RA 5013 - Air Safety Management of Equipment and Commodity Items

Rationale

Equipment may be provided to support operation of an Air System. The organization providing the equipment is required to operate a Safety Management System (SMS)¹ which specifically supports the Type Airworthiness Safety Assessment (TASA)² and / or Air System Safety Case (ASSC)³ and which interfaces with adjoining Air Safety Management Systems (ASMS). An ineffective SMS and incomplete Safety Assessment are likely to compromise safe operation and Hazard management, which may undermine the ASSC and thus Air Safety. This Regulatory Article (RA) sets out the requirements for an independently assured equipment-specific SMS and Safety Assessment in support of a TASA and / or ASSC.

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Definitions

Definitions Relevant to this RA

1. ▶◀

Regulation 5013(1)

Air Safety Management of Equipment and Commodity Items

5013(1) The Commodity Chief Engineer (CE) **shall** be responsible for the Air Safety Management of the equipment.

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Air Safety Management of Equipment and Commodity Items

- The Commodity CE should hold a Letter of Air Safety Notification (LoAN) ►4.
- 3. ► The Commodity CE **should** develop, own and manage an SMS which is described in a Safety Management Plan (SMP) and meets the requirements of RA 1200¹. ◀
- 4. During the generation and management of the SMP, the Commodity CE **should** consult with all relevant stakeholders⁵.
- 5. The SMP **should** include:
 - a. Description of the Safety requirements, targets and attributes.
 - b. Detail on the scope and boundaries between the DT and all interfacing DTs and organizations.
 - c. Detail on the approach to establishing and maintaining safe equipment design.
 - d. Detail on the arrangements for effective integration and coordination with relevant Type Airworthiness (Taw) SMS⁶ or ASSC requirements.
 - e. Detail on the arrangements for effective integration and coordination with relevant Safety Management documentation generated by the Design Organization (DO)⁷ to cover their activities⁸.

¹ Refer to RA 1200 – Air Safety Management.

² Refer to RA 5012 – Type Airworthiness Safety Assessment.

³ Refer to RA 1205 – Air System Safety Cases.

⁴ Refer to RA 1003 – Delegation of Airworthiness Authority and Notification of Air Safety Responsibility.

⁵ ► Stakeholders, ► dependent on the phase of the project and approach to delivery, are likely to include the Senior Responsible Officer (SRO), Aviation Duty Holder (ADH), Accountable Manager (Military Flying) (AM(MF)), Defence Equipment and Support (DE&S) Operating Centre Director (OCD), Sponsor, ► relevant Type Airworthiness Authority (TAA), Type Airworthiness Manager (TAM) and Commodity CEs.

⁶ Refer to RA 5011 – Type Airworthiness Safety Management System.

⁷ The DO is required to develop an SMP in accordance with (iaw) Def Stan 00-056.

⁸ Refer to RA 1014 – Design Organizations and Co-ordinating Design Organizations – Airworthiness Responsibilities.

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- Detail on the approach to delivering and sustaining equipment Safety through proactive Integrity Management ▶9◀ and reactive Fault and Occurrence investigation.
- The approach to Configuration Management, Air System Document Set management¹⁰, Air Safety Data Management and Exploitation¹¹.
- The approach to Assurance and review of Safety Management activities, including Quality Management Systems, Independent Technical Evaluation ▶12◀, Independent Safety Auditing^{▶12} and independent review of publications.

Hazard Management Process

- As part of the SMP, the Commodity CE should implement a process to identify and review all Hazards within scope of the SMP.
- The Hazard management process should account for Hazards identified through certification activity, in-service civil or military usage, and any emerging Hazards.
- The Hazard management process should be conducted in conjunction with the relevant TAA / TAM►13◀, in line with the recognized principles of Risk Management1⁴.
- As a subset of this Hazard management process¹⁵, when a Hazard is identified that may lead to a Risk to Life (RtL)16, the Commodity CE should communicate this to the relevant TAA / TAM¹⁷ and / or the ADH / AM(MF). In either case, formal acknowledgement should be obtained.

