

# Data Collection

## Best Practices

### How to Manage Common Missteps

- Captain Brian Noyes, Member, Flight Time/Duty Time Committee, Air Line Pilots Association, Int'l
- Captain Philip Otis, United Airlines
- Dr. Thomas Nesthus, Office of Aerospace Medicine, Civil Aerospace Medical Institute, Federal Aviation Administration
- First Officer Christine Daniel, Allied Pilots Association

# Fatigue Management: The Evolution of Part 117

## FRMS Data Collection Requirements and Best Practices

**Thomas E Nesthus, Ph.D.**  
**FAA**  
**Civil Aerospace Medical Institute**  
**Oklahoma City, OK**



**Federal Aviation  
Administration**

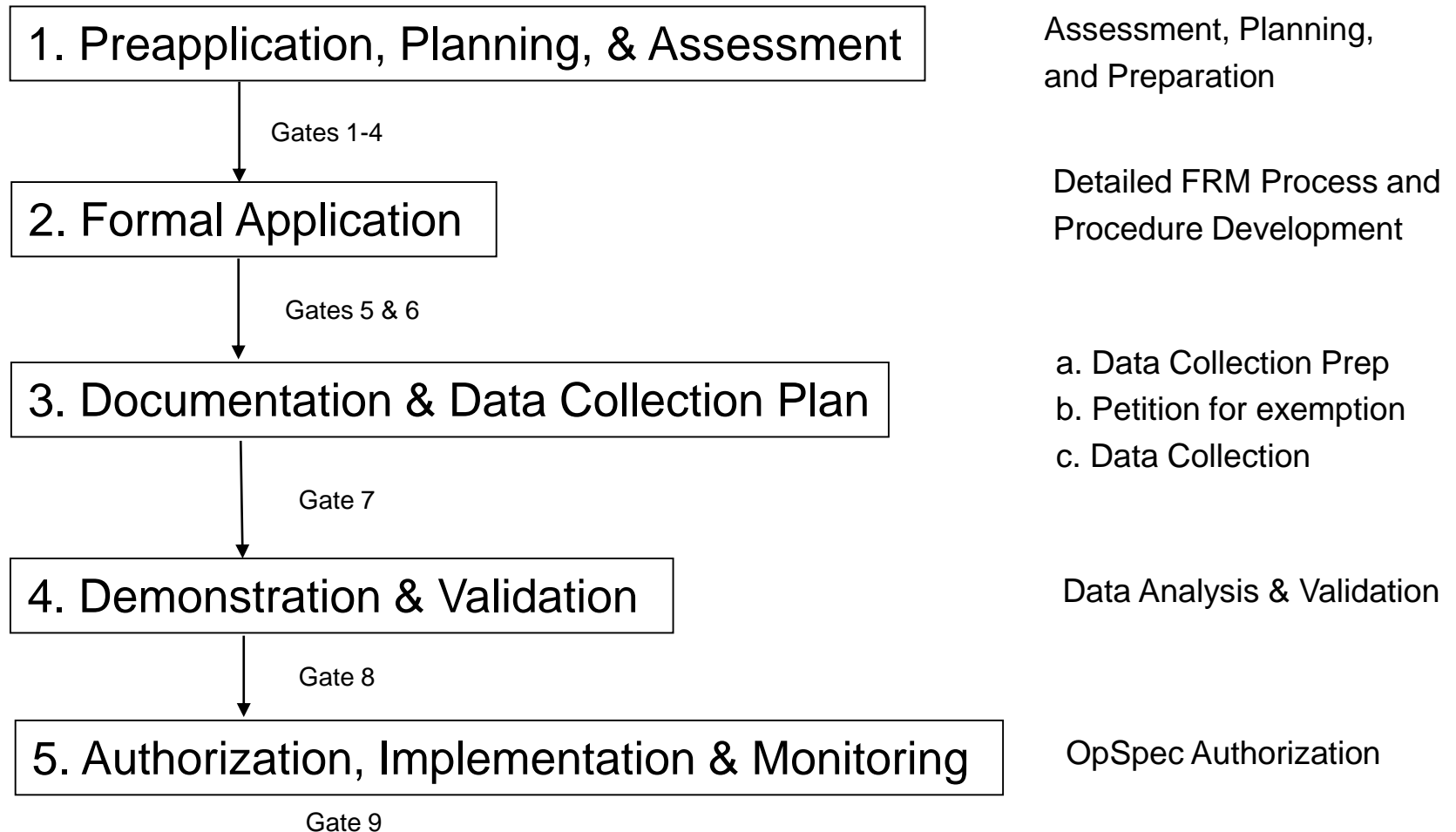


# Guidance for FRMS Authorization Process

## FAA AC 120-103A: FRMS for Aviation Safety

- 1) Describes the basic concepts of Fatigue Risk Management Systems
- 2) Provides information on critical FRMS components
- 3) Defines an operations-specific process for a certificate holder's particular conditions
- 4) Provides certificate holder with necessary detailed guidance to prepare for the FRMS approval process, develop the required documentation, develop and apply fatigue risk management and Safety Assurance processes, collect and analyze data, develop flightcrew FRMS operations procedures and a step-by-step process required for Federal Aviation Administration evaluation and validation of the proposed FRMS application

# Overview of FRMS Authorization Process



### 3. Documentation & Data Collection Plan

The FAA will evaluate FRMS plan and all documentation supporting flight ops during data collection.

