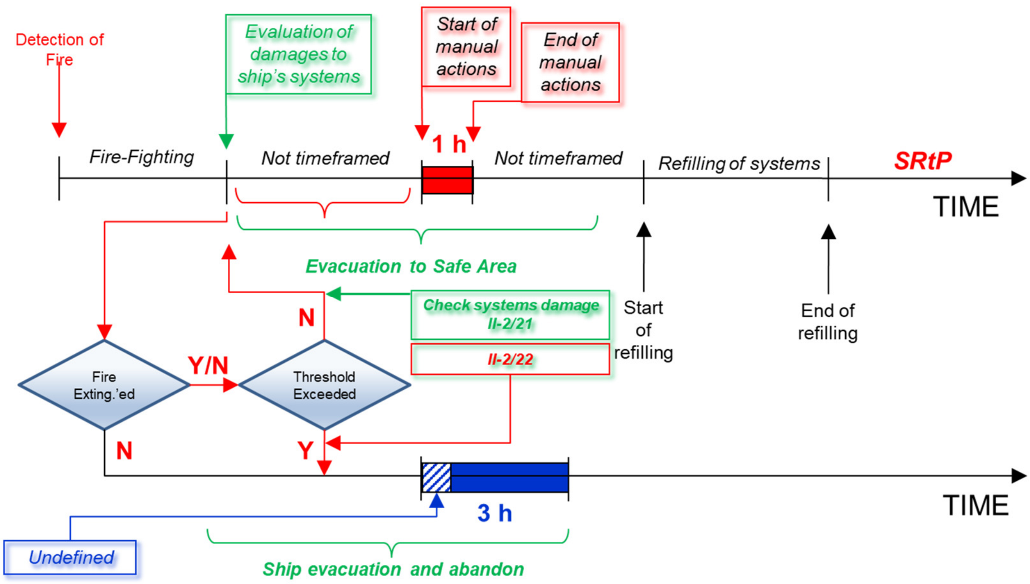

Figure 2: Integration of emergency response in fire casualty and Safe Return to Port (source: RINA)

In case the "casualty threshold" is exceeded, SOLAS requires some essential systems to be still operational for three hours in order to support the "orderly evacuation and abandonment" of the vessel, considering one entire main fire zone lost as a design scenario.

The procedure requires that an integration should be established between the ship's emergency management procedures and the SRtP instructions. An illustrative example for the fire casualty is given in Figure 2.

Explanatory Notes on the assessment of passenger ship systems' capabilities after a fire or flooding casualty have been developed with the coordination of five leading Classification societies (DNV, GL, RINA, LR and BV) and supported by European shipyards and some operators. These notes were approved by IMO and were published as interim Explanatory Notes in June 2010 (MSC.1/Circ.1369).

The verification of the ship design according to the MSC.1/Circ.1369 is a system-based approach. The design criteria for each individual essential system or group of systems to meet the requirements may include separation, duplication, redundancy, protection, or a combination of the above.

According to these Explanatory Notes, the essential ship systems capabilities in fire and flooding casualties should be addressing:

1. Availability after a flooding casualty, according to SOLAS regulation II-1/8-1;
2. Availability to support a ship's safe return to port under its own propulsion after a fire casualty, according to SOLAS regulation II-2/21.4 (including functional requirements for safe areas according to SOLAS regulation II-2/21.5); and
3. Availably to support a ship's evacuation and abandonment after a fire casualty, according to SOLAS Ch. II-2/22.

The systems deemed essential for the ship in the SRtP condition are given in SOLAS (Ch. II-2/21.4) and include:

- propulsion (including auxiliaries and control systems)
- electrical generation (including auxiliaries vital to ship's survivability and safety)
- steering and steering-control systems
- systems for fill, transfer, and service of fuel oil
- internal and external communications systems
- fire main system
- fixed fire-extinguishing systems (gaseous and water)
- fire/smoke detection systems
- bilge and ballast systems
- navigation systems
- water ingress detection and flood level monitoring
- basic services to safe areas
- any other systems vital to the damage control

SRtP provisions and deduced performance requirements can affect the design and integration of the SafePASS components onboard. Most remarkably SRtP is relevant to design, while the innovative systems proposed in SafePASS are also considering operational scenarios, and this different approach may further evidence the need for harmonization in the regulations, as well as an update of the Explanatory Notes.

Emergency Instructions

The muster list is prepared and approved by the Flag Administration or the Recognised Organisation (Class Society) before the ship proceeds to sea. Any change in the crew which demands a subsequent change in the muster list, should be handled by the master who either revises the list or prepares a new one. Being the document with specific job assignments for the crew in case of emergencies, the muster list must be posted at visible locations onboard.

The muster list specifies (SOLAS Ch.III Reg. 37):

- details of the general emergency alarm and public address system
- action to be taken by crew and passengers when this alarm is sounded
- how the order to abandon ship will be given
- duties assigned to crew (e.g. closing of watertight doors, calves, scuppers, preparation, and deployment of LSAs)
- officers assigned to ensure that lifesaving and fire appliances are maintained in good condition
- substitutes for key persons who may become disabled.
- duties assigned to members of the crew in relation to passengers in case of emergency.

New amendments in SOLAS Reg. 37, that entered into force in 2020, require passenger ships to specify duties to crew for fire-fighting equipment and for the damage control in flooding emergencies. (MSC.421(98)).

The role of the crew and the tools to facilitate their duties are identified as key factors in the SafePASS analysis.

2.1.4 ISM Code

The “International Management Code for the Safe Operation of Ships and for Pollution Prevention” (ISM Code), is mandatory for all ships to which SOLAS applies and to any other ship if required by the Flag Administration. SOLAS Chapter IX “Management for the Safe Operation of Ships” is dedicated to the ISM Code.

The purpose of ISM Code is to provide an international standard for the safe management and operation of ships and for pollution prevention. The main requirement for the ship operator is the development and implementation of a Safety Management System (SMS) which is defined as a structured and documented system enabling the company’s personnel to effectively apply the company safety and environmental protection policy.

Compliance with the ISM Code involves a periodic verification process through external ISM audits (by the Flag Administration or the authorised Classification Society as Recognised Organization), which result in the certification of the company and its ships.

The importance of the ISM Code is illustrated by the fact that the loss of the validity of the relevant ISM certificates makes it impossible for the ship or the company to continue operations.

According to the ISM Code, the main safety management objectives of the company should include:

1. To assess all identified risks to its ships, personnel and the environment and establish appropriate safeguards (ISM Code par. 1.2.1.2)
2. To continuously improve safety management skills of personnel ashore and aboard ships, including preparing for emergencies (ISM Code par. 1.2.2.3)

The possible implications for the SafePASS components that arise from the above safety management objectives concern the ship operation and in specific the emergency preparedness and the maintenance of the ship systems.

Emergency preparedness is covered in Element 8 of the ISM Code. The company should identify potential emergency shipboard situations and establish procedures to respond to them. Abandoning ship is one of the scenarios that should be addressed by an emergency response plan. This emergency response plan for abandoning ship is mandated by SOLAS (Chapter III) and should be available onboard for the ISM verification as also recommended by IACS in the Rec. 41/Rev.5, (IACS, 2019). The implications for SafePASS that refer to the accurate representation of the crew duties in the Muster List have been already discussed.

The emergency preparedness of the crew needs to be ensured by regular onboard training (drills) such as the usual abandon ship drill using lifeboats. According to the IMO guidelines (MSC.1/Circ.1578), the procedures for holding safety drills should be included in the SMS and the potential special risks of these should be evident from workplace assessments adjusted to the relevant life-saving appliance.

Training was also noted as a need which could be improved, by using means of new training methods based on disruptive technologies such as Virtual Reality, and Augmented Reality, which can increase crew competence in emergencies (SafePASS D3.1). A new element included in SafePASS smart technologies is the use of AR technology as an alternative training option for emergency preparedness. This must be included in the training scheduling and the relevant training records onboard as requested by the ISM Code. No further implications are expected for SafePASS in the SMS verification.

Maintenance of ship systems should be part of the SMS as requested in Element 10 of the ISM Code. According to the IACS recommendations (IACS Rec74 “A Guide to Managing Maintenance with the Requirements of the ISM Code”), the maintenance procedures should take into account international conventions, flag and Port State regulations, classification rules, requirements from manufacturers, feedback information from failures, damages, defects and malfunctions. SafePASS proposal for using Augmented Reality tools for the maintenance of LSAs will have to be included in the planned maintenance system and described in the company’s SMS. No further implications are excepted.

According to par. 10.3 of the ISM Code of the ‘*The Company should identify equipment and technical systems the sudden operational failure of which may result in hazardous situations. …. measures should include the regular testing of stand-by arrangements and equipment or technical systems that are not in continuous use*’

IACS (IACS Rec 41) states that the intention of the above ISM paragraph is to increase the reliability of the equipment and technical systems by controlling the risk of failure. Identification of systems falling in this category should be made through risk assessment and measures should be taken to increase the reliability of such equipment or system, to ensure that it is in fully operational condition whenever it is needed.

These systems are referred to as "critical equipment" and include all life-saving equipment and systems for internal and external communication. The IACS interpretation of par. 10.3 of the ISM Code, included in Rec. 74, Rev.2 2018, proposes the following possible options to increase the reliability of critical equipment that are stand-by or not in frequent use (IACS, 2018):

a. Redundancy
b. Functional tests
c. Maintenance routines
d. Replacement

2.1.5 Cyber Security in ISM Code

IMO adopted in 2017, the Resolution MSC.428(98) on the Maritime Cyber Risk Management in Safety Management Systems. The resolution requires cyber risks onboard ships to be appropriately addressed in existing safety management systems (as defined in the ISM Code) no later than the first annual verification of the company's Document of Compliance after 1st January 2021 (IMO, 2017).

