



# Regulators expectations of the demonstration of equivalent level of safety

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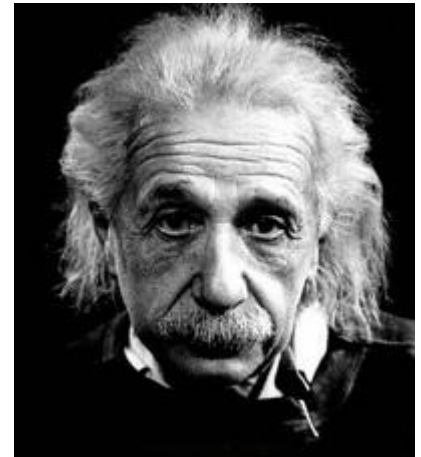
# Using FRM to Demonstrate Equivalent Level of Safety under EASA Subpart FTL

- Demonstrate of an understanding of the regulations
- Detail all the considerations when developing a safety case
- Relevant level of evidence and a detailed plan for assurance



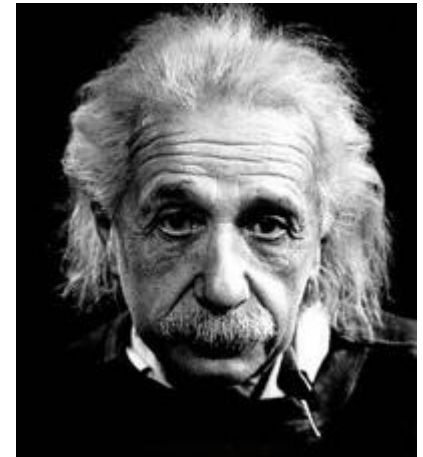
# It's Simple, or is it?

- Write down the issue
  - Think about it
  - Write down the answer
- 
- “If I had an hour to solve a problem I'd spend 55 minutes thinking about the problem and 5 minutes thinking about solutions.”  
— [Albert Einstein](#)



# Well maybe not so simple

- “Fatigue” can be tricky to measure
- **Need a variety of measures**
- Some measures require specialist knowledge
- Fatigue needs to be measured as part of an FRM to:
  - Identify times of higher fatigue risk
  - Monitor effectiveness of mitigations
- Continuous review process required



# Questions an Operator will be asked

- What is your understanding of the regulations?
- What is your understanding of how the regulations work in your operation?
- Why you believe that you can demonstrate through a safety case that what you are planning to do provides at least the same or a better level of safety?
- What are you going to do to demonstrate that it actually does achieve the predicted level of safety in your operation?

# Philosophy behind the Operator Responsibilities ORO.FTL.110

## Remember:-

- Prescriptive Limits alone cannot effectively control fatigue risk, since the causes of fatigue are not directly addressed
- The single day perspective needs to be widened to a consecutive duty perspective, taking into account cumulative effects of sleep loss, circadian factors, wakefulness and workload.

# Core Principles to be managed

Sleep Loss

Extended Wakefulness

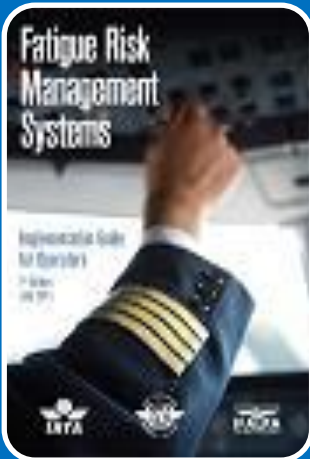
Circadian Phase

Workload



## FRMS Manual for Regulators

- Explains the intent of the SARPs
- **Provides scientific background**
- Explains the minimum requirements in Appendix 8
- Discusses approval and oversight of FRMS



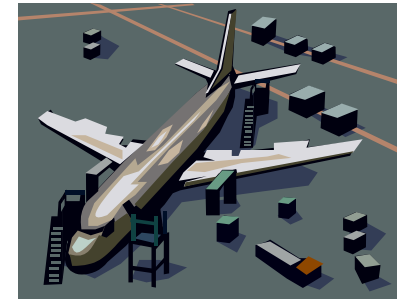
## FRMS Implementation Guide for Operators

- **Summarises supporting science**
- Explains the minimum requirements in Appendix 8
- **Describes how to implement an FRMS**
- Provides examples of various means of compliance



# Workload – Task related considerations

- The mental or physical demand
- Environmental conditions
- Airports
- Aircraft
- Experience
- Facilities for support
- Type of operation



# Establishing a baseline

- Comparison must be made to the EASA Subpart FTL regulations
- Which includes all elements of operators responsibility
- Demonstrate knowledge of operational context
- Demonstrate knowledge of known responsibilities
- Demonstrate stakeholder engagement process

# First steps

- Needs to be methodical
- Clear language
- Remember data is not the same as information – data drives the process when it is processed into something that is meaningful and useful (relevant to the case being presented)
- Do you need support from a Subject Matter Expert (internally and / or externally)?

## Project Plan

## BACKGROUND

## Research

# Questions the NAA will ask themselves

- Has the operator demonstrated they have been able to collect meaningful data and translated it into useful information?
- Have the scientific principles been used appropriately?
- What has been the benchmark to establish the equivalent level of safety?
- Is the baseline scenario reasonable?
- Are all the statements supported by evidence?
- Does the evidence support the claims?
- Are the proposed mitigations effective to manage the fatigue risk?
- What assurance actions are proposed?
- Has the equivalent level of safety been demonstrated?



# Challenges

- Current compliance issues
- Fatigue integration into SMS
- Over-reliance on model outputs
- Disconnect between decision thresholds and risk decision making
- Monitoring and evaluation not well developed



# Using Models

- **All models have limitations**
- Good tool for comparison tasks
- Good tool for prediction where no other data exists (ULR)
- Good tool for meta data
- Don't reduce decision making to model output – e.g. score
- Should not replace good practice scheduling principles
- Appropriate instruction and training essential for users



# Core principles

- Identify similar long duties or combinations and some performance measures to assess (hours of sleep / alertness / behaviours)
- Understand how different options present themselves and how accurate the tools used reflect reality
- Mitigations must address the fatigue risk
- Demonstrate how the proposed mitigations are going to address the identified issues and produce an equivalent level of safety
- Assurance processes contain robust and varied measures.

# ULR Example

- Significant amount of discussion at the start
- Focus on amount of sleep obtained at Top of Descent (actigraphy / sleep diaries)
- Performance in simple tests (PVT / subjective scoring)
- Data on these points (sleep and performance) gathered in normal operations
- Modeling as part of the predictive assessment
- Data gathered on sleep and performance in “normal” operations
- Crew surveyed under normal circumstances
- Data and survey repeated under trial conditions
- Agreement on the level of difference that would be acceptable (based on assessment of other research information)



# What good looks like

- Clear objectives, scope and measures of success (SPI's)
- Considerations of operation context
- Scientific principles clearly considered
- Fatigue reporting policy and process
- Acceptance – assessment / demonstration
- Change assessment for operation
- Risk assessment
- Mitigations
- Ongoing review
- Management commitment
- Ongoing internal data collection and analysis methods
- Gap analysis – known unknowns
- Checklist – Internal / NAA



# Summary

- Focus on scientific principles to be managed
- Proportionate
- Thorough
- Each case is unique and presents its own challenges
- Operator to demonstrate equivalent level of safety
- Mitigations must be relevant
- Flight risk assessment approach

**Thank you for your attention**