Submitted by the OPI on Safety Assessment provisions

Document ADS-04-08 4th ADS IWG session 8-11 October 2024

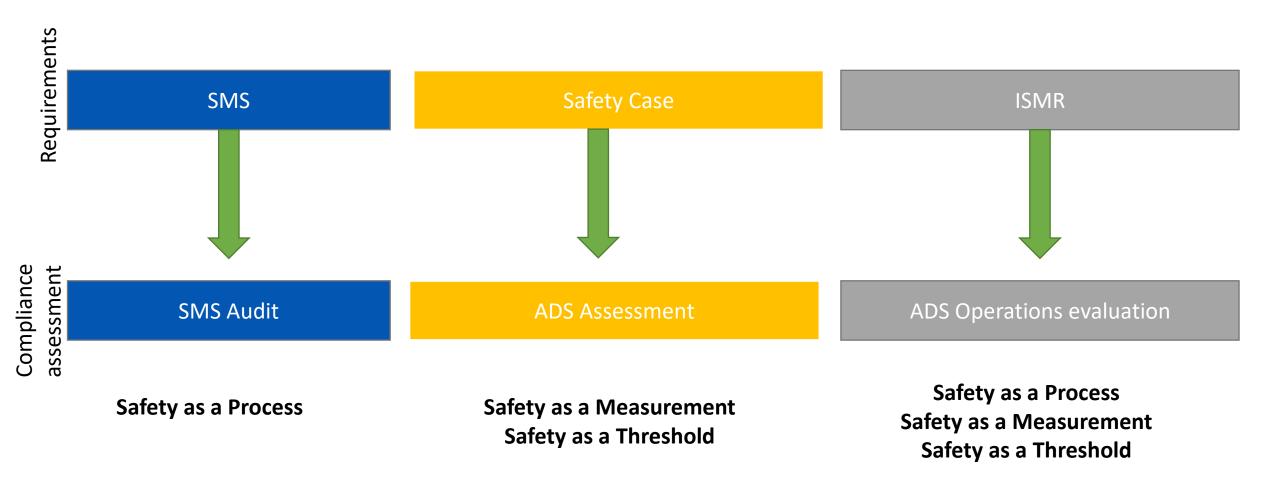
ADS Regulation Structure

Moving from Guidelines to Regulation

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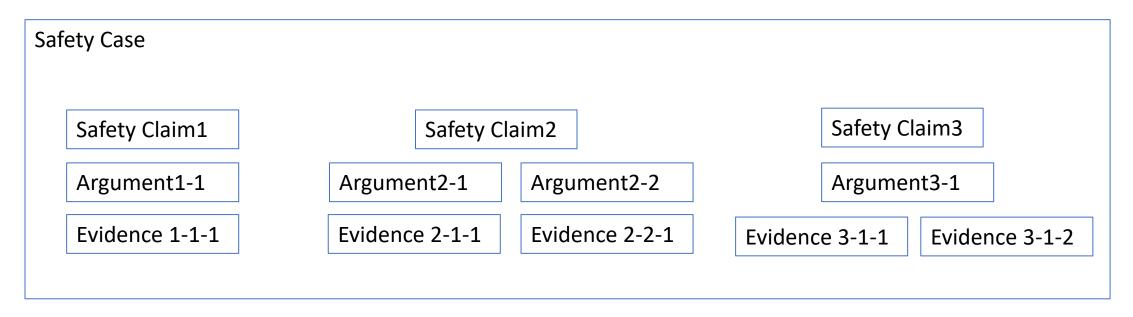
- Many recommendations developed in parallel
- No clear line between what the manufacturer or authority do
- How to treat safety assessment?
 - Some overlap in requirements
 - Different methods to assess each group of requirements
 - How to link assessment methods to requirements?