Safety Panel

- The Commodity CE **should** establish and chair a Safety Panel every 6 months, with the appropriate stakeholder attendance, to coordinate and manage the SMS. The Safety Panel should review the continued validity of the Safety Assessment Report and the sufficiency of supporting products¹⁸.
- 11. The Commodity CE **should** ensure that the Safety Panel:
 - Reviews Hazard management activities and ensures ADH / AM(MF) agreement that Hazards which may lead to a RtL have been communicated.
 - Reviews relevant design changes¹⁹ for impact on activities within the SMP.
 - Provides advice, depending on the phase of the project, to the appropriate SRO, Operating Duty Holder (ODH), AM(MF), TAA, TAM and their staff in support of the ASSC.
 - Reviews independent evaluation and Assurance activity. d.
 - Reviews Fault Reporting²⁰, Occurrence Reporting²¹, Data Exploitation¹¹ and Air System Integrity Management activity¹⁷, including the impact of changes to the Air system Statement of Operating Intent and Usage (SOIU).

⁹ ► Refer to RA 5726 – Integrity Management. ◀

¹⁰ Refer to RA 1310 – Air System Document Set.

¹¹ Refer to RA 1207 – Air Safety Data Management and Exploitation.

¹² ► Refer to – https://www.gov.uk/guidance/knowledge-in-defence-kid. https://www.gov.uk/guidance/knowledge-in-defence-kid.

¹³ Where the Air System is not UK MOD-Owned, ownership of regulatory responsibility by either the TAA or TAM needs to be agreed within the Sponsor's approved model for TAw management; refer to RA 1162 – Air Safety Governance Arrangements for Civilian Operated (Development) and (In-Service) Air Systems, or refer to RA 1163 – Air Safety Governance Arrangements for Special Case Flying Air Systems. Dependant on the agreed delegation of TAw responsibilities the TAM or Competent organization supporting the TAM may be read in place of Delivery Team (DT) as appropriate throughout this RA.

¹⁴ Refer to Manual of Air Safety (MAS), Figure 4 – The Risk Management Cycle.

¹⁵ RA 1210 specifically excludes damage to assets where no injury results, but Hazards leading to such damage still require management.

¹⁶ Refer to RA 1210 – Ownership and Management of Operating Risk (Risk to Life).

¹⁷ Where the Safety Assessment supports the TASA.

¹⁸ Refer to RA 5013(2): Air Safety Assessment of Equipment and Commodity Items.

¹⁹ Refer to RA 5305(2): In-Service Design Changes – Safety.

Refer to RA 5825 – Fault Reporting and Investigation.
Refer to RA 1410 – Occurrence Reporting and Management.

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- f. Reviews the Support Policy Statement (SPS) or information contributing to the Air System SPS²².
- g. Co-ordinates the SMP.
- 12. Regardless of whether equipment or commodity items are discussed within the Type Airworthiness Safety Panel associated with the organization receiving the equipment, the Commodity CE **should** still conduct their own Safety Assessment review through a separate Safety Panel.
- 13. To support the Safety Panel, the Commodity CE **should** ensure they are suitably represented at equivalent DO Safety Management meetings²³.
- 14. The Commodity CE **should** ensure either that a Commodity SPS²² is produced, or that the required information is provided to support the Air System SPS.

Independent Audit

15. The Commodity CE **should** ensure that the SMS and its outputs are subjected to Audit iaw Def Stan 00-056, by a Competent and suitably qualified Independent Safety Auditor (ISA), independent of the outcome or processes they are reviewing.

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Air Safety Management of Equipment and Commodity Items

- 16. A Commodity DT SMS ▶ must ◀ appropriately address the requirements of RA 1200¹. RA 5013(1) contains specific requirements for a Commodity DT SMS, which augment and complement the standing requirements of RA 1200.
- 17. Where the TAM has regulatory responsibility for the Air System, they are expected to ensure appropriate SMS arrangements, including the management of Hazards, are in place to meet the requirements of RA 1200 for commodity items not provided by a DE&S Commodity DT.
- 18. A TAw Strategy is not mandated for equipment and commodity items, but there is a requirement for the SMP to detail how it interfaces with the Air System TAw SMS⁶ and / or the ASSC³.

