Preparing Safety Cases for Operating Outside Prescriptive Fatigue Risk Management Regulations

Philippa Gander; Jim Mangie; Lora Wu; Margo van den Berg; Leigh Signal; Adrienne Phillips

INTRODUCTION: Transport operators seeking to operate outside prescriptive fatigue management regulations are typically required to present a safety case justifying how they will manage the associated risk. This paper details a method for constructing a successful safety case.

METHODS: The method includes four elements: 1) scope (prescriptive rules and operations affected); 2) risk assessment; 3) risk mitigation strategies; and 4) monitoring ongoing risk. A successful safety case illustrates this method. It enables landing pilots in 3-pilot crews to choose the second or third in-flight rest break, rather than the regulatory requirement to take the third break. Scope was defined using a month of scheduled flights that would be covered ($N = 4151$). These were analyzed in the risk assessment using existing literature on factors affecting fatigue to estimate the maximum time awake at top of descent and sleep opportunities in each break. Additionally, limited data collected before the new regulations showed that pilots flying at landing chose the third break on only 6% of flights.

RESULTS: A prospective survey comparing subjective reports ($N = 280$) of sleep in the second vs. third break and fatigue and sleepiness ratings at top of descent confirmed that the third break is not consistently superior. The safety case also summarized established systems for fatigue monitoring, risk assessment and hazard identification, and multiple fatigue mitigation strategies that are in place.

DISCUSSION: Other successful safety cases have used this method. The evidence required depends on the expected level of risk and should evolve as experience with fatigue risk management systems builds.

KEYWORDS: fatigue risk management systems, in-flight sleep in 3-pilot airline crews, equivalent level of safety.

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Pilot fatigue is a recognized safety issue in commercial aviation.[14] To manage it, the International Civil Aviation Organization (ICAO) requires States to have prescriptive fatigue management regulations, including flight and duty time limits. Countries may also establish regulations that allow airlines to propose a performance-based Fatigue Risk Management System (FRMS) as an alternative means of compliance (AMOC).[15] An airline seeking to gain operational flexibility by using an FRMS or other variation(s) from the prescriptive regulations has to be able to demonstrate to its national regulatory authority that it can deliver an equivalent level of safety to that achieved by operating within the prescriptive regulations.

For example, the U.S. Federal Aviation Administration (FAA) requires airlines to present a safety case for any operation that does not meet all the prescriptive requirements for managing pilot fatigue risk (14 CFR Part 117).[3] The nature and complexity of each safety case needs to be sufficient to persuade the FAA that the airline can use their FRMS to manage the associated fatigue risk.

This is effectively stricter than the ICAO regulatory framework, which does allow regulators to approve airline requests for minor variations to the prescriptive fatigue risk management rules without requiring the airline to have a full FRMS.[14] Nevertheless, where a regulator does allow variations without a full FRMS (for example the European Aviation Safety Authority),

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airlines are still expected to provide a safety case to persuade the regulator that they can manage the fatigue risk associated with the variation. When multiple variations are in place it can become increasingly difficult to assess the combined risk. The point at which an FRMS is required is determined by the regulator after discussions with the airline.[14]

This paper presents an approach we have developed for safety cases that have been approved by the FAA, illustrating it with an example used to argue for an alternative way of allocating in-flight rest periods for three-pilot crews. The approach is consistent with recommendations in the international Fatigue Management Guide for Airlines.[14]

METHODS

In this approach, a safety case addresses four elements: 1) the scope (which prescriptive rules and flight operations are affected); 2) assessment of the fatigue hazard(s) and fatigue-related risk associated with the proposed alternative approach; 3) the processes and mitigations that will be used to manage that risk; and 4) the ongoing monitoring that will be used to track fatigue risk in affected operations. The last three elements map to the components of the fatigue risk management processes loop (**Fig. 1**).[14]

The scope section of a safety case needs to clearly state:

- the part(s) of the prescriptive rules that would not be met by operations covered by the proposed AMOC;
- why an AMOC is needed, i.e., why the prescriptive requirements are not adequate for the specific operations covered by the AMOC;
- for flight duty period or flight time extensions:
    - o specify whether the extension(s) will be scheduled or used only to allow completion of operations with delays due to unforeseen circumstances; and
    - o specify the maximum extension(s) requested;
- a detailed description of the operation(s) to which the AMOC applies.