Requirements vs Compliance Assessment



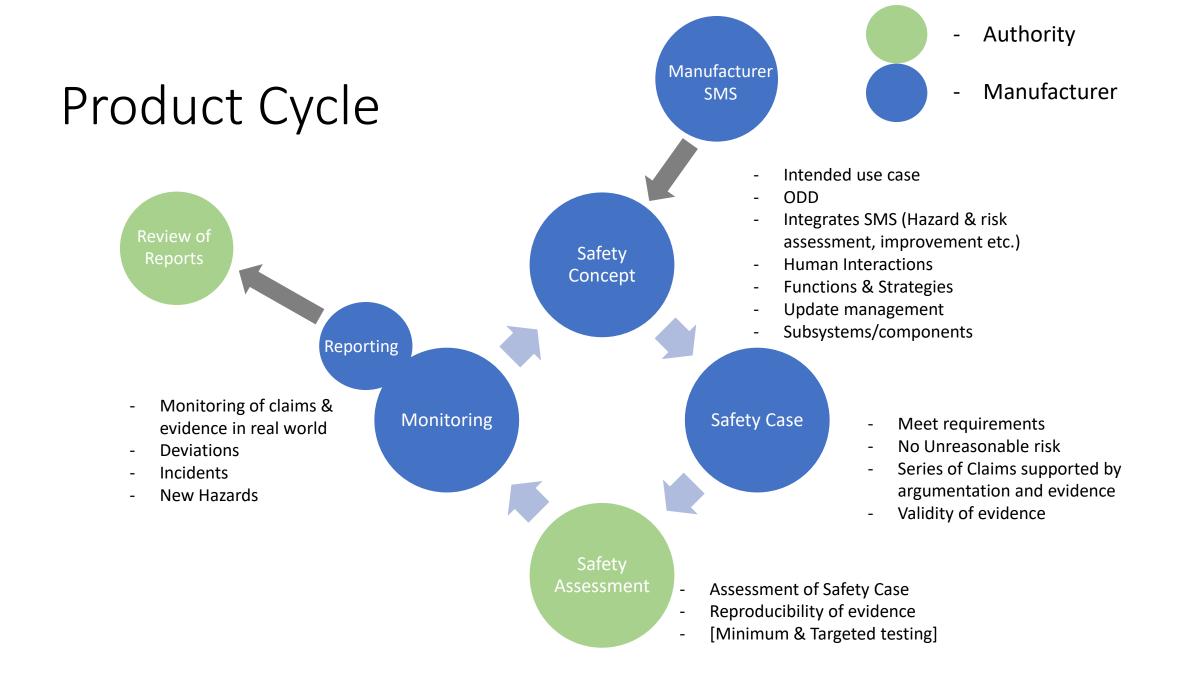
Holistic Approach to the Regulation

 "Safety case" means a structured argument supported by a body of evidence that provides a compelling, comprehensible, and valid case that the ADS is or will be free from unreasonable risk for a given application in a given environment. (Already required in the document by 5.4.4.1)