Hazard Management Process

- 19. The Commodity CE is expected to manage a variety of Hazards. A subset of this Hazard management activity is the management of Hazards associated with RtL, which require management at ADH / AM(MF) level. In these cases, the Commodity CE will communicate this to the TAA / TAM¹⁷ or ADH / AM(MF) for formal acknowledgement and a decision on Tolerability.
- 20. The recording of Commodity DT Hazards is best achieved through a Hazard Log that supports the legal requirement for an ADH / AM(MF) to ensure that Risk Assessments are carried out¹⁶. Hazard attributes will, therefore, need to complement their standardized approach to managing RtL.
- 21. A Hazard Log accounts for Hazards, a subset of which contribute to RtL. It is expected to incorporate information from a number of Hazard data sources.
- 22. Where Hazards are managed by external organizations, the Hazard Log will need to incorporate information resulting from clear and robust interfaces with these organizations.
- 23. The Hazard Log may need to absorb information on transient / emerging Hazards, due to DE&S driven Occurrence / Fault investigations, global Faults which have not yet been addressed by appropriate mandatory, advisory and deferred instructions, or proactive investigations identified through Integrity Management activity. This allows the transient Hazard to be assessed and communicated to the TAA / TAM¹⁷, SRO, ADH or AM(MF).

²² Refer to RA 5407 – Support Policy Statement.

²³ Such as a DO Project Safety Committee (PSC).

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Safety Panel

- 24. A Commodity CE may choose to group multiple similar equipment types into one Safety Panel or hold standalone Safety Panels, providing each equipment or commodity item is reviewed every 6 months.
- 25. The Safety Panel will include representatives from the following areas as appropriate:
 - a. The Commodity DT (technical, contracts and finance officers as required).
 - b. Other relevant TAA, TAM or Commodity CE.
 - c. Front Line Command Capability Organization.
 - d. Continuing Airworthiness Management Organization.
 - e. Release To Service Authority.
 - f. ADH and AM(MF).
 - g. Co-ordinating Design Organization (CDO) / DO.
 - h. The appropriate Test and Evaluation organization.
 - i. Defence Aircrew Publications Squadron (DAPS) or Competent appointed contractor.
 - j. ISA.
 - k. DE&S Operating Centre Safety Team.
 - I. Specialist advisers where appropriate.
- 26. SRO, ADH, AM(MF), TAA or TAM involvement with the Safety Panel will vary dependant on project phase; for each phase the relative role of the Commodity CE, TAA, TAM, SRO, ADH or AM(MF) will need to be described in the SMP, and when appropriate, in an Internal Business Agreement.
- 27. To support the Safety Panel the Commodity CE may establish one or more Working Groups (WGs) (proportionate to the scale of the Project). Possible examples include a WG to assess Hazards or review the integrity of specific systems.

Independent Audit

- 28. ISA Assurance will cover such activities as (but not limited to) the Safety Panel and supporting products, Commodity DT organizational processes, and DO Safety Management documentation.
- 29.
- 30. Def Stan 00-056 states that the appointment of an ISA will be at the sole discretion of the MOD. Early appointment will allow the ISA to engage with the DO and better assess early versions of the SMP, assist with tendering and provide Safety advice throughout the project's life. The ISA could also provide generic Safety advice about the SMS to the DT, the DO and other stakeholders.
- 31. It is acceptable for the ISA and Independent Technical Evaluator (ITE)¹⁸ to be involved in the joint working environment between the Commodity DT and DO; for example, in a Hazard Log WG or in a Combined Test Team approach. Duplication of effort will be avoided if the ISA and ITE work collaboratively with the MOD and DO so that their assessments can be incorporated in the overall project schedule.
- 32. It is important that the ISA and ITE work is conducted on behalf of the Commodity CE and that any advice they may have about the design and / or Safety is directed to them.

Regulation 5013(2)

Air Safety Assessment of Equipment and Commodity Items 5013(2) The Commodity CE shall own and manage a Safety Assessment.

Acceptable Means of Compliance 5013(2)

Air Safety Assessment of Equipment and Commodity Items

- 33. The Commodity CE **should** initiate and maintain a Safety Assessment for each equipment or commodity item they are responsible for²⁴.
- 34. The scale of Commodity CE Safety Assessments **should** be proportionate to the Hazards and the level of RtL presented by the particular equipment.
- 35. Each Safety Assessment **should** consist of a claim (or number of claims), a structured and explicit argument, and supporting body of evidence, that together provide a compelling, comprehensible and valid case which supports the host Air System TASA and / or the ODH / AM(MF) ASSC.
- 36. The Commodity CE **should** ensure that the Safety Assessment:
 - a. Defines the approved Configuration and operating environment for the equipment to which it applies, referencing the appropriate Air System SOIU where applicable¹⁰.
 - b. Describes the Safety requirements, targets and attributes.
 - c. Provides a justification for the design standards chosen for use, and demonstration of compliance, supported by Safety analysis iaw the Def Stan²⁵.
 - d. Identifies the limitations and procedures²⁶ necessary to achieve the required level of Safety for the subject Configuration.