#### Gate 7

(7) Concerns all aspects of flight operations data collection, including: modeling fatigue predictions/mitigations, demonstration of an effective AMOC, another review of safety performance indicators & data analysis methodology.

Lastly, determination of applicable exemptions with specific limitations and conditions for data collection flights.

## 4. Demonstration & Validation

Certificate holder will collect & analyze all data associated with the FRMS proposal and submit an analysis package to FAA for review/validation

### Gate 8

(8) Certificate holder provides “...a complete review and analysis of results...with specific emphasis on how the data confirm that the alternative operation outside the prescriptive rules provides an effective AMOC with safety standards” to the FAA

# FAA AC 120-103A: FRMS for Aviation Safety

Fatigue Risk Management System (FRMS).

- A management system that certificate holders may use to mitigate the effects of fatigue in their operations where the FRMS is applied.
- Specifically, an FRMS is the method by which a certificate holder may exceed a flightcrew member flight, duty, or rest limitation, provided the FRMS demonstrates an AMOC and is approved by the FAA.
- FRMS is a performance-based fatigue mitigation tool.

# PERFORMANCE-BASED APPROACH

Essentially, an FRMS represents a performance-based regulatory approach.

- This means that the FRMS defines the requirements and processes required for certificate holders to measure, manage, mitigate, and monitor potential fatigue risk associated with the operation for which the FRMS is applied.
- Data collection and analysis are vital in determining the flightcrew members' level of performance during that operation proposed by the certificate holder.



# FRMS LIMITATIONS AND CONDITIONS

The certificate holder's FAA-approved FRMS authorization will be based on analyzed and validated data applicable to the specific limitation to be exceeded under the FRMS.

- Therefore, the FAA will impose specific limitations and conditions applicable to the FRMS authorization.
- While conducting operations under an FRMS authorization, the certificate holder must comply with these limitations and conditions along with their FAA-approved FRMS processes and procedures.

# DATA ANALYSIS

To be effective at managing risks,

- FRM processes require data input from a number of sources, including measurements of the crewmembers' fatigue levels and measurement of operational performance.
- The key is choosing the right combination of measurements applicable to each operation covered by the FRMS.

# GAP ANALYSIS

The certificate holder needs to clearly identify the operations where the FRMS will be applied.

Different types of flight operations can involve different causes of crewmember fatigue and may require different controls and strategies to mitigate the associated risks.

# Federal Register / Vol. 77, No. 2 / Wednesday, January 4, 2012 / Rules and Regulations

117.1 Applicability.

117.3 Definitions.

117.5 Fitness for duty.

117.7 Fatigue risk management system.

117.9 Fatigue education and awareness training program.

117.11 Flight time limitation.

117.13 Flight duty period:  
Unaugmented operations.

117.15 Flight duty period: Split duty.

117.17 Flight duty period:  
Augmented flightcrew.

117.19 Flight duty period extensions.

117.21 Reserve status.

117.23 Cumulative limitations.

117.25 Rest period.

117.27 Consecutive nighttime operations.

117.29 Emergency and government sponsored operations.

Table A to Part 117—Maximum Flight Time Limits for Unaugmented Operations

Table B to Part 117—Flight Duty Period: Unaugmented Operations

Table C to Part 117—Flight Duty Period: Augmented Operations

# CAUSES OF FATIGUE

Generally speaking, the main causes of fatigue in aviation are:

- Amount, timing, and quality of sleep each day (*sleep/wake schedule*)
- Amount of time since last sleep period (*continuous hours awake*)
- Time of day (*circadian rhythm*)
- Operations through multiple time zones
- *Workload and time on task*

# ALTERNATIVE METHOD OF COMPLIANCE

The FRMS must provide an AMOC and demonstrate that it meets or exceeds the limitations (safety standards) prescribed in part 117. To demonstrate an AMOC, the certificate holder must define measurements of fatigue that will serve as performance safety standards for the evaluation of the effectiveness of the FRMS.

(1) Measurements Summary. An AMOC demonstration of effectiveness of the FRMS will require a combination of measurements.