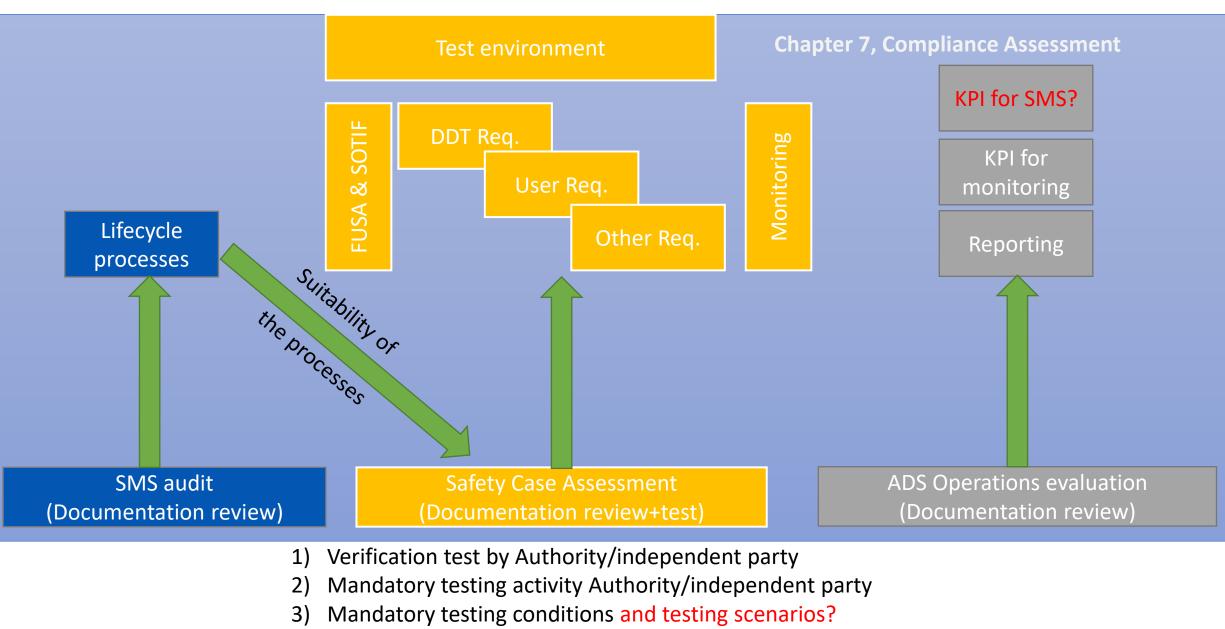


Most Requirements Could Be Claims In A Safety Case – Harmonized approach

- Regulators:
 - Write requirements how claims, arguments and evidence are provided
 - Include minimum set of functional requirements to be addressed
- Based on their safety concept & ODD, manufacturers create:
 - Safety claims (e.g. meet requirement X)
 - Arguments for those claims (e.g. analysis, diagrams)
 - Supporting evidence (e.g test results)
 - Implement a process for in-service monitoring of claims/hazards & updating
- "Authorities":
 - Verify through auditing: claims, arguments and evidence are sound and complete
 - Verify repeatability of claimed evidence through testing
 - Conduct minimum and targeted testing



Compliance assessment



Current vs Proposed structure

- Purpose ٠
- Scope
- Definitions
- **General Requirements** ٠
 - SMS
 - ADS Performance of the DDT ٠
 - ADS Interaction with users ٠
 - Safety Assessment ٠
 - In service monitoring and reporting
- Requirements/Specifications ٠
 - SMS
 - ADS Performance of the DDT ٠
 - Interactions between users and ADS ٠
 - Safety Assessment ٠
 - Cybersecurity and Software updates management ٠
 - Data Storage System ٠
 - In service monitoring and reporting Assessment and Test Methods
- - ٠ Audit
 - Virtual Testing ٠
 - Track •
 - Real-World •
- Annexes

- Purpose
- Scope
- Definitions
- [Documentation/General] Requirements
 - General
 - Safety Management System
 - Safety Case
 - Demonstrate ADS meets requirements
 - Demonstrate ADS is free of unreasonable risk
 - Reporting
 - Other Documentation •
- **Requirements**/Specifications
 - SMS processes applied to ADS ٠
 - ADS performance of the DDT
 - Absence of unreasonable risk
 - ADS interaction with users
 - ٠ Cybersecurity
 - Data storage system ٠
 - Software updates
 - Credibility & suitability of tools (Test Environment)
 - Monitoring of in-service performance
- Reporting
 Compliance Assessment
 - Audit of SMS
 - Safety Case (Claims, Arguments & Evidence are sound & complete)
 - Reporting system
 - Conditions for Track and Real-world testing
 - Verification tests (reproducibility of some safety case evidence)
 - Other tests (minimum mandatory/targeted) •
- Annexes