Safety Assessment Reports

- 37. The Safety Assessment **should** be summarized periodically in a Safety Assessment Report, communicated to and acknowledged by the TAA / TAM and / or ODH / AM(MF) accordingly.
- 38. The Safety Assessment Report **should** be produced to support the initial Approval of the relevant TASA and / or ASSC³.
- 39. The Safety Assessment Report **should** be updated as a complete new issue:
 - a. At least every 5 years.
 - b. Following a change which drives a Major Type Design Change (TDC) to the Air System²⁷.
 - c. Additionally, as determined by the Commodity CE or requested by the related TAA and / or TAM.
- 40. For all other equipment changes, the Safety Assessment Report **should** be reviewed and updated with an Addendum to the previous Report, ensuring that the content of the addendum does not alter the validity of the claims, arguments and evidence within the Safety Assessment Report main body.
- 41. The Commodity CE **should** make a declaration regarding the validity of the Safety Assessment and any addenda at the Safety Panel. If this declaration cannot be made, then a new issue of the Safety Assessment Report **should** be produced.

Independent Evaluation and Audit

42. The Commodity CE **should** ensure that the Safety Assessment is subjected to evaluation by a Competent and suitably qualified ITE, independent of the outcome or processes they are reviewing, and recognized by the Commodity CE as a SME in the field which is being reviewed.

²⁴ These include items being installed in the Air System as part of the Type Design (see RA 5810 – Military Type Certificate (MRP Part 21 Subpart B) / RA 5305 – In-Service Design Changes), Aircrew Equipment Assemblies etc that are required to be worn to comply with Type Design requirements, and items which may be carried on to support delivery of the capability (see RA 1340 – Equipment Not Basic to the Air System).

²⁵ Refer to Def Stan 00-056 – Safety Management Requirements for Defence Systems.

²⁶ Including where appropriate reference to the Support Policy Statement. Refer to RA 5407 – Support Policy Statement.

²⁷ Agreement for the use of the addendum procedure can be gained from the MAA as part of the Form 30 process. Refer to RA 5820

⁻ Changes in Type Design (MRP 21 Subpart D).

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43. The Commodity CE **should** ensure that the Safety Assessment is subjected to Audit iaw Defence Standard (Def Stan) 00-056, by a Competent and suitably qualified ISA, independent of the outcome or processes they are reviewing.

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Air Safety Assessment of Equipment and Commodity Items

- 44. The Safety Assessment will need to be treated as Airworthiness information²⁸.
- 45. Before completing the Safety Assessment, the Commodity CE will need to understand the context in which the assessment will be used by the TAA / TAM or ODH / AM(MF). The TAA / TAM may use the Safety Assessment to support the Type Design assessment or to enable the use of Equipment Not Basic to the Air System (ENBAS).
- 46. The Commodity Safety Assessment, such as for a life raft, may be incorporated within the TASA alongside a number of Commodity items, in addition to integration information and Configuration Control activity. However, some Commodity DTs may provide assets directly to the ODH / AM(MF), such as a Portable Electronic Device (PED). In these cases, the Safety Assessment, integration and Configuration Control activity is provided to the ODH / AM(MF) and incorporated directly in the ASSC. This relationship of artefacts is shown in Figure 1²⁹.

ASSC Claim Other Element Other Element Other Element Safety of ASSC of ASSC Assessment of ASSC & Report Independent Technical Commodity Evaluator (ITE) Auditor (ISA) CE Safety Assessment & Report TAA Commodity DAPS Safety DO Safety CE Safety and/or Assessment Assessment TAM Assessment & Technical Evaluator Safety Auditor (ISA) Artefacts Report Independent Technical Evaluator (ITE) Independent Safety Auditor (ISA) DO Safety Chief Engineer Assessment Artefacts DO Safety Chief Engineer Assessment Artefacts

Figure 1. Relationship of ASSC

- 47. A Safety Assessment may be produced for an individual equipment or commodity item, or may be provided as combined Safety Assessment for multiple items, in order to be appropriate and proportionate to the level of RtL presented by the particular equipment.
- 48. When scaling the proportionality of a Safety Assessment, any assessment on the level of RtL will be made in consultation with all relevant TAA / TAM and ADH / AM(MF) accordingly.
- 49. Whether a Safety Assessment is for one or more item, there is a requirement for clear articulation on the extent of the clearance, and the limitations for use relating to specific Air Systems or roles.