For complying with the new ISM requirement on cybersecurity, the shipping company should carry out a risk assessment to identify cyber-related risks, select proper safeguards and assign the corresponded responsibilities. (MSC-FAL.1/Circ.3, 2017). In the risk assessment, the differences between Operational Technology (OT) and Information Technology (IT) Systems onboard should be considered (RINA, 2020). Important (OT) systems onboard (some of them are passenger ship specific) that are expected to be included in the Cyber Risk assessment are:

- Alarm Systems
- Control Systems
- Safety Systems
- Navigation Systems
- ESD (Emergency Shut Down) system
- Emergency source of electrical power
- UPS (Uninterruptable Power Supplies)
- Internal and external communication systems
- Fire extinguishing systems
- Safety centre control system (passenger ships)
- Anti-heeling pumps
- Valves control and monitoring
- Power-operated watertight and semi-watertight doors (for passenger ships)
- Fire doors (passenger ships)
- Flooding detection system (passenger ships)
- Lighting

- Ventilation and air conditioning
- Lifts (passenger ships)

Information Technology (IT) systems onboard:

- Specific Hotel services (for passenger ships)
- HVAC
- Ship Owner Network
- Performance monitoring systems
- Networks and devices used data updates on onboard systems (e.g. ECDIS).

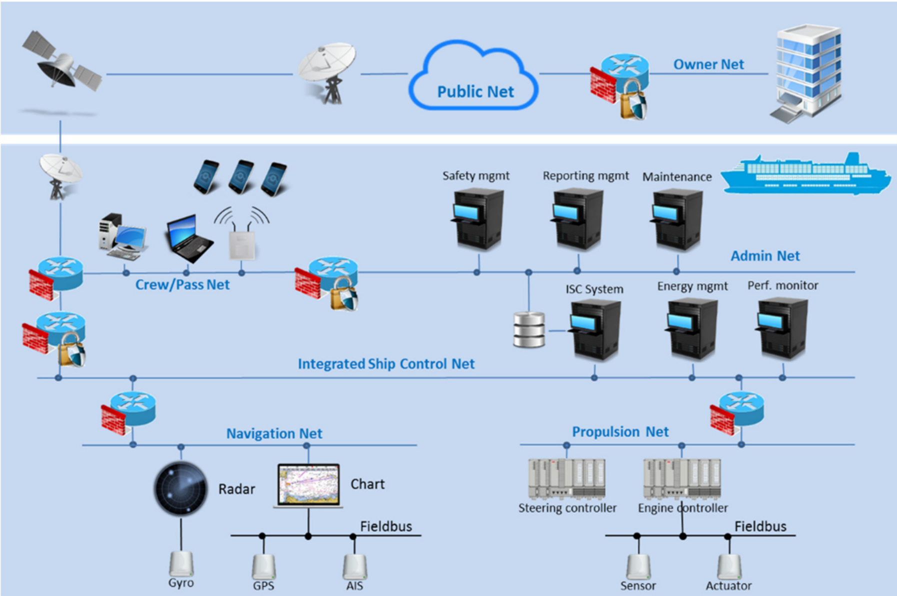

Figure 3: Typical network of a passenger ship (source: RINA)

A typical network of a passenger ship is shown in Figure 3. Among other protection measures, the requirement for cyber risk management asks for new technical and procedural measures to protect the ship's networks, including, but not limited to (RINA, 2020):

a. Network segregation, in particular separation between OT and IT networks,
b. Firewalling,
c. Selection/control of IP addresses,
d. Implementation of Intrusion Prevention Systems (IPS),
e. WiFi hardening,
f. Use of controlled Virtual Private Networks (VPN)

2.1.6 Polar Code

The International Code for Ships Operating in Polar Waters (Polar Code) came into force in 2017 and has an impact on the fast-growing market of expedition cruises in the Arctic and Antarctic.

The Polar Code is applicable within clearly defined Arctic and Antarctic waters, for new ships constructed on or after 1 January 2017. Ships constructed before 1 January 2017 and operating in the areas defined in the Code must meet its relevant requirements by the first intermediate or renewal survey, whichever occurs first, after 1 January 2018.

The focal points of the Polar Code are safety, pollution prevention, manning, training, and qualification of the ship's personnel. Design, construction, and maintenance are other key areas affected. In this context, the Polar Code introduced changes to SOLAS (new chapter XIV), and MARPOL (amendments were made to Annexes I, II, IV and V). Since master and crew qualifications are also covered, the Seafarers' Training, Certification and Watchkeeping (STCW) has been amended to consider the Polar Code.

The Polar Code has four Parts:

a. Part I-A, that contains mandatory safety-related provisions (Reference to SOLAS Ch. XIV/Reg.2)
b. Part I-B (not mandatory) provides additional guidance to achieve the goals specified in Part I-A
c. Part II-A contains mandatory environment-related provisions (Reference to Annex I – II – IV – V of MARPOL)
d. Part II-B (not mandatory) provides additional guidance to achieve the goals specified in Part II-A

Regarding the LSA equipment, Chapter 8 of the Polar Code contains three functional requirements (namely: escape, evacuation, and survival), in a context which is over and beyond other related requirements of SOLAS and the LSA Code. It is noted that the Polar Code (Ch. 8, par. 8.2.3 and 8.3.3) is the only SOLAS area that covers the survival of passengers and crew after abandoning the ship.

The core of the Polar Code certification is an operational assessment to establish procedures and operational limitations for the ship. The assessment determines the content of the Polar Waters Operational Manual (PWOM), a manual that must be kept on board to support the master and crew when sailing in these areas.

The Polar Code is the first IMO instrument to introduce an actual "design temperature" concept, the so-called Polar Service Temperature (PST), which should be referenced when specifying demands for LSA equipment and systems. Notable examples include (VIKING, 2021):

- Survival systems and equipment shall be fully operational at the PST
- Materials used for ship structures, exposed machinery, electrical installations, and fire safety systems shall be suitable for operation at the PST
- Fire safety systems and appliances shall be available/effective at the PST

The survival functional requirement permits only partially or totally enclosed survival craft and requires personal thermal protection devices (e.g. thermal protective aids, and immersion suits) to be available for everyone onboard in order to support their survival on land, water, or ice for the maximum expected time of rescue, which should be, at least, five days.

These exclusive requirements should be taken into consideration in SafePASS, as they can pose significant challenges in the design, operation, and management of emergencies of passenger vessels carrying hundreds or thousands of people onboard.

2.2 STCW

The International Convention on Standards of Training, Certification and Watchkeeping for Seafarers, STCW 78 (STCW) was adopted by the International Conference on Training and Certification of Seafarers on 7 July 1978. In 1995, the requirements of the regulation transferred to the STCW Code. Important amendments have been decided in 2010, at a dedicated conference in Manilla, Philippines (known as the 2010 Manilla Amendments).

STCW is described as one of the four pillars of the global maritime regulatory system, along with two other IMO Conventions, (i.e. SOLAS and MARPOL), and one Convention from the International Labour Organisation (ILO), the Maritime Labour Convention.

The purpose of the STCW Code is to set international minimum standards for training, certification and watchkeeping for seafarers that countries are obliged to meet or exceed.

The global coverage of STCW is secured by its application to ships of non-party states, when visiting ports of a state party to the convention. Out of the scope of the STCW are the onboard manning levels which are covered by SOLAS (Ch. V, Reg 14).

Relevant to SafePASS are the following areas of the STCW Code:

1. Ch. 5: Special Training Requirements for Personnel on Certain Types of Ships
    a. STCW V/2: Masters, officers, ratings, and other personnel on passenger ships
    b. STCW V/4: Masters and deck officers on ships operating in polar waters (Polar Code)
2. Ch. 6: Standards Regarding Emergency, Occupational Safety, Security, Medical Care and Survival Functions
    c. STCW VI/1: Safety familiarization, basic training, and instruction for all seafarers
    d. STCW VI/2: Issue of certificates of proficiency in survival craft, rescue boats and fast rescue boats.

STCW Code sets requirements in tables that specify per rank, standards of competence which refer to the minimum knowledge, understanding and proficiency that the seafarer must demonstrate to gain the respective certification.

These tables are included in Part A of the STCW Code, which is mandatory. For illustrating how these tables work the example of STCW V/2 of Ch. 5 is taken. Here the minimum requirements are divided in the following topics:

a. Passenger ship emergency familiarization
b. Safety training for personnel providing direct service to passengers in passenger spaces
c. Passenger ship crowd management training (part of the relevant STCW competence table is shown in Figure 4)
d. Crisis management and human behaviour training
e. Passenger safety, cargo safety and hull integrity training

Column 1	Column 2	Column 3	Column 4
Competence	**Knowledge, understanding and proficiency**	**Methods for demonstrating competence**	**Criteria for evaluating competence**
Contribute to the implementation of shipboard emergency plans and procedures to muster and evacuate passengers	Knowledge of the shipboard emergency plans, instructions and procedures related to the management and evacuation of passengers Knowledge of applicable crowd management techniques and relevant equipment to be used to assistpassengers in an emergency situation Knowledge of muster lists and emergency instructions	Assessment of evidence obtained from training and/or instruction	Actions taken in case of an emergency are appropriate and comply with established procedures

Figure 4: Extraction from STCW Code Table A-V/2-1 (standard of competence in passenger ship crowd management training)

The effective use of the SafePASS components in the novel evacuation process might require specific competencies from some crew members which may exceed the current listed in STCW. This should be evaluated at a later stage of the project when all designs of LSA equipment, components and arrangements have been finalised.

