

Progress of the Safety Assessment workstream

Initial review

- Modification of text from guidance to requirements (Brussels)
- Mix of requirements aimed at manufacturer & authority
 - Unclear process to follow to assess safety
- Continuity issues in text due to development in parallel
 - Overlapping/conflicting requirements
 - Requirements repeated with different formulation
 - Multiple kinds of requirements (broad, specific, different subject matter) in same paragraph

Review of process (How to do a safety assessment)

- Safety Case approach highlighted in several existing paragraphs
- Confusion of terms used – clarified after discussion, essentially:
 - Safety Case – comprehensive document with structure claims supported by arguments and supporting evidence
 - Safety Concept – a part of safety case that explain how the ADS was designed with safety in mind
- Manufacturer builds Safety Case – “Safety Case” (Phase 1)
- Assessor (Authority) assesses Safety Case – “Assessment of the Safety Case” (Phase 2)

Moving towards Safety Case & Assessment

- Modifications to paragraphs and ordering required to:
 - Clarify safety case-based approach
 - Split requirements for manufacturer (build safety case) from authority (assess safety case)
 - Align requirements in safety case or safety concept
 - Clean up continuity issues

Phase 1 – Safety Case

- With safety case process in mind and requirements extracted from paragraphs, develop appropriate structure
 - Draft structure complete
- Use existing text as baseline with additional text to be developed for gaps
 - Underway
- Key Gaps:
 - Process to update ADS software & Safety Case based on monitoring
 - General approach for software updates needs to be clarified (internal processes vs assessment – UNR156) – further discussions/OPI? required for this topic
 - How to present the Safety Case
 - Requirements for traceability & facilitating assessor's task
 - General requirements for generation of Claims, Argumentation & Evidence

Phase 2 – Assessment of Safety Case

- Focus is on role/task of assessor
 - Review of documentation
 - Testing (testing OPI?)
- New text will have to be developed, guideline document scan required to identify potential source paragraphs
- Work to begin after Phase 1 complete