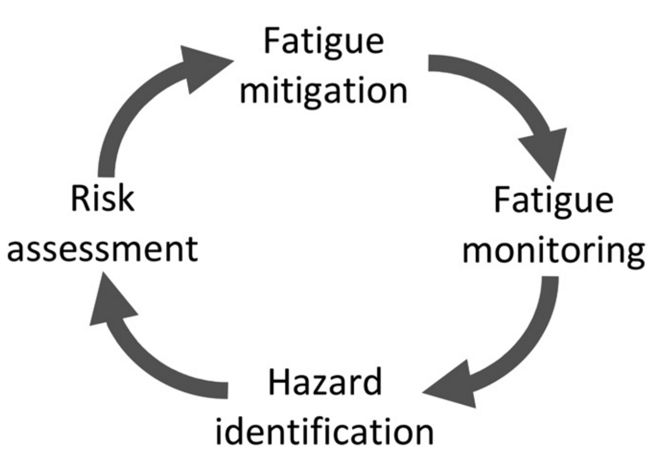

Fig. 1. The fatigue risk management processes loop.[14]

The risk assessment should present a well-substantiated estimate of the likely level of pilot fatigue and the related safety risk associated with the requested AMOC. The risk assessment can be supported by (but need not be limited to): available scientific studies addressing the factors that are likely to be causing fatigue in the operations covered by the AMOC; available data from previous studies of similar operations; and predictions of fatigue levels from appropriate bio-mathematical models. The regulator may also request that additional data be gathered (a validation study) to support the risk assessment. The FAA must approve the design of the validation study before they will grant provisional approval of the AMOC for a fixed period of time to allow completion of the study.

The risk management section of the safety case needs to describe in detail the processes and mitigations that will be used to manage the estimated levels of crewmember fatigue and the associated safety risk. This includes identifying additional mitigations that can be implemented if needed. The regulator needs to be convinced that the processes and mitigations are functioning effectively.

The monitoring section of the safety case needs to describe in detail the monitoring that will be undertaken to evaluate the actual risk. This monitoring must be integrated into the fatigue risk management processes in the operator's FRMS (Fig. 1). The regulator may require a trial phase with more extensive monitoring for a specified time period. Agreed safety performance indicators collected during the trial phase[9] can be used to decide when the operation(s) covered by the AMOC can revert to routine monitoring.[16] The following example illustrates this approach.

All pilot fatigue monitoring studies that contribute data to our safety cases undergo independent ethical review and are approved by a statutory Ethics Committee. For the studies contributing to the safety case presented below, this was the Massey University Human Ethics Committee: Southern A, which is a registered Institutional Review Board (IRB # 00,006,014, FWA # 00,011,627). Participation was voluntary and data confidentiality was strictly maintained.

RESULTS

Example of a Successful Safety Case

This section describes an example of a successful safety case that used these methods to obtain regulatory approval for an AMOC for in-flight rest allocation on flights with three-pilot crews.

Scope. The AMOC sought an alternative to the rules introduced in 14 CFR 117 (effective from 4 January 2014) that prescribe the distribution of in-flight rest breaks on flights with augmented crews. These state that the pilot flying during landing must have at least 2 consecutive hours in the second half of the flight duty period (FDP) available for in-flight rest and the pilot monitoring at landing must have a minimum break of 90 min during the FDP. The intent of these provisions is to protect the alertness of the pilot flying by providing an adequate opportunity for in-flight sleep and by limiting time awake at top of descent, as well as ensuring an acceptable level of alertness of the pilot monitoring. However, on shorter flights with three-pilot crews (FDPs up to about 14 h), these provisions can have the unintended consequence of requiring the pilot flying the landing to always take the last of the three rest breaks.

The need for an AMOC was argued on the basis of three main concerns. First, the third break does not always offer the best physiological opportunity for sleep, which depends on when the break occurs in the pilot's circadian body clock cycle.[11] Second, most of the aircraft used in operations covered by this AMOC have Class 2 rest facilities (a seat in the aircraft cabin with a flat or near-flat sleeping position and separated from passengers by a minimum of a curtain[4]). Prior to 14 CFR Part 117.17, it was customary practice in the airline for the pilot flying the landing to take the second break while the pilot monitoring at landing took the third break, with the captain retaining the flexibility to alter the break allocation to accommodate individual pilot's rest needs on the day of operation. Anecdotally, a common reason for the preference for the second break among pilots flying the landing was that it falls between two meal services and thus has the least disturbance associated with cabin activities. Third, as a mitigation to reduce the workload of the pilots flying and monitoring at landing, the airline had developed procedures whereby the relief pilot performs all ancillary and administrative duties from top of descent (TOD). This allows the pilots flying and monitoring at landing to focus on operating the aircraft. For the relief pilot to take this role, he/she also requires adequate in-flight rest, which limits reallocation of the available rest time from the relief pilot to the pilots flying and monitoring at landing.

The airline therefore requested an AMOC as follows: on three-pilot flights, break times can be calculated such that the pilot flying the landing can take the second or the third rest break and be given at least one-third of the available rest time, but not less than 1 h 45 min. The rest break for the pilot flying the landing can begin up to an hour earlier than the last half of the flight duty period, to allow the second break to be taken.

The operations potentially covered by these provisions were described by providing details on 4151 scheduled flights for April 2014 which had three-pilot crews and scheduled FDPs less than 14 h. For each flight, this included information on: the departure and arrival cities, the number of flights per month, the aircraft fleets servicing the flight, the maximum scheduled flight duration (block time), and the scheduled departure time [local time and coordinated universal time (UTC)].