3. Compliance options

3.1.1 Alternative design and arrangements

With the Alternative Design and Arrangements (AD&A) concept, innovation in ship design and technology is allowed, without escaping from the current SOLAS regulatory framework. The concept is viewed as the IMO acknowledgement of the fact that SOLAS can cause delays in the introduction of novel design and technologies in the shipping industry.

Some of the underlying principles of the AD&A process are to allow direct assessment of safety goals, to use new methods and simulation tools for the effective application of SOLAS regulations, and more importantly, to support the development of the future regulatory framework within SOLAS. Hence, the AD&D framework is matching with the SafePASS goals and therefore needs to be examined as the most suitable option of compliance for (at least some of) the project's proposed solutions.

While the AD&A concept cannot be used for all innovative designs, different parts of SOLAS are opened to it. A wide range of measures may be authorised as an alternative, including alternate shipboard structures and systems based on novel or unique designs, as well as traditional shipboard structures and systems that are installed in different arrangements or configurations.

The alternative design analysis may extend to the whole ship or can be focused on ship systems, subsystems, or individual components. However, the AD&D is not intended to be applied to the type-approval of individual material, components, or portable equipment.

Examples of alternative design application:

- Large MVZ, large fire doors,
- Alternative fire protection arrangements/layouts
- Lightweight non-metallic components vs. A-class regulations
- Large lifeboats
- All-MES instead of lifeboats
- Innovative low-flashpoint fuels
- Alternative stability assessment

The process for analysing safety equivalency for alternative designs and arrangements is limited to specific SOLAS chapters and outlined in the following IMO circulars (connected also with SOLAS in Table 2):

- MSC.1/Circ.1455 "Guidelines for the approval of alternatives and equivalents as provided for in various IMO instruments" defines the approval process and obligations of the design team, Administration, Recognised Organisation (RO)
- MSC/Circ.1002 "Guidelines on alternative design and arrangements for fire safety" provides a structured approach for AD&A's related to fire safety

- MSC.1/Circ.1212 "Guidelines for the approval of alternative design and arrangements for SOLAS Chapters II-1 and III" provides a structured approach for AD&A's related to stability and lifesaving.
- MSC.1/Circ.1552 "Amendments to the Guidelines on alternative design and arrangements for fire safety" provide a methodology for the selection of performance criteria used to address the survivability of persons on board when exposed to the effects of heat, smoke, toxicity and reduced visibility.

Table 2: The SOLAS instruments for the alternative design and arrangements concept

SOLAS Chapter	Regulation	Guideline	Focus
Chapter I	Reg. 5		Definitions of equivalents
Chapter II-1	55	MSC.1/Circ. 1212 MSC.1/Circ. 1455	Machinery, electrical installations
Chapter II-2	17	MSC/Circ.1002 MSC.1/Circ.1455 MSC.1/Circ. 1552	Fire Safety
Chapter III	38	MSC.1/Circ. 1212 MSC.1/Circ.1455	Life-Saving Appliances

The term ''Prescriptive Design'' in SOLAS is used for a design of safety measures which comply with the regulatory requirements set out in chapter III of SOLAS. "Alternative design and arrangements" in SOLAS, means safety measures which deviate from one or more prescriptive requirements of SOLAS but provide an equivalent level of safety, measured against the goals and functional requirements.

Put in simple terms, SOLAS chapter III on LSA allows AD&A, thus superseding prescriptive limitations regarding the use of new technologies, if it can be demonstrated that $R_{novel} \leq R_{SOLAS/LSA}$.

The process starts with the Submitter approaching the Administration for obtaining approval to proceed, and the Administration takes the responsibility of entering this process which may lead to the final approval and safety certification. The work in each step in the flowchart of Figure 5 may vary subject to the design or whether the Submitter is applying for preliminary or final approval.

The classification society plays an important role in the AD&D process and is kept fully informed of the contents of the correspondence between the owner's representative teams and the Flag administration. Classifications Societies acting as the recognized organization on behalf of the Administration are strongly involved in AD&D projects, and their role as "observers" in the Design Team is not a passive one. In any case, as a statutory requirement under SOLAS, the responsibility for the final approval of the alternative and/or equivalent design rests with the Flag administration of the vessel.

The work should start at the early design stages and requires continuous communication between the two sides (Administration or Class and Submitter).

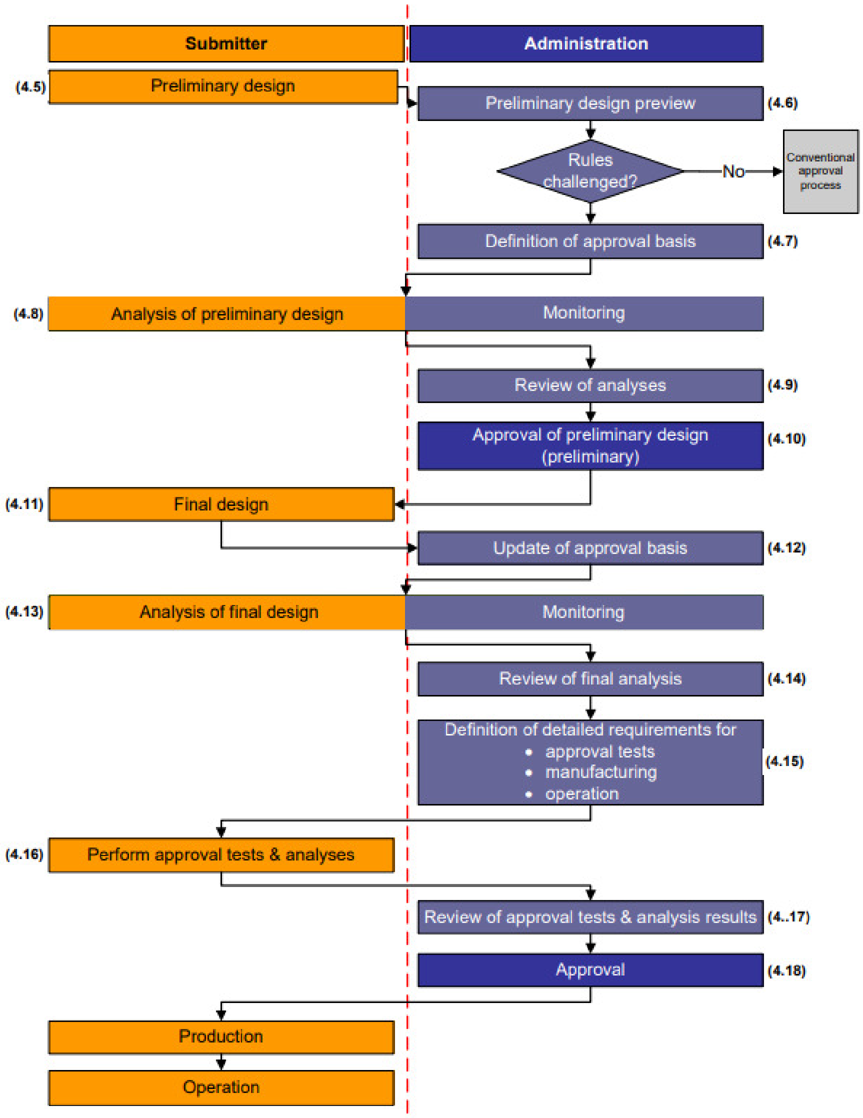

Figure 5: Alternative design and arrangements process flowchart in MSC.1/1455 (Source: IMO, 2013)

It is noted that currently, the AD&D approval is valid only for the ship flagged by the Administration at the time the approval was issued. Work is ongoing from industrial stakeholders (i.e. the Cruise Ship Safety Forum, (CSSF)) to introduce the concept of similar alternative designs in the AD&A framework, for two specific alternative design cases. The objective of CSSF is to develop a concept for the re-use of already approved AD&D to accelerate the approval of new similar studies (CSSF, 2018).

According to the AD&A guidelines (MSC.1/Circ.1455), the stakeholders involved in the are:

- Designer
- Shipyard/Subcontractor
- Design team
- Consultants and external experts
- Administrations
- Owner's supervisors and Flag or RO surveyors
- Port State Control officers
- Crew

The ways of involvement are also described in detail in the guidelines and presented in the following involvement map (Figure 6).

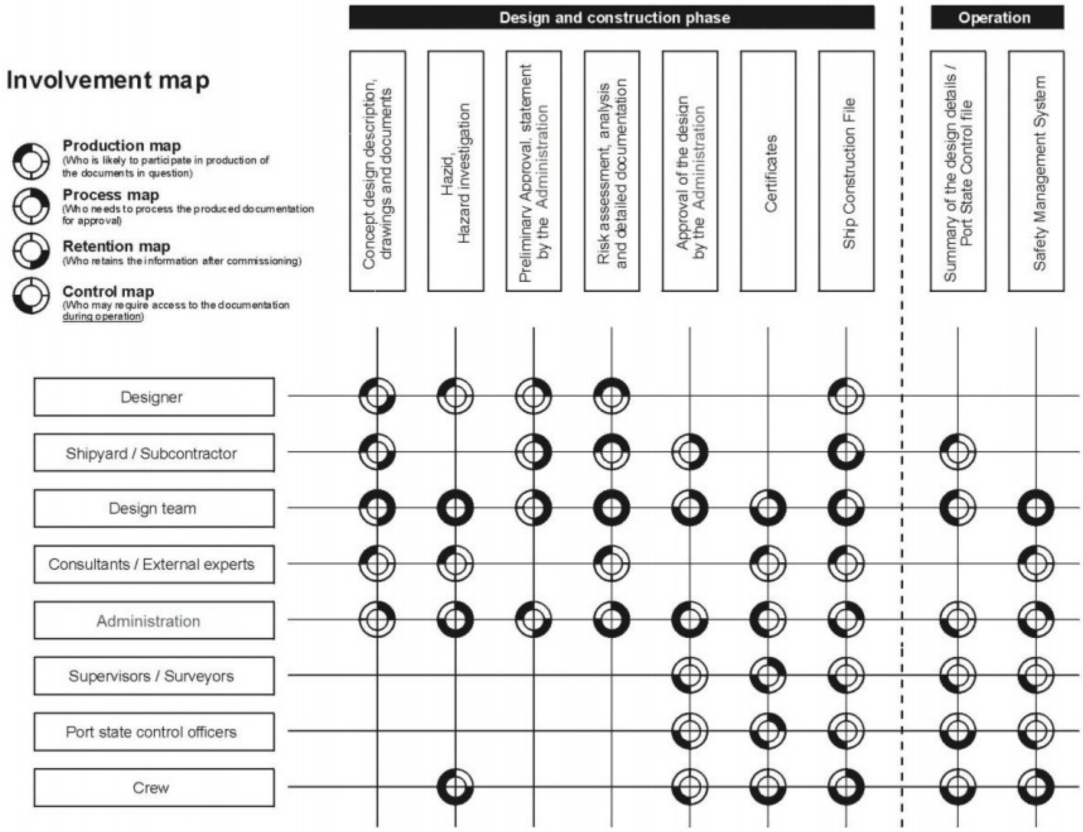

Figure 6: Stakeholders' involvement map in the AD&A process of MSC.1/Circ.1455 (IMO, 2013)