²⁸ ► Refer to RA 1225 – Air Safety Documentation Audit Trail. <</p>

²⁹ A Safety Assessment provided by DAPS is an example of an appropriate independent operator evaluation.

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Safety Assessment Report

- 50. The scale of a Commodity CE Safety Assessment Report will be proportionate to the Hazards and the level of RtL presented by the particular equipment.
- 51. The initial Safety Assessment Report supports the ASSC (in some cases via the TASA) to enable activation on the military register. The Safety Assessment Report does not then require reissue prior to each ASSC review, but a valid Safety Assessment Report, reviewed at the Safety Panel, provides the basis for the input to the TASA and / or ASSC.
- 52. When an existing equipment or commodity item is being provided to a new Air System, the Commodity CE may choose (or be requested) to update an existing Safety Assessment Report as a complete new issue, to demonstrate current Safety Assessment activity to the TAA and / or TAM.
- 53. In addition to the requirements listed in this RA, the Commodity CE may choose to update the Safety Assessment Report with an Addendum, including a declaration that the content of the Addendum does not alter the validity of the claims, arguments or evidence within the Safety Assessment main body. Such an update may be required following counter-evidence identified through Fault Reporting and Data Exploitation activities¹¹, or a change of information from Safety Panel review or other source of evidence, as long as the circumstances are not listed in this RA as requiring a complete new issue.
- 54. If a proposed change drives a Major TDC to the Air System, but has minimal impact to the Safety Assessment Report, the Commodity CE may request the Safety Assessment for the change is captured in an addendum rather than a re-issue of the report. This request will be submitted by the relevant TAA / TAM as part of the Form 30 process²⁷.
- 55. The guidance provided within Def Stan 00-056 may be regarded as one method of achieving a suitable Safety Assessment Report structure.

Safety Analysis

- 56. The Commodity CE will need to ensure that, where applicable, the Safety Assessment:
 - a. Addresses any differences in the operating environment and usage from those in the certification basis of the Competent certifying body.
 - b. Addresses the Risks and mitigations of not complying with UK legislation and standards.
- 57. Safety analysis will be carried out on new equipment and subsequent changes, in support of claims and arguments within a Safety Assessment, by the equipment DO, or by specialist agencies contracted by the Commodity DT.

Commercial Off The Shelf (COTS) Systems and Software

- 58. The Commodity CE for projects involving the use of COTS systems or software will need to ensure that the Safety Assessment contains an adequate Safety justification for the COTS components.
- 59. Guidance on the Safety Assessment of COTS systems is contained in Def Stan 00-056²⁵. Guidance on the assessment of Programmable Elements of Unknown Pedigree is available within the Knowledge in Defence portal ▶12◀. Ultimately, Def Stan 00-970³⁰ refers to acceptable standards for Programmable Elements.

Independent Evaluation and Audit

- 60. ITE Assurance will consist of independent analysis of the evidence supporting the Safety Assessment, including, where appropriate³¹, a qualitative assessment of Air System handling, Human Machine Interface (HMI) and crew workload.
- 61. Care will need to be taken to ensure that independent Auditing of the Safety Assessment is undertaken by demonstrably Suitably Qualified and Experienced

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³⁰ Refer to Def Stan 00-970 – Certification Specifications for Airworthiness.

³¹ As decided by the SRO or receiving ODH.

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Person(s) or organization(s) that are not unduly influenced by commercial, peer or rank / status pressures.

- 62. Multiple ITEs may be employed to provide evaluation of different aspects of a Safety Assessment.
- 63. Where a contractor is employed as ITE, it is important that this is exclusively by the Commodity CE to act on their behalf and not via the Prime Contractor and / or DO; with any advice the ITE may have about the design and / or Safety directed to the Commodity CE. It is noted that if the MOD has the required Competence, and based on the level of acceptable Risk, then this independent technical evaluation could be provided from within the MOD.
- 64. It is acceptable for the ISA and ITE to be involved in the joint working environment between the DT and DO; for example, in a Hazard Log WG or in a Combined Test Team approach. Duplication of effort will be avoided if the ISA and ITE work collaboratively with the MOD and DO so that their assessments can be incorporated in the overall project schedule.