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Guidance Sheet SMP12/G/02 Safety Cases During the Project Life Cycle

1 SAFETY CASE CONSIDERATIONS AT DIFFERENT STAGES

1.1 Concept Stage/Initial Gate Safety Case

1.1.1 During the production of the User Requirement Document (URD), the ECC and the PTL are to ensure that the safety requirements are identified and recorded in the developing Safety Case. At this early stage of the project, there will be little technical data available and the Safety Case will be in outline form, with the Risk Estimation being carried out for each business option on a functional basis. Safety assessment should test ideas embedded in initial requirements and identify hazards to facilitate safety-led design.

1.1.2 Each potential acquisition strategy may have a different safety philosophy and Safety Case. In particular, potential solutions may involve the acquisition of complete services rather than just equipments, and in these cases, the safety assessment must cover the whole service and not just the equipment design. By the end of the Concept phase, the PTL should have developed the project safety strategy in sufficient detail to demonstrate that: the safety risks are understood; the Safety Case can be properly managed throughout the remainder of the acquisition phases; and that key milestones and acceptable feasible high level safety targets have been identified. The PTL should describe these factors in a Safety Case Report in support of the Business Case seeking approval at Initial Gate.

1.1.3 There is likely at this stage in a programme to be a number of unknown factors, or areas that are not fully defined, the submission should identify these areas and the assumptions made, justifying the strategy for dealing with them as the programme progresses.

1.2 Assessment Phase/Main Gate Safety Case

1.2.1 The safety aspects of the Main Gate Business Case should be based on a Safety Case Report that updates and reviews the work done in the first iteration, based on improved knowledge of the options being followed. It should consider the Safety work undertaken on the possible solutions being followed, and argue the strength, and weaknesses from a safety point of view, for the recommended technical and acquisition option.

1.2.2 During the development of the SRD, the PTL is to ensure that the technical solutions under consideration are subject to a safety assessment, and that the strategies for achieving the safety requirements are documented. Preliminary safety assessments of each of the competing technical solutions, identifying the hazards and risks through life and the strategies for their control, are to be undertaken. The ECC and the PTL must then consider, the feasibility of meeting, or in accordance with the ALARP principle exceeding, the baseline safety criteria, for each of the potential technical solutions. The PTL should describe these assessments in Safety Case Reports in support of the Business Case seeking approval at Main Gate.

1.3 Demonstration/Manufacture and Trials Safety Case

1.3.1 The safety of the planned Demonstration phase tests and trials must be assessed and documented to justify embarking on the trials programme. In particular, prior to the commencement of significant trials phases, the safety of the planned trials must be addressed by Safety Case Reports.

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- 1.3.2 Test and Trials can form an important role in demonstrating the achievement of safety Requirements. PT Leaders have a duty of care to consider the risks associated with the conduct of the tests and trials they require. In particular, they should review circumstances that fall outside the assumptions regarding normal operation, so that the design intention/material state of the platform, system or equipment concerned is not compromised.
- 1.3.3 The Safety Assessment should influence how Safety requirements are demonstrated to be achieved. This might be through calculation, simulation, test, inspection, factory equipment test, user trails, with the optimum balance reflected in the Integrated Trials, Evaluation and Assessment Plan (ITEAP). The Safety Case should address the PT Leader's responsibilities for ensuring that sufficient instruction, guidance, training and resources are available and that all those with safety responsibilities clearly understand their duties (ie the SMS in operation during the trials is appropriate).
- 1.3.4 Where Contractors conduct trials the arrangements for limiting MOD's liability may be specified contractually. The PT Leader's representatives should ensure that the safety arrangements for attending MOD staff are adequate and that the arrangements for MOD's assets and of equipment it seeks to own are sufficient before each test or trial occurs (in accordance with the ITEAP). Such assurance will must be in place before any services personnel are contracted or co-opted for testing, approval or acceptance activities or whenever they assist in platform/system operation prior to its entry into service. Given the management complexity and the potential Hazards during Contractor Trials, it is considered best practice for PT Leaders to commission specific Safety Assessment and raise a Trials Safety Management Plan (TSMP) for such events, as part of, or cascaded from, the PSP and the ITEAP.

1.4 Safety Case for Introduction to Service

- 1.4.1 The Safety Case must be developed to support the introduction of the system to service. In particular, this must demonstrate that the prerequisites for continuing Safety during the in-service phase are adequate and in place. This could typically include aspects such as support facilities, training arrangements, competent Users and Maintainers, Logistic Support arrangements etc.
- 1.4.2 This Safety Case must be maintained throughout the in-Service life as changes are introduced to the design, the equipment's operation or the conditions under which it is used.