Tests, analyses, simulations, and software used in the engineering studies, need to be validated and background information and credentials for the personnel responsible for performing these should be made available. For certain types of tests, certification of the personnel and the supplier may have to be submitted.

It is noted that the future operation and maintenance of the proposed system is within the scope of study in the AD&D which should work on aspects such as: operational limits and maintenance, the definition of operation and maintenance procedures, as data acquisition and reliability tests, assessments during operation.

The IMO guidelines also define the documentation process that should be followed throughout the AD&D phases. This is essential since the approval process for an alternative design is different from a conventional approval process, and therefore needs to be clear, transparent, and well described to avoid misinterpretations between the submitter and the Flag or RO.

Risk analysis and performance criteria

The basic principle for the evaluation is the "safety equivalence". The alternative and/or equivalent should be designed to perform its intended safety-related function(s) in a manner that is equivalent to, or better than, the SOLAS requirement it is deviating from. This is a crucial step in the whole assessment process because, according to SOLAS, the equivalent safety should be assessed by comparing the innovative/alternative design with a prescriptive one. But, very often, the prescriptive design does not exist, e.g. a ship designed to have the MVZs exceeding SOLAS limits does not have the same layout and arrangement of a fully compliant SOLAS ship. Consequently, the AD&A approach is rather adopted to assess the equivalence against the goals and functional criteria of SOLAS rather than comparing "design A (compliant)" vs. "design B (alternative)". The clarification of this approach should always be the first step in the discussion with any Administration, forming the basis for the qualitative analysis, followed by the quantitative analysis and compliance with the acceptance criteria outlined in the IMO procedures.

The safety equivalency must be demonstrated through risk assessment studies, (risk-based design and approval). The generic risk assessment process, including the various stakeholders and their involvement, is described in MSC.1/Circ.1455.

The scope and extent of the risk assessment study need to be agreed upon with the vessel's Administration on a case by case basis. The analysis should be based on sound science and engineering practice such as accepted methods, empirical data, calculations, correlations, and computer models as contained in engineering textbooks and technical literature.

The evaluation criterion used shall be specified either based on prescriptive requirements or an equivalent, regulations compliant design.

An alternative design for which no appropriate IMO regulations or industry standard exists, needs to define evaluation criteria (as risk acceptance criteria) in agreement with the administration (IMO, 2013).

The performance criteria are related to the usual possible negative consequences: to humans, to property and the environment:

1. life safety criteria (e.g. impact on humans, survivability in case of flooding, fire, etc.) as in MSC.1/Circ.1552 (IMO, 2016)
2. damage to ship structure/systems (e.g. mechanical/electrical systems, fire protection systems, etc.)
3. damage to the environment (e.g. impact on the atmosphere, the marine environment).

Typical evaluation criteria used are the individual and societal risk. Criteria for societal risk (e.g. fatalities from fire, collision, structural damage, etc.) are available from studies on historical data. Criteria for individual risk relating to a single activity (hazard) have not been developed nor established to date (IMO, 2016).

In concluding, it is a requirement for the AD&A work to define the risk acceptance criteria either from the IMO guidelines or by an agreement with the Administration.

Examples of approved alternative design and arrangements

The industry is continuously gaining experience on alternative designs and analyses for passenger ships, over the years. This paragraph includes an example of an AD&A for a different arrangement of an MES system.

In the present AD&A example, the Flag Administration has accepted an MES arrangement that is deviating from SOLAS Ch. III, and specific from Reg. 15 (Stowage of Marine Evacuation Systems).

The port side MES of the subject passenger ship (Figure 7), is located at frame 115. The arrangement is in line with the side shell door (between frames 114 – 117) that serves as passenger entrance and tendering door. This arrangement constitutes a violation of SOLAS Ch III, Reg. 15, par. 1 which states that: "*The ship's side shall not have any openings between the embarkation station of the marine evacuation system and the waterline in the lightest seagoing condition and means shall be provided to protect the system from any projections*".

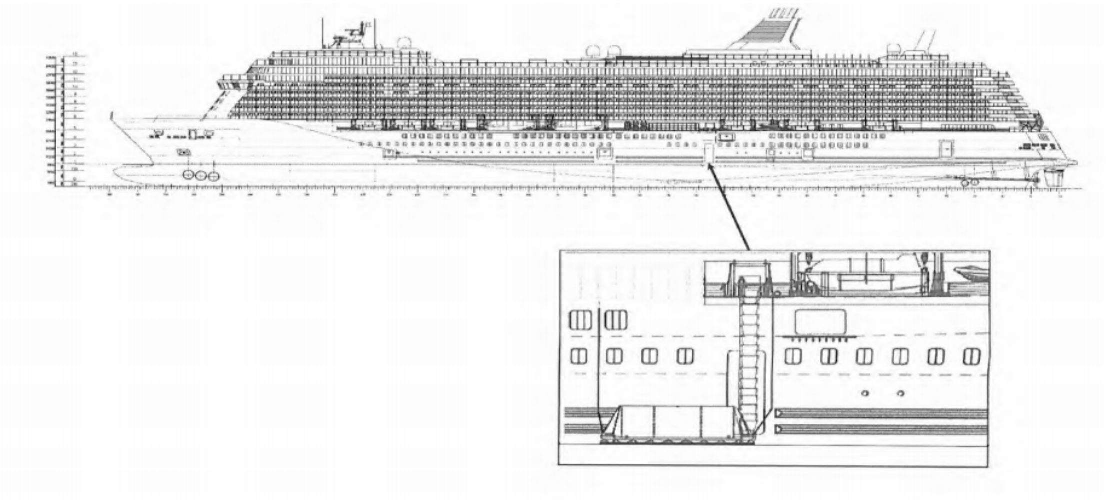

Figure 7: Approved alternative design and arrangement for MES (source: SLS.14/Circ.517, 2013)

The Flag Administration accepted the MES arrangement by taking into consideration the submitted by the owner AD&A study with a set of equivalent safety measures. The safety measures are shown below and concern both the construction and the operation of the vessel:

a) Safety design measures
    - The side shell door is made of steel of significant thickness. The scantling of side plates as a minimum is the same as for the side shell of the hull within the same area. The thickness of the coaming and insert plate for the door is 25 mm;
    - The sealing of the door is protected against fire with the aid of both a "steel labyrinth" and a coating of fire protection paint. The same paint is used for the treatment of the frames;
    - The side shell door is insulated with the same mineral wool insulation used in the side shell structure to provide an A-30 fire standard;
    - The door opening mechanism is with an internal mechanical locking device to eliminate the risk of doors to become loose due to the failure of a hydraulic pipe.

b) Safety operational measures
    - Procedures in the ship's safety management system for the side door operation and maintenance;

- The door is kept closed while underway;
- Hinges and toggles on the door are provided in regular intervals and included in the plan maintenance system; and
- Instructions and onboard training to the crew responsible for the door opening (and their substitutes).

3.1.2 Ship evacuation analysis framework

The current IMO framework for evacuation analysis is formed in MSC.1/Circ.1533, with the “Revised Guidelines on evacuation analysis for new and existing passenger ships” which are in force since 1st January 2020 (IMO, 2016_1).

These Guidelines aim to assess the performance of the ship against benchmark scenarios rather than simulate an actual evacuation emergency. IMO acknowledges that limited verification data are available for the actual application of the models proposed in the guidelines and that the parameters used are not ship-specific and originate from civil building studies. In other words, the objective of these Guidelines is to establish a basic safety-level of RoPax and Cruise vessel and not to assess real emergency situations.

The method for the evacuation duration is restricted by the “common assumptions” which must be followed in the analysis and do not reflect real conditions. This is also the case for the standard scenarios considered. The performance standard to meet, is the total time to evacuate.

Two options are available for the evacuation analysis, the simplified (in Annex 2) and the advanced (Annex 3). The simplified method is basic, initially developed to verify the evacuation procedure in RoPax ships and makes use of many assumptions and fixed values for parameters and therefore is not important for the SafePASS scope of work.

The advanced method is using parameters in four categories namely: geometrical, population, environmental and procedural.

1. Geometrical: Scenarios for the initial distribution of passengers from the FSS Code
2. Population: Identical population composition in all scenarios and standard formulas for calculating walking speeds
3. Environmental: static and dynamic condition of the ship that affects the moving speed of persons. Not yet considered.
4. Procedural: No special crew procedures are modelled in the four benchmark scenarios.

