

Implementing Commercial Grade Item Dedication Guidance

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When is commercial grade item dedication guidance implemented?

- When Appendix B controls alone are not being used to assure the item meets applicable design requirements

Condition	Supplier	Licensee
Design requirements and acceptance criteria are not known (safety function and FMEA are used to establish “critical characteristics”)	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Design requirements and acceptance criteria are known and become critical characteristics (desire to document acceptance using dedication)	<input checked="" type="checkbox"/>	

Implementation challenges

- Dedication “at the level of supply”

- It is possible to dedicate at the device or component-level
- A replacement part sold “stand alone” may require a different acceptance method (dedication) than a part sold installed in a completed assembly.
 - Valve stem sold alone versus sold as part of an entire valve

- A completed and accepted design (including seismic and environmental qualification) is required prior to beginning the commercial grade dedication process

- Dedication is not a substitute for establishing suitability of design or qualification
- Suitability of design and qualification can not be established during the dedication process

Implementation Challenges

- Dedication must be performed by a dedicating entity with an Appendix B-compliant QA program
 - Delegating acceptance activities such as testing to commercial sub-tier suppliers may require separate technical evaluations to dedicate commercial-grade services
- Licensee review of supplier dedication evaluations may be appropriate
 - Uncertainty about safety function upon which the technical evaluation is based (not based upon known design requirements for the item)
 - Known challenges / issues
 - First-of-a-kind dedication
- Commercial grade surveys must be based upon critical characteristics & specific controls over those characteristics

Documenting the technical evaluation & acceptance plan

- Provide basis statements that explain how the critical characteristics are related to safety function(s) and failure modes,
 - Particularly important when design requirements are not known
- Document the source of critical characteristic acceptance criteria
- Document engineering judgements – explain reasoning applied to reach conclusions



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Questions?



A world map is centered on the slide, showing the continents of North America, South America, Europe, Africa, Asia, and Australia. The map is overlaid with a white grid of vertical and horizontal lines, creating a coordinate system across the globe. The map itself is a light blue color, contrasting with the dark blue background of the slide.

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