- Subjective fatigue and sleepiness ratings
- Objective performance measurements
- Sleep monitoring and measurement, and
- Circadian rhythm measurements

# PERFORMANCE MEASUREMENT

A range of objective performance tests are used in scientific research. Things to consider when choosing a performance test for measuring crewmember fatigue include the following:

1. *How long does the test last?* Can it be completed at multiple time points (e.g., in the operations room during preflight preparations, near top of climb, near top of descent, and post-flight before disembarking from the aircraft) without compromising a crewmember's ability to meet duty requirements?
2. *Has it been validated?* For example, has it been shown to be sensitive to the effects of sleep loss and the circadian body clock cycle under controlled experimental conditions?
3. *Is the test predictive of more complex tasks* (e.g., crew performance in a flight simulator)?
4. *Has it been used in other aviation operations*, and are data available to compare fatigue levels between operations?

## Recommended FRMS Measures

**Actigraphy:** Sleep monitoring using wrist actigraphy and *duty/sleep logs*, for 3 days before each study trip, during the study trip(s), and for at least 3 days after completion of each study trip

**Sleepiness Ratings:** Sleepiness ratings on the Karolinska Sleepiness Scale (KSS) from 1-9 are:

1= extremely alert

3= alert

5= neither sleepy nor alert

7= sleepy, but no difficulty remaining awake

9= extremely sleepy, fighting sleep



# Recommended FRMS Measures

## **Subjective Fatigue:**

Fatigue was rated on the Samn-Perelli Crew Status Check using a scale from 1-7 are:

1='fully alert, wide awake'; 2='very lively, responsive, but not at peak'; 3='okay, somewhat fresh'; 4='a little tired, less than fresh'; 5= 'moderately tired, let down'; 6='extremely tired, very difficult to concentrate'; and 7='completely exhausted, unable to function effectively'.

## **PVT Performance:**

Performance on duty days measured using the Psychomotor Vigilance Task (PVT).

Either the 5-min or 10-min PVTs taken before take-off, upon reaching cruising altitude (TOC), before each in-flight rest opportunity, immediately before descent (TOD), and post-flight prior to disembarking the aircraft

## Recommended FRMS Measures

**Fatigue Safety Performance Indicators (SPIs)** need to be calculated for every flight.

For measures of fatigue status at the beginning of the duty period:

**SPIs** = pre-flight KSS ratings; pre-flight Samn-Perelli fatigue ratings; and pre-flight PVT performance (mean response speed and slowest 10% of responses).

For measures of fatigue status for landing:

**SPIs** = total in-flight sleep; KSS ratings at TOD; Samn-Perelli fatigue ratings at TOD; and PVT performance at TOD (mean response speed and slowest 10% of responses).

# References for Recommended Measures

## Actigraphy

Signal TL, Gale J, Gander PH. Sleep measurement in flight crew: comparing actigraphic and subjective estimates of sleep with polysomnography. *Aviat Space Environ Med* 2005; 76:1058-1063.

## Sleepiness Ratings

Kaida K, Takahashi M, Åkerstedt T, Nakata A, Otsuka Y, Haratani T, Fukasawa K. Validation of the Karolinska sleepiness scale against performance and EEG variables. *Clin Neurophys* 2006; 117:1574-1581.

## Subjective Fatigue

Samn SW, Perelli LP. *Estimating aircrew fatigue: a technique with implications to airlift operations*. SAM-TR-82-21. Brooks AFB, TX: USAF School of Aerospace Medicine; 1982.

Retrieved from <http://www.dtic.mil/cgi-in/GetTRDoc?AD=ADA125319>

# References for Recommended Measures

## PVT Performance

Basner M, Dinges DF. Maximizing the sensitivity of the psychomotor vigilance task (PVT) to sleep loss. *Sleep* 2011; 34:581-591.

## Safety Performance Indicators

Gander PH, Mangie JM, van den Berg MJ, Smith AAT, Mulrine HM, Signal TL. Crew fatigue safety performance indicators for fatigue risk management systems. *Aviat Space Environ Med* 2013; 84:1 – 9.



# ESTABLISHING AN ACCEPTABLE ALTERNATIVE METHOD OF COMPLIANCE

Steven R. Hursh, Ph.D.  
Institutes for Behavior Resources



# Establishing an Acceptable “Alternative Method of Compliance” (AMOC)

- Under an FRMS, a certificate holder develops processes that manage and mitigate fatigue that serve as an alternate method of compliance (AMOC) to the prescriptive rule.
- The certificate holder must demonstrate to the FAA that their proposed FRMS satisfactorily demonstrates that the AMOC provides an equivalent level of safety to the safety standards set forth in part 117.
- Data collection and analysis are vital in determining the flightcrew members' level of performance during that operation proposed by the certificate holder.
- A statistical method call “Equivalence Analysis” is used to establish that performance (and/or sleep) provides an equivalent level of safety.