Travel duration is calculated with a given procedure (in par 5, Annex 3 of MSC.1/Circ.1533), as a random variable due to the probabilistic nature of the evacuation that requires specific runs from the simulation models per scenario (500).

Finally, the various software used in the advanced evacuation analysis should be verified through predefined component tests as suggested in Appendix 2 of MSC.1/Circ.1533. Quantitative verification of the simulation results with reliable experimental data is not required as these data are not yet widely available (IMO, 2016). A typical example of such an unavailability is for the calculation of the actual time for lifeboat embarkation. Most of the models calculate the time to evacuate until the assembly station and are not able to calculate the time for lifeboat boarding due mainly to the lack of operational or experimental data that would allow a sound verification (Stefanidis et al., 2019). Comparison with the aviation industry shows how challenging such tests are with respect to the selection of volunteers that need to reflect the typical population on board and the risk for the volunteers (often accidents are reported for aviation evacuation tests).

4. Possible Regulatory Implications for SafePASS Systems

4.1.1 New Ship Architecture

The novel ship architecture solutions are being conceptualized within the scope of Task 3.3 of SafePASS and cover the integration of the novel lifeboats on the ship structure. In total, three distinct novel solutions are proposed to improve the availability of evacuation routes and LSAs, reduce the congestion and the time until mustering, and increase the accessibility in the assembly stations. In the design of these solutions, and the unique characteristics of various passenger groups (e.g. elderly, and people with mobility impairment issues) are considered.

More specifically, the solutions aim at faster providing alternative routes for passengers' evacuation in case their movement is obstructed due to a hazardous event (e.g., fire, smoke), or reduce the time to muster when no routes are obstructed. In addition, the solutions may improve the movement of passengers during the mustering process focusing on people with mobility impairment, families with infants and elderly people with mobility difficulties, for whom the effort to use staircases, or guide themselves through long distances on crowded deck spaces is definitely a challenge. The solutions also aim at improving the accessibility of the assembly stations of novel cruise vessels when the movement of passengers and crew members within those areas is slowed due to high congestion, especially for people on wheelchairs and families using baby strollers. Provisions are also taken into consideration to enhance LSA availability for the total number of passengers and crew members onboard to evacuate safely.

During the conceptual design phase of the solutions, no deviations from SOLAS regulations have been identified. More specifically, in the context of SafePASS, the specific regulations taken into consideration for the new design solutions are the following:

- SOLAS Chapter II, Reg. 13, Means of escape, (7.1.5, 3.1.2, 7.3, G6.1)
- The LSA Code (Chapter VI 6.1.1.3)

In this context, the AD&A concept might not be used for the approval of these new designs in the context it is used for novel MVZ designs approval. SafePASS design team aims the proposed new design solutions to comply with the prescriptive SOLAS regulations and all regulatory indirect challenges that have been arisen are being accommodated with minor design alternations on the initial design. It is possible though that the AD&A will be utilised for approving a different arrangement of an existing design solution. Other possible compliance challenges may be related to structural Class Rules.

Regarding the evacuation analysis, the common assumptions of MSC.1/Circ. 1533 are applicable the new solutions. Notably, it is feasible to go beyond the benchmark that is set by the common assumptions (e.g., unavailability of the escape routes can be considered) to demonstrate the increase in safety with the SafePASS solutions.

The performance criteria and scenarios that are set in the guidelines for evacuation analysis can be applied. Additionally, higher performance standards and additional scenarios can be also considered. For instance, different (lower) values for the initial specific flow and initial speed as a function of density can be employed, and all possible additional escape routes that may be introduced from the solutions, apart from the main routes, should be considered, regarding the first assumption.

4.1.2 Novel LSAs

New LSA SafePASS concepts under study concern novel Lifeboats, MES and PSE. The requirements for the future LSA equipment that have been identified within the project show that equipment needs to be smart, easy to use, and inclusive for all the persons onboard and that one size of LSA and PSE does not fit all. This was one of the key issues that the Glasgow workshop also highlighted (SafePASS D3.1).

The AD&A framework of SOLAS is adequate for the design approval of LSAs that deviate from the prescriptive requirements and many AD&A studies concern lifeboats exceeding the capacity limits. In recent years a growing number of alternative designs in large cruise vessels has added knowledge on the approval of these large lifeboats. The Cruise Ship Safety Forum (CSSF) has collected and compared engineering approaches used in AD&A processes for large lifeboats, as well as when AD&A studies should be revisited (e.g., sister ship), and has issued a recommendation report. The CSSF recommendation proposes an AD&D concept for large lifeboats that will allow for the re-use of already approved AD&D to accelerate the approval of new similar studies (CSSF, 2018).

Type Approval is a separate process if the lifeboat is a prototype and may include life boarding test, davit, lifeboat structure, release system, manoeuvrability, etc. Type approval certificates are issued from Classification Societies to very large lifeboats with a capacity above the limits permitted by SOLAS (e.g. for the newest cruise ships there are approved lifeboats exceeding three times the permitted limit of 150 persons). Class certification is granted to the lifeboat after a set of appraisals and prototype tests using the AD&A framework of SOLAS and the applicable requirements of the LSA Code.

The limitations of the current SOLAS framework for LSA has been reported in D3.2. Possible challenges that will derive from the LSA concepts under study in SafePASS are:

a. Alternative positioning of LSA equipment and ease of access to allow faster evacuation
b. Varying LSA performance subject to the evolving ship emergency scenario
c. Alternative design interface between the LSA and the ship Different types of LSA to match the passenger’s specific profile

More details on the regulatory implications for the novel SafePASS LSA will be examined and reported in month 36, in Deliverable 7.3, when the relevant designs and evacuation methods will be finalised.

4.1.3 Novel ship evacuation analysis

IMO acknowledges that the current framework of ship evacuation analysis has many restrictions, lacks real-time verification data and overall needs further development.

In par 10.1 of the revised ship evacuation analysis guidelines (MSC.1/Circ.1533), it is stated that member states are encouraged to: *"collect and submit to the Sub-Committee on Ship Systems and Equipment for further consideration, any information and data resulting from research and development activities, full-scale tests and findings on human behaviour, which may be relevant for the necessary future upgrading of the present guidelines"*. (IMO, 2016_1)

The evaluation method proposed by IMO in MSC.1/Circ.1533 is based on certain scenarios that should be evaluated following the so-called "common assumptions".

In Table 3, a comparison is presented between these assumptions and the SafePASS evacuation analysis approach.

Table 3: Comparison of SafePASS approach with the current IMO framework for evacuation analysis

Aspect	IMO evacuation analysis framework	SafePASS approach
Main escape routes	Passengers and crew evacuate via the main escape routes	Alternative escape routes will be examined subject to the developing emergency scenario
Signage, low lighting	Fixed	Varying, signage changes to show the optimum escape route
Assigned assembly station	Passengers and crew will assembly in assigned assembly stations.	Assigned assembly stations may be unavailable, or different to improve the accessibility to novel LSA
Passenger load and initial distribution	Based on scenarios taken from Ch. 13, FSS Code	Different scenarios and population distribution
Response duration	Logarithmic normal distributions	Direct assessment. For the simulations of the proposed architectural structures, a response duration will not be considered.
Environmental (smoke heat, toxicity)	Not considered affecting human performance during the evacuation	Taken into account by the evacuation analysis software
Dynamic ship motions	Not considered	Considered
Escape arrangements	Full availability unless otherwise stated	Availability is evaluated in real-time
Crew initial position	Immediately be at the evacuation duty locations	The crew has different duties subject to the emergency scenario
Crew procedures	Not required to be modelled in the benchmark scenarios	May be needed to match the improved process
Family group behaviour	Not considered	Considered
Population composition	Identical in all scenarios	Can be tuned to real data
Walking speed	Calculated through standard formulas for walking speeds	Varies

Risk criteria	Societal risk	Individual risk
Performance criteria	Evacuation duration (R, T, E+L)	Evacuation duration and risk
Simulation procedure	Standard procedure to calculate travel duration	To be verified
Model verification	Through component testing (standard tests)	To be verified

For many of the aspects shown in Table 3, work is still ongoing in SafePASS that may alter the final approach from the one described in this table.

For example, in T3.3, two groups of simulations for the evacuation will be performed, one only for the proposed architectural structures and the other incorporating the whole SafePASS solutions. Currently, the scenarios and the evacuation strategies are under discussion.

Another example is the final evacuation strategy which will be decided in WP8. The assembly stations will be defined in this evacuation strategy.

SafePASS will incorporate real-time data, from the various sensors monitoring both the type and propagation of damage and human physiological factors, in an evacuation analysis model that can evaluate different route alternatives for individuals while taking the human behaviour under consideration.

4.1.4 SafePASS components integration onboard

The components of novel LSA, new ship architecture, and the evacuation and risk modelling have been discussed in the previous paragraphs. Table 4 contains a first attempt to identify possible challenges for the onboard integration (operation, maintenance) of the remaining components that comprise the smart environment of the SafePASS solutions. This evaluation has been made by considering the role and main functionalities of these components as have been presented in D2.6. Excluded are the components intended to support the evacuation on a non-compulsory setting (i.e. passengers mobile apps).

Table 4: Summary of possible SOLAS implications in the integration of SafePASS components onboard.