1.5 Disposal Safety Case

- 1.5.1 The safety risks related to planned or inadvertent disposal require consideration at the earliest stages of the programme to avoid designing into the equipment hazardous features such as materials or stored energy which cannot be recovered, disarmed or made safe when required.
- 1.5.2 It should be remembered that 'Disposal' also occurs throughout life (typically from the Demonstration phase onwards) as, for example, prototypes or test articles are no longer used, consumables are discarded, lubricants changed, parts are made redundant through wear or modification, repair schemes are implemented and accident damaged systems are made safe and recovered. The PTL must ensure that all eventual and through life disposal safety risks are addressed in the Safety Case for each phase; defining the procedures to be followed for the safe management of all disposal risks.
- 1.5.3 The PTL is to ensure that the Safety Case addresses decommissioning and disposal of the system or equipment. The Safety Case should cover:
- a. Disposal of hazardous materials.
 - b. Safe recovery and disposal, or neutralisation of the hazard if recovery is impractical, following an incident or accident.

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1.5.4 MOD is increasingly being expected to operate in an environmentally sustainable manner. PT Leaders should design for the disposal of systems and equipment, considering the increasing need to eventually recycle components. Systems sold at the end of life should comply with all current health, safety and environmental legislation and should not be sold in a condition that would be considered unacceptable for continued UK service.

1.5.5 The PT Leader remains responsible for ensuring that the disposal agent (eg Disposal Sales Agency) is informed of the relevant safety issues, prior to their joint agreement as to the best contractual route for disposal. Design Authorities are reminded that they may only transfer their responsibilities to a competent body.

1.5.6 A disposal Safety Case must therefore be created for systems sold for scrap as well as for those sold or transferred on loan for further use. In cases of loan or continuing use, the PT Leader should focus effort on confirming their contractual and legal obligations for safety in order to minimise MOD's liability for subsequent claims for compensation. Disposal customers may require evidence of a Safety Case.

Stage in Project	SCR Purpose	Authorise by PT Leader	Endorse after PTL Authorisation (not able to "Red Card")	Approval of Activity after PTL Authorisation (able to "Red Card")	Comments
Initial Gate	To demonstrate, through an adequate assessment of the capability being pursued, that the potential safety risks are understood and a strategy has been developed to control them.	After reviews by: 1. Stakeholders & Subject Matter Experts (Safety Panel) 2. Independent Safety Assessors (if relevant) 3. Independent Safety Auditors (if relevant) And taking account of their recommendations		None	IG submission contains short summary of SCR. Scrutineers examine Business Case only (not SCR itself). PTL should consult potential MOD Regulators (Naval Authorities & OSRP) and approval authorities under Stakeholder and SME review.
Individual Assessment Phase Option (Where necessary)	To document the Safety Feasibility for a specific Project Option	As above		None	PTL should consult potential MOD Regulators (Naval Authorities & OSRP) and approval authorities under Stakeholder and SME review. Document may conclude that the Option cannot be made tolerably Safe.

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Stage in Project	SCR Purpose	Authorise by PT Leader	Endorse after PTL Authorisation (<u>not</u> able to “Red Card”)	Approval of Activity after PTL Authorisation (able to “Red Card”)	Comments
Main Gate	To compare Safety of Assessment Phase options, identifying any Safety aspects which prevent an Option being taken forward. Demonstrates that the identified safety risks can be managed and controlled for the selected Option.	As above		None	MG submission contains short summary of SCR. Scrutineers examine Business Case only (not SCR itself). PTL should consult potential MOD Regulators (Naval Authorities & OSRP) and approval authorities under Stakeholder and SME review.
Demonstration Trials (Where necessary)	To demonstrate that specific Demonstration Trials using MOD facilities and/or personnel can be conducted with adequate and known level of Safety.	As above		MOD Trials Authorities	Only relevant where MOD provides Trials facilities or personnel (if MOD are only observers, they should be covered by Contractor’s SMS and Risk Assessments) PTL should consult potential MOD Regulators (Naval Authorities & OSRP) and approval authorities under Stakeholder and SME review.
System Acceptance	To demonstrate that System meets all Safety elements of URD and SRD.	As above		Equipment Capability Customer	SCR for System Acceptance
User Trials (where necessary)	To demonstrate that specific User Trials can be conducted with adequate and known level of Safety.	As above		Trials Authorities acting for Equipment User	
Safety Submission for Individual Hazard or Group of Hazards	To demonstrate for the System of interest that specific Hazards are managed in accordance with MOD Policy.	As above	Some Naval Authorities OME Safety Review Panel/MLSC	Some Naval Authorities	Subset of System Safety Case relevant to a specific Hazard or Group of Hazards. The OSRP and some Naval Authorities cannot “Red Card” Safety Case and prevent entry to service.
Introduction to Service (Release to Service) /Major Change (Whole System)	To demonstrate that complete System is Safe for Use within defined limits and necessary support elements (Including Disposal Strategy are in place to sustain Safe Operation through life.	As above	Some Naval Authorities OME Safety Review Panel/MLSC	Release to Service Authorities or Nuclear Regulator Platform authority Some Naval Authorities	The OSRP and some Naval Authorities cannot “Red Card” Safety Case and prevent entry to service. Platform authority may prevent System from being integrated onto his Platform, but not from entry to Service.
Disposal (where necessary)	To validate Disposal Strategy for “Out of Service”	As above		None	May be “Permissioning” Regulator for Nuclear systems

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