Anforderungsmanagement – im Kontext der neuen MDR

- There is a way to increase engineering efficiency

„When the pitch mode is FLCH or TOGA, or the airplane is below 400 feet above the airport on takeoff, or below 100 feet radio altitude on approach, the autothrottle will not automatically activate."

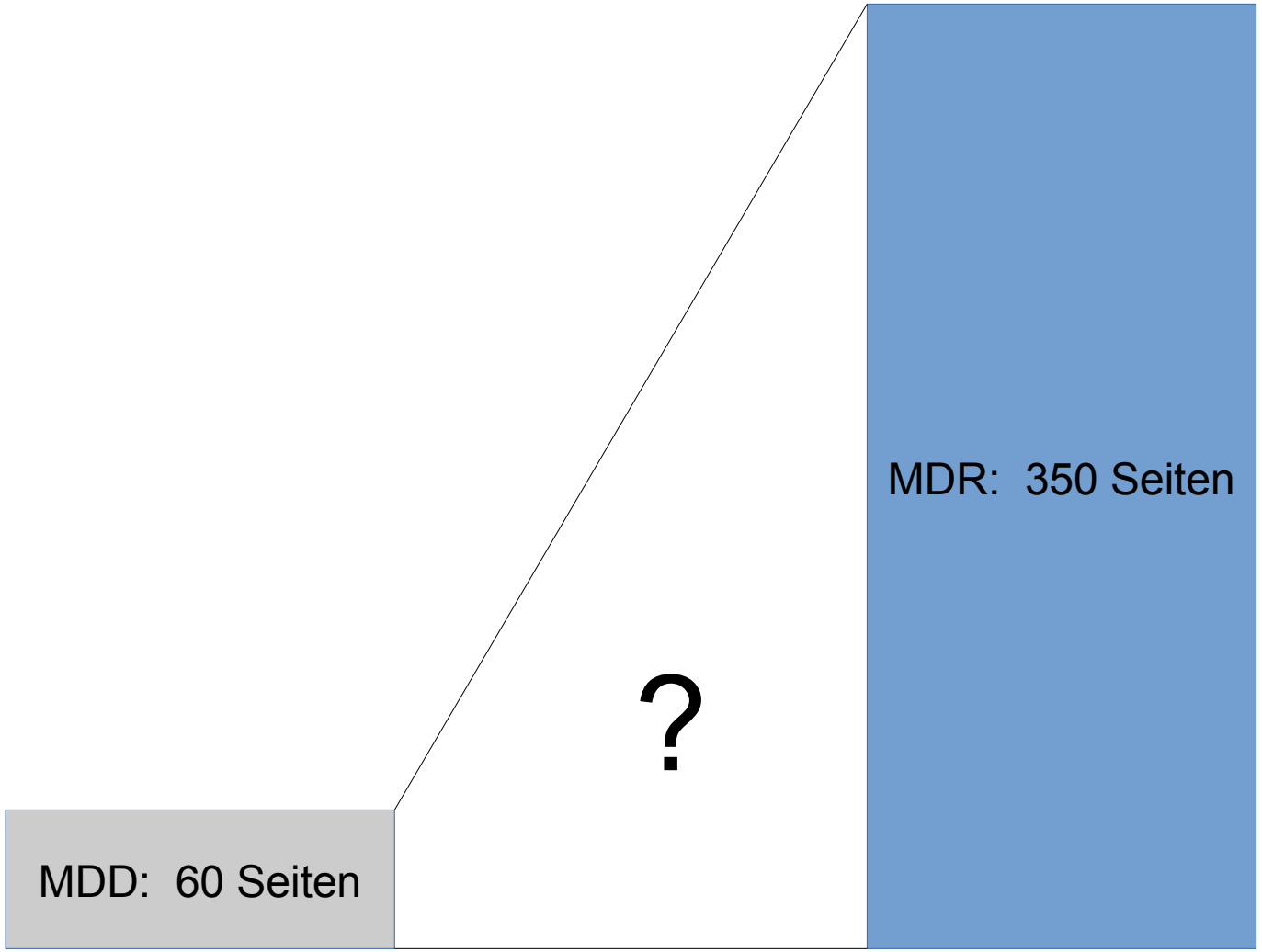
Flight Controls - System Description

QATAR AIRWAYS

777 Flight Crew Operations Manual

The autothrottle can support stall protection if armed and not activated. If speed decreases to near stick shaker activation, the autothrottle automatically activates in the appropriate mode (SPD or THR REF) and advances thrust to maintain minimum maneuvering speed (approximately the top of the amber band) or the speed set in the mode control panel speed window, whichever is greater. The EICAS message AIRSPEED LOW is displayed.

Note: When the pitch mode is FLCH or TOGA, or the airplane is below 400 feet above the airport on takeoff, or below 100 feet radio altitude on approach, the autothrottle will not automatically activate.


MDR: 350 Seiten
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MDD: 60 Seiten

Ein Ausschnitt aus der MDR:

Union legislation, in particular Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004 8 and Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells9, is incomplete in respect of certain products manufactured utilising derivatives of tissues or cells of human origin that are non-viable or are rendered non-viable. Such finished products utilising those derivatives should come under the scope of this Regulation, provided they comply with the definition of a medical device, or are covered by this Regulation.

Conventional Path for Compliance

The steps commonly exercised for achieving compliance to a specific standard or regulation are:

1. Identify the relevant chapter
2. Read the original text
3. Decompose original text into meaningful parts
4. Understand the decomposed text and the implications
5. Define verifiable activities resulting from the decomposed text
6. Validate the activities
7. Document the results
8. Create traceability

- To complete these steps it takes between 120-160 hours for one person for a standard, such as ISO-13485.
- 70% of the time are consumed between step 2 and step 5.
- This usually is done individually in each company.

Semantische Analyse einer Sicherheitsanforderung

Subject Predicate Object Parameter Condition

(1.1.1) For the scenario “one door is unlocked (with train crew not correctly informed of this door status)” in inappropriate areas (e.g. wrong side of train), it shall be demonstrated that the risk is controlled to an acceptable level, considering that the functional failure has typical credible potential to lead directly to “single fatality” for units in which passengers are not supposed to stay in standing position in the door area (long distance).

Auch in der MDR gilt:

- Wer
- Was
- Womit
- Welcher Qualität
- Welche Bedingungen

… in der Verantwortung auch der benannten Stellen

Wie planen Sie die Umstellung auf die neue MDR?

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