SOLAS	Subject	Implications for SafePASS	Regulatory requirement
Chapter IX (ISM Code)	Cyber Security	SafePASS architecture establishes interconnections between the Core Platform and onboard OT systems (i.e. safety centre, emergency detection systems, etc.) to collect and utilise sensitive data for the ship's safety.	Cyber threats should be identified and technical and operational measures should be implemented with a risk-based management approach and included in the SMS

Chapter IX (ISM Code)	Cyber Security	New external components (as independent systems), which will be connected to the Core Platform to keep a continuous communication and exchange of information in real-time. Passengers and crew will be using such devices as well.	1) Networks used by passenger and crew are separated/segregated from other important ship networks. 2) The network configuration should be cyber secured 3) Demonstrated through a risk assessment and included in the SMS
Chapter IX (ISM Code)	Maintenance	SafePASS introduces equipment and smart devices that will be available in large numbers onboard, ready to be handed to all passengers to support mustering and evacuation	Regular testing of the reliability of these systems and devices as required could be challenging.
Chapter IX (ISM Code)	Maintenance	The functioning of devices transmitting real data should be efficient in different conditions and locations onboard	1) Demonstration through reliability assessment 2) Functional tests 3) Procedures in the SMS
Ch II-2 Reg.23	Safety Centre	Communication systems of SafePASS, characterised as essential safety systems	The option of redundancy may need to be examined
Ch II-2 Reg.21	SRtP	Components characterised as essential for the SRtP condition should be able to meet design requirements included in MSC.1/Circ.1369	System-based verification, which needs to be conducted in the early design stages.
Chapter III	Reg. 37	Dynamic mustering and evacuation which deploys the crew in multiple tasks according to the evolving emergency scenario	May be difficult to be portrayed in the current form of muster lists

5. Contribution to the improvement of the ship evacuation regulatory framework

IMO requirements for life-saving appliances are provided by SOLAS Chapter III and the LSA Code whereas MSC.81(70) provides the test requirements for verification of compliance. The whole framework is historically grown, driven by incidents and accidents, and thereafter is lacking consistency as well as insufficiently reflecting the actual situation. Already in 2006 (IMO, 2006), Japan highlighted that distributing the process of escape, evacuation, abandonment and search and rescue on different IMO Sub-Committees (and considering related regulation in different parts of the framework) may not be the optimal approach.

As proposed by Japan at that time, IMO agreed on the development of a new framework of requirements for life-saving appliances, i.e. review of the different requirements and subsequent restructuring. The process to revise SOLAS chapter III should have matched what done about 20 years ago, when SOLAS chapter II-2 was revised to restructure the provisions and include in each section the goals and functional requirements – which are a necessary requisite to apply the AD&A. SOLAS Ch. II-2 Reg. 17 was the first example of AD&A in the regulatory framework.

Recapitulating the IMO work of the following years only little process was made. However, in 2017 Germany "refreshed" the need for a revision of SOLAS chapter III and the LSA Code, which was subsequently agreed by the 98th meeting of the Maritime Safety Committee (IMO, 2017) with enhanced scope considering not only revisions to remove gaps, inconsistencies and ambiguities but also the development of functional requirements. In this context notable is the invitation to consider IMO safety-level approach that "*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*"(IMO, 2019). After fulfilling the prerequisites agreed by Maritime Safety Committee, work has been commenced at SSE7 and is currently continued by an intersessional correspondence group (IMO, 2020).

As is often the case, IMO instruments offer space for interpretations, respectively provide not very specific guidance and thus it is worth to have a closer look at the possible role of risk-based methods in the context of IMO Goal-Based Standards (GBS).

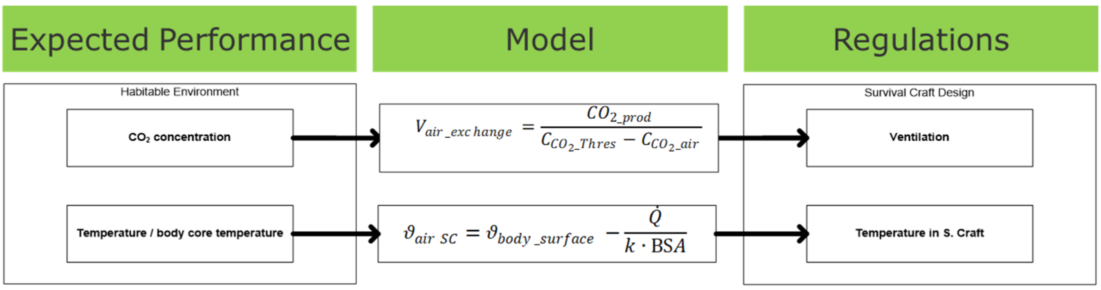

Figure 8: Goal-based process of developing regulations (Hamann & Assheuer, 2019)

The development of a goal-based standard is exemplarily shown in Figure 7 by the example of ventilation requirements for totally enclosed lifeboats (habitable environment with respect to CO_2 and temperature). The goal has been further developed into a so-called expected performance (part of functional requirement, IMO (2019a)), either in qualitative or quantitative terms and subsequently a “model” is applied to translate this into performance requirements for the regulations, i.e. a ventilation rate per passenger in the lifeboat. According to Hamann & Assheuer (2019), this is GBS but not a safety-level approach.

They proposed that for the safety-level approach the expected performance needs to be adjusted by means of risk assessment. Thus, the relation between “performance” and “risk” needs to be established, in **Error! Reference source not found.** 8 shown by the example “temperature”. Survivability is a function of body core temperature, which again depends on factors like environmental temperature, clothing, activity etc. To protect passengers of a lifeboat in Polar Waters different risk control options can be used, each having certain effectivity and costs. In an iterative process, risk is reduced either by using the IMO cost-benefit assessment process (IMO, 2018) or by the ALARP process (As Low As Reasonably Practical).

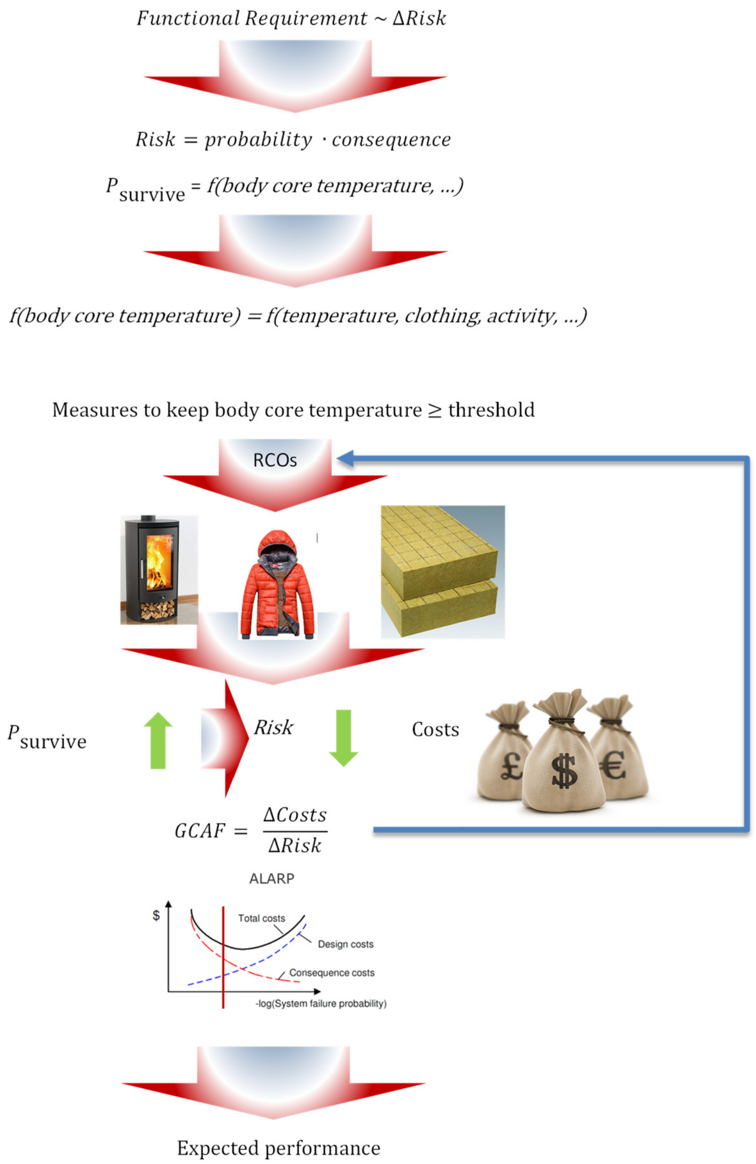

Figure 9: The safety element (Hamann & Assheuer, 2019)

Considering GBS safety-level approach in the revision of IMO LSA requires a risk model for escape, abandonment, waiting for rescue until reaching a safe haven[3]. The SafePASS risk model developed in work package 6 will be a quantitative model for determining the risk to people on board (PoB) of passenger ships covering the period starting with the incident/accident and ending with waiting for rescue. Considering all relevant influences on the survivability of PoB, it will provide the framework for developing risk-based expected performance as an integral part of the GBS functional requirements. The regulatory implications could be huge because the risk model in combination with cost-benefit assessment enables a critical assessment of existing provisions.

[3] The authors like to note that the current IMO framework ends somehow in the phase of *waiting for rescue*. Only the Polar Code specifies a minimum time for *waiting for rescue*.

6. Ethical Framework

SafePASS has an ethical requirement to facilitate and perform ethical technology design which ensures future end-users' privacy is respected. In line with the European Commission's perspectives on "responsible research and innovation", SafePASS adopts a general ethical requirement to ensure that "societal actors (researchers, citizens, policymakers, businesses, third sector organisations, etc.), work together during the whole research and innovation process on order to better align both the process and its outcomes with the values, needs and expectations of society" (Geohegan-Quinn, 2014)[4].

The SafePASS project, as a research and innovation project, will take conceptual ideas and translate these into a concrete technology design and then test prototypes. Thus, according to Reijers et al.'s[5] (2018) categorisation of ethics practice, the approach to be adopted is 'Intra Methods' (dealing with technology design). This means:

1. Integrating ethicists into the research lifecycle
2. Disclosing ethical issues in the design of the technology
3. Embedding ethical values in the technology design
4. Organising ethical practice in the design process

The SafePASS Ethical Framework thus has four pillars which support its goal to identify and evaluate the ethical considerations which the SafePASS solutions will create.