# Establishing an AMOC involves a Comparison

- The performance under the AMOC is compared to a safety standard operation (SSO).
- Characteristics of an acceptable SSO compared to the AMOC operation:
  - Similar crewing
  - Similar aircraft
  - Similar rest facility
  - Similar time of day
  - Similar direction of travel and similar duration (within Part 117)
- Measures of performance:
  - Psychomotor Vigilance Task (PVT)
  - Sleep patterns – usually actigraph
  - Ratings of sleep (time, duration, quality)
  - Subjective ratings (KSS or Samn-Perelli)

# Non-significant difference is not Equivalence

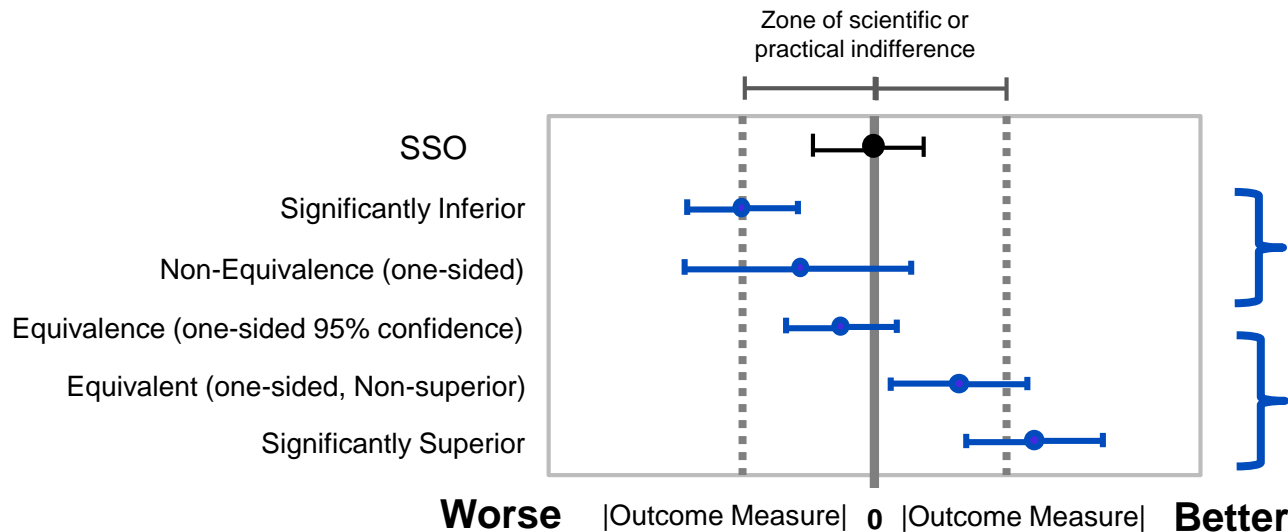
- Showing that the measures from the AMOC are NOT statistically different from the SSO does not establish equivalence.
- What is required is a test that shows that the AMOC is at least close enough to the SSO that there is 95% confidence that it is above a margin of practical indifference.
- Note: if the AMOC is statistically SUPERIOR to the SSO, then it is not equivalent “statistically” but it still meets the requirement of providing an equivalent level of safety.



# Establishing AMOC Equivalence to SSO

- Equivalence is a significance test on proximity to the standard.
- Equivalence tests whether there is 95% confidence that the actual performance is within a zone of indifference relative to the SSO or better than the SSO?

—●— Outcome in SSO, Confidence Intervals  
—●— Outcome in AMOC, Confidence Intervals



These AMOC cases do not meet the requirements of a satisfactory AMOC

These AMOC cases all meet the requirements of a satisfactory AMOC

Statistically, these cases establish "non-inferiority" relative to SSO

# Equivalence Testing References

- Lawrence E. Barker, Elizabeth T. Luman, Mary M. McCauley, and Susan Y. Chu. Assessing Equivalence: An Alternative to the Use of Difference Tests for Measuring Disparities in Vaccination Coverage, *American Journal of Epidemiology*, Vol. 156, No. 11.
- Esteban Walker and Amy S. Nowacki. Understanding Equivalence and Noninferiority Testing, *Journal of General Internal Medicine*, 26(2):192–6.
- Scott J. Richter and Carri Richter. A Method for Determining Equivalence in Industrial Applications, *Quality Engineering*, 14(3), 375–380 (2002).
- Jennifer Schumi and Janet T. Wittes. Through the looking glass: understanding non-inferiority, *Trials*, 12:106, (2011).