Integrating ethicists into the research lifecycle

SafePASS is following a co-design (evolved participative design) approach whereby stakeholders are involved in the entire project lifecycle (requirements-design-implementation-evaluation). The management structure of the project has the usual technical, scientific, and administrative functions typical of research projects. It also has an Ethical Review Committee (ERC) to ensure that all project activities comply with good practice as well as legal aspects of ethical, privacy and data protection issues. The SafePASS project has also appointed an Ethics and Data Protection Manager (Dr. Paul Liston, TCD) who will work in cooperation with the Ethics Review Committee who will formally review all research activities which have ethical impacts on human participants. The Ethics and Data Protection Manager is responsible for:

- Monitoring the compliance of the project activities with respect to ethics and data protection norms in cooperation with the Ethics Committee; and

Supporting the consortium to think ahead about possible problems that may arise and solutions to address these problems. The ERC is responsible for:

- Monitoring compliance with requirements regarding ethical, privacy and data protection issues throughout the project;

[4] Geohegan-Quinn,M. (2014). Responsible Research & Innovation. Brussels: European Union Publications Office.

[5] Reijers, W., Wright, D., Brey, P. et al. Methods for Practising Ethics in Research and Innovation: A Literature Review, Critical Analysis and Recommendations. Sci Eng Ethics 24, 1437–1481 (2018). https://doi.org/10.1007/s11948-017-9961-8

- Liaising with the SafePASS Dissemination Manager to support the assessment of the sensitivity of all deliverables prior to publication; and
- Reviewing progress regularly to ensure an appropriate classification level of all dissemination material.

Independent Ethics Expert

An external independent Ethics and Data Protection expert has been appointed to oversee with impartiality the ethical concerns and privacy of personal data involved in this research, as reported in Deliverable "D1.2 Updated Project Management Plan". The Ethics and Data Protection expert's role is to provide consul to the Consortium regarding doubts about the proper implementation of principles and procedures related to ethical values and privacy protection.

Disclosing ethical issues in the design of the technology

The SafePASS consortium will conduct a socio-technical dynamic assessment to properly understand the social, behavioural, and ethical aspects that need to be factored into the design of evacuation and lifesaving systems onboard passenger ships and the processes which manage them.

An evidence-based assessment methodology for socio-technical modelling is being used in SafePASS. The overall objective is to ensure that both social and technical perspectives are working together. Oftentimes in technology development projects, the social, behavioural, and even human aspects of the technology play a secondary role to the technological aspects. SafePASS is, through a Community of Practice, championing social and behavioural aspects and prioritising the role of the human in development. Doing so will ensure that implementation will not encounter barriers relating to user acceptance, usability, and other human barriers. SafePASS derived stakeholder requirements are following a co-design approach, in order ensure that all demographic, behavioural and social aspects are represented within the SafePASS Community of Practice (passengers, crew members, operators, decision-makers, regulators, etc). This integrated approach to fully understanding and eliciting the needs of all demographic groups and adopting a co-design approach to design, implementation and evaluation represents a cutting-edge approach to socio-technical innovation in passenger ship safety. A further element of this approach is the Social Licence to Operate (SLO) concept. This concept relates to the continued acceptance of a set of business practices or operating procedures by a company's employees, stakeholders and the general public. The concept of social license is closely related to the concept of sustainability and the work to define and develop a SLO in SafePASS helps ensure that the technical innovations can be supported by sustained social and behavioural change, even beyond the project lifecycle. SafePASS WP7 will advance a Social License to Operate (SLO) as part of the development of the Community of Practice. The Social License relates to when a project has the ongoing approval within the stakeholder community and has ongoing approval or broad social acceptance. SafePASS, as part of its co-design approach, will develop an SLO for the technology solutions developed within the project. The SLO is part of ensuring the sustainability of the SafePASS solutions – without broad acceptance from users and the wider stakeholder community there can be no real impact at a societal level. The SLO in turn is part of an approach to achieve broader social responsibility in the passenger ship sector. Organisations which have an SLO build trust with the community they operate in and with other stakeholders. Operating responsibly, taking care of employees and passengers, prioritising the environment and being a good corporate citizen is part of the broader picture. Once an SLO is established, it provides a roadmap for establishing a “Triple Bottom Line” (TBL). This refers to a concept proposed by John Elkington in 1994 and later elaborated in his 1997 book "Cannibals with Forks: The Triple Bottom Line of 21st Century Business." A triple bottom line measures a company's degree of social responsibility[6], its economic value[7], and its environmental impact. SafePASS will provide a mechanism for operators who use the SAFEPASS solutions to demonstrate their contribution to social responsibility and provide a roadmap for further elaboration of the Triple Bottom Line concept to measure social and environmental impacts.

Embedding ethical values in the technology design

The SafePASS Partners adhere to ethical rules and comply with European legislation on data protection (Regulation (EU) 2016/679 General Data Protection Regulation[8]), the national legislation applicable in countries where the research will be carried out, as well as recommendations and codes of conduct relevant to research activities. The SafePASS Consortium has not identified any specific ethical issues related to the activities of the Project that are not already addressed in the Grant Agreement. Ethical procedures have been specified within the project (and disseminated between consortium members) and these procedures have been embedded in project activities. The surveillance activities using SafePASS technologies are being designed and implemented while taking into consideration the dignity of the participants as well as other fundamental rights and freedoms (freedom, non-discrimination, etc.) and core values will be respected (proportionality, minimization, confidentiality) and will conform with The General Data Protection Regulation (EU) 2016/679 ("GDPR"). As national and EU laws and recommendations on privacy and data protection issues play an important role, the design of activities within the SafePASS project actively involves all partners’ engagement in designing, deploying and testing SafePASS, which may raise concerns on data sharing and protection issues. Each partner is responsible for informing their own staff involved in the SafePASS project about the need to comply with the legal and ethical principles and provisions with regard to data processing. The Consortium considers all necessary and appropriate measures to mitigate risks, which include:

- The handing over of any data;
- The collection of data and its secure storage and transfer;
- The confidentiality declaration to be signed by staff;
- The process for conducting trials, participant’s recruitment and gaining informed consent.

[6] https://www.injacketopedia.com/terms/s/socialresponsibility.asp

[7] https://www.injacketopedia.com/terms/e/economic-value.asp

[8] https://ec.europa.eu/info/law/law-topic/data-protection_en

Since the early 1990s, the European Commission has been pursuing a more user-oriented approach in RTD policy-making. To this end, the Green Paper on Innovation[9], stressed the urgency of involving end-users in the research and development of new technologies as a crucial component of innovation itself. In 2008, the EC commissioned a study[10] that investigated the inclusion of end-users in decision-making processes regarding the RTD sector, mainly regarding the development of new technologies. The study analysed both theoretical frameworks and experimental approaches that focused on the end-user involvement in innovation and highlighted several positive aspects of user involvement.

The importance of direct involvement of end-users is stressed as well in the H2020 - EU Framework Programme for Research and Innovation, as a priority measure in facing Societal Challenges - "…The active involvement of end-users is of high importance…"[11].

End-users and stakeholders' involvement through the SafePASS Community of Practice and other co-design methods will ensure that the project deliverables/products will be compliant with actual end-users' needs and preferences.

The involvement of end-users in all project phases (planning, design and validation of products and solutions) responds to the EC approach to citizens' involvement in decision-making processes, contributing to the strengthening of the democratic process and a more responsible citizens' approach to innovation, research and development. Moreover, such an approach allows for a high level of transparency in the design and validation of project products, which, in the long term, contributes to increasing the corporate social responsibility of the cruise ship industry. Such an approach guarantees social responsibility and ethical behaviour through the achievement of the EC's aim of promoting direct dialogue between ship manufacturers, LSA manufacturers, cruise ship operators, crew, and passengers, as a strategy to stimulate innovation and to overcome societal challenges at EU level (H2020 - Secure Societies and Transport).

Organising ethical practice in the design process

Ethical practice in the context of the SafePASS design process relates to the research and development conducted by SafePASS partners and the ethical treatment of the research participants. Ethical treatment of research participants relates to how any passengers, crew members, operators, manufacturers who assist the SafePASS consortium in their research and development activities are treated in an ethical manner. And more broadly, the research and development work performed by the SafePASS consortium must be ethical – it should follow best practice in all aspects. In terms of research practice, the SafePASS Ethics and Data Protection Manager developed and led a training session for all consortium members on Ethics for Research with Human Participants. The training was specifically designed for technical

[9] http://europa.eu/documents/comm/green_papers/pdf/com95_688_en.pdf

[10] Hertog et all, 2008, "User Involvement in RTD Concepts, Practices and Policy Lessons - Final Report of the study commissioned by the European Commission";

[11] European Commission website, Horizon 2020 - Secure societies – Protecting freedom and security of Europe and its citizens.

partners who typically do not interact with human research participants, but who would be involved in this type of activity in the SafePASS project. The training covered all best-practice concepts related to ethics in research-informed consent, privacy, data protection, limitation of harm, etc. But crucially, the training included simulated exercises and behavioural-based sessions in order to familiarize trainees with the practicalities of performing research with human participants and the ethical dilemmas that can crop up. This training was recorded and is available as a resource for the entire consortium. The Ethics and Data Protection Manager further drew up the following documents to guide all research activities in the project (Detailed in D10.1 and D10.2):

- The procedures and criteria that will be used to identify/recruit research participants;
- The informed consent procedures that will be implemented for the participation of humans;
- Templates of the informed consent/assent forms and information sheets;
- How all of the data intended to be processed is relevant and limited to the purposes of the research project ("data minimisation" principle);
- How the research participants will be informed of the existence of the profiling, its possible consequences and how their fundamental rights will be safeguarded.

The procedures regarding personal data management and consent forms are analysed in the following chapter, where the GDPR framework is presented.

7. GDPR Framework

The privacy of people and the protection of their personal data are taken seriously into account in SafePASS project activities, in order to ensure the compliance with all relevant directives and regulations. This approach refers to both internal and external people that are involved in SafePASS project, including the members of the consortium, external stakeholders, participants in interviews, workshops and questionnaires, actors and observers of demonstration activities etc. In order to ensure that all these activities are conducted with respect to privacy, a data protection framework has been defined and is applied to any procedure that includes the collection, processing and/or storage of personal data. This framework is based on the following:

- Data protection regulations and directives
- Establishment of Ethical Review Committee (ERC) regarding personal data protection
- SafePASS data management plan with respect to personal data
- "Privacy by design" and "privacy by default" principles for development and implementation of systems and components
- Personal data management for research participants and relevant procedures for obtaining consent

The legal framework on data protection for SafePASS project includes the following regulations and directives:

- Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation)
- Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC
- Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector (Directive on privacy and electronic communications).
- Charter of Fundamental Rights of the European Union (2012/C 326/02), became legally binding on the EU institutions and on national governments on 1 December 2009, with the entry into force of the Treaty of Lisbon
- Trade and Cooperation Agreement Between the European Union and the European Atomic Energy Community, of the One Part, and the United Kingdom of Great Britain and Northern Ireland, of the Other Part (24 December 2020)

Many of these regulations might have overlapping principles and rules, but all of them aim to the provision of guidelines towards the protection of personal data. More specifically, the General Data Protection Regulation (EU) 2016/679 (GDPR), which has been widely in force, is a regulation in EU law on data protection and privacy in the

European Union (EU) and the European Economic Area (EEA). The GDPR's primary aim is to give individuals control over their personal data and to simplify the regulatory environment for international business by unifying the regulation within the EU. Controllers and processors of personal data must put in place appropriate technical and organizational measures to implement the data protection principles. Business processes that handle personal data must be designed and built with consideration of these principles and provide safeguards to protect data (for example, using pseudonymization or full anonymization where appropriate). Data controllers must design information systems with privacy in mind.

In the maritime sector and specifically in the cruise industry, the compliance with GDPR is quite more complex than other sectors, as cruise lines deal with hundreds and thousands of people and are required to manage (collect, process, store) a significant amount of personal data. The data subjects of cruise ships are both the passengers (customers) and the crew members (employees) and their personal data may include identities, contact details, transactions on board (in case of passengers), CVs (in case of crew members), health information etc. in parallel, all of this information is likely to cross national borders and be exposed from time to time to physical and cybersecurity risk[12]. In order to protect this data and ensure the privacy of the data subject, the cruise lines must use the highest-possible privacy settings by default, so that the datasets are not publicly available by default and cannot be used to identify a subject. No personal data may be processed unless this processing is done under one of the six lawful bases specified by the regulation (consent, contract, public task, vital interest, legitimate interest, or legal requirement). When the processing is based on consent, the data subject has the right to revoke it at any time.

As it was mentioned in the previous section, the Ethical Review Committee (ERC) is assigned to ensure that all project activities comply with good practice as well as legal aspects of ethical, privacy and data protection issues. The responsibilities of the Ethical Review Committee and the Ethics and Data Protection Manager are clearly depicted in the Project Management Plan (Deliverables D1.1 & D1.2), where the overall organizational structure of the consortium is presented, along with the duties assigned to each body and role. Among other responsibilities, the ERC is responsible for reviewing any procedure related to the management, processing and storage of personal data collected for project purposes, in order to ensure the compliance of all SafePASS procedures with the General Data Protection Regulation (GDPR). The Committee - consisting of 3 internal members of the consortium (TCD, MSRC, EXUS) and 1 external independent Ethics and data protection expert - ensures that data gathering procedures are done on the basis of consent forms that follow Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 (GDPR) on the protection of individuals with regard to the processing of personal data and on the free movement of such data.

In SafePASS, the data management approach is clearly presented in the Data Management Plan (D1.4 & D1.5), concerning the data processed, generated and preserved during and after the project, as well as relative concerns generated from

[12] https://www.hfw.com/The-GDPR-iceberg-data-protection-in-the-cruise-industry-October-2017

their usage. Even though this report depicts the overall data management, all kinds of data that are generated, processed, collected and stored have been listed and the ones that may concern personal data and require GDPR compliance have been identified, in order to be managed according to the regulations. Also, a special reference is made regarding the ethical aspect of data management and the procedures that are followed to ensure the protection of personal data in SafePASS. Any personal data that is collected and/or processed by the SafePASS consortium is treated in that way, so as to ensure the protection and privacy of the data subject and fulfil the compliance of all relevant procedures and activities with GDPR. To achieve this, SafePASS consortium puts in place appropriate technical and organizational measures, while the activities that handle personal data are designed and organised to implement the data protection principles, ensuring data security, getting data subjects' consent and safeguarding data subjects' rights.

Furthermore, one of the key principles of the General Data Protection Regulation is the "privacy by default" principle according to which the data controller ensures that only data strictly necessary for each specific purpose of the processing are processed by default (without the intervention of the user). Data controllers are encouraged to implement technical and organisational measures, at the earliest stages of the design of the processing operations, in such a way that safeguards privacy and data protection principles right from the start ("data protection by design"). By default, data controllers should ensure that personal data is processed with the highest privacy protection (for example only the data necessary should be processed, short storage period, limited accessibility) so that by default personal data isn't made accessible to an indefinite number of persons ("data protection by default")[13]. In SafePASS project, the four criteria listed in Article 25(2) GDPR (see Chapter 2, section 2.4.5) are followed, i.e: minimum amount of personal data, minimum extent of the processing of personal data, minimum period of storage of personal data, minimum accessibility of personal data[14]. All SafePASS systems and subsystems have been designed and developed with consideration of these principles and criteria and provide safeguards to protect data (for example, using pseudonymization or full anonymization where appropriate). Every possible privacy aspect of the systems that are going to be implemented has been taken into account during the design phase of each component, while privacy-related issues have been also identified in the system specifications analysis (D2.4 & D2.5). In parallel, the principle of data minimization is also followed, meaning that only the absolutely necessary personal data is collected and that the data subjects are fully aware of this process and have given their consent.

The SafePASS project processes personal data under the lawful basis of consent (as set out under Article 6 GDPR). In case of the collection, transmission, storage and protection of personal data, an informed consent procedure must be defined and implemented. As described on Deliverabels D10.1: H - Requirement No. 1 and D10.2: POPD - Requirement No. 2, relevant participants in the research must be asked to sign

[13]https://ec.europa.eu/info/law/law-topic/data-protection/reform/rules-business-and-organisations/obligations/what-does-data-protection-design-and-default-mean_en

[14] https://www.enisa.europa.eu/publications/recommendations-on-shaping-technology-according-to-gdpr-provisions-part-2

a form, where required, in order to express their consent to the processing of their personal data prior to their participation and after they are given an appropriate timeframe, to be informed about the project's information. The participants will be offered a paper Consent Form and/or online consent forms and they will be asked to complete it, indicating their consent or not. This form must be composed in accordance with legal requirements, including the description of how the data will be used, what type of information will be collected, and what the aim is. The voluntary character of participation will be stated explicitly in the consent form. When using the information consent form, it must include generic details about the project and contact information as well as the participants' rights regarding their personal data. The participants will be assured that their answers will be used only for the purpose of the specific survey. Consent Forms templates are reported in Deliverable D10.1. The participants will also be offered the relevant project's Information sheet, also provided in Deliverable D10.1, where subjects will be able to get general information about the project, their involvement, matters regarding the processing of their personal data, withdrawal of consent or exercise their rights if they feel some kind of violation.

Also, the consent procedures for recruiting/contacting participants for in-depth interviews, surveys and workshops follow the standard practices/protocols within the research organizations in each country in which a case study is carried out. In all cases, these practices satisfy all requirements as laid down by the EU in Horizon 2020. Stakeholders participating in interviews are asked to sign a consent form, which is provided to them in a reasonable time so that it can be studied, prior to the interview. The form outlines the research intentions and provides details on how the interview information will be used. In case of the project's internal processes and events, SafePASS notifies persons that their personal data will be collected and or stored if any. In case of external actors contributing, SafePASS aims to minimize the collection and processing of personal data. If personal data is processed and or stored, the project handles these data with the same care as the project does when performing this with internal data. In the event of any issues concerning sensitive data, they are also treated carefully. If any personal sensitive data is given, special policies are used to ensure that the opinions cannot directly be associated with any individual.

The signed consent forms are kept securely by the Ethics and Data Protection Manager and a copy will be given to the data subject should it be requested. The SafePASS Ethics and Data Protection Manager reviews the consent forms on a regular basis and consults with the SafePASS partners, to check that the processing and purposes have not changed from what has been communicated to subjects. Data files collected during the research are anonymised irrevocably at the time of collection. As a result, it is not possible to link any data in the study to the participant.

On the consent forms and information sheets, there is an explanatory text, allowing the participant to contact the Ethics and Data Protection Manager, request access to their personal data or request rectification or erasure or restriction of processing of their personal data or object to the processing of their personal data. If such a request is received, the Ethics and Data Protection Manager informs the project Steering Committee, so that appropriate actions are taken. It is possible for a participant to request a copy of his/her personal data. If such a request is received, the Ethics and Data Protection Manager informs the project Steering Committee and the consortium provides the personal data in a structured, commonly used and machine-readable csv file for free.

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