The maximum scheduled durations of these flights are summarized in **Fig. 2**. Some flights require only two pilots (14 CFR Part 117, Table A),[2] but they have three pilots because the airline has a policy of augmenting both the outbound and inbound flights between a city pair if either flight requires augmentation.

Risk assessment. The risk assessment was based on five sources of information: 1) previous field studies monitoring pilots in augmented crews; 2) estimates of the maximum time awake at top of descent (TOD) for the shortest and longest flights that would be covered by the AMOC; 3) an evaluation of the sleep opportunities offered by the second vs. the third rest period, grouping flights according their domicile arrival times; 4) limited data available from three-pilot operations in the airline prior to the new prescriptive rules; and 5) a validation study requested by the FAA to confirm the conclusions drawn from the other sources of information.

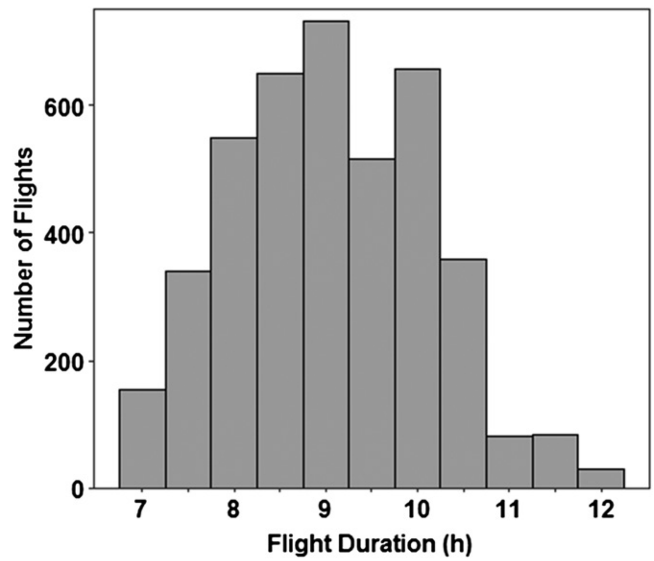

Fig. 2. Distribution of scheduled duration of flights during April 2014 that would be covered by the alternative means of compliance.

Most of the published studies that have investigated the factors affecting in-flight sleep duration and quality, and the relationships between sleep history and measures of pilot fatigue at TOD have focused on four-pilot crews with Class 1 rest facilities, i.e., with horizontal bunks in facilities separated from the main cabin. In general, pilots report that they find sleeping on board the aircraft more difficult than sleeping at home. Studies measuring sleep objectively (using polysomnography) confirm that bunk sleep is lighter and more fragmented than sleep on the ground.[19,20] In-flight sleep is reported to be disturbed by a range of factors with the most frequently cited being noise, turbulence, and having thoughts on one's mind.[17,18] Analyses on combined data from 4 studies (237 crewmembers in 4-pilot crews, 730 out-and-back flights between 13 city pairs, 1–3 d layovers) have highlighted that total in-flight sleep varies with domicile departure time (a surrogate measure of circadian phase) and increases with flight duration (longer flights provide longer rest breaks).[10] Higher fatigue and sleepiness ratings at TOD are associated with less in-flight sleep, longer time awake at TOD, and domicile arrival time (a surrogate measure of circadian phase).[11] Psychomotor vigilance task (PVT) response speed at TOD also varies with domicile arrival time, but not with sleep history in the last 24 h.[11]

In light of these findings and the intent of the prescriptive regulations to limit the time awake at TOD of the pilot flying, the safety case provided estimates of the maximum time awake at TOD after each break on the shortest and longest of the 4151 flights in Fig. 2. These calculations are summarized in **Table I**.

Compared to the nominal 16-h waking day, time awake at TOD is relatively short after any of the rest breaks on these flights if pilots obtain sleep during their break. In addition, 14 CFR Part 117 Table A allows two-pilot crews with no in-flight sleep to operate flights up to 9 h if their flight duty period starts between 05:00 and 19:59, i.e., being awake at least 10 h is acceptable on such flights.

The safety case also included an evaluation of the likely sleep opportunity in the second vs. the third break on the flights in Fig. 2, excluding the 1537 flights that did not require augmentation. We argued that since these 1537 flights could legally be operated by two-pilot crews, any in-flight sleep obtained when they are operated by three-pilot crews would reduce the time awake of the landing crew at TOD and thus offer an enhanced level of safety compared to operating under the prescriptive regulations.

The comparison of sleep opportunities was based on laboratory and field studies that have identified the times in the circadian body clock cycle when falling asleep and staying asleep are easier, and times when sleep is more difficult. These times are visualized in **Fig. 3** as resulting from a drive from the circadian pacemaker to centers in the brain that promote wakefulness.

In summary, it is relatively easy to fall asleep when the circadian wake drive reaches its daily minimum and sleepiness is maximal (the so-called window of circadian low, or WOCL), and during the afternoon nap window, when the circadian wake drive is visualized as plateauing briefly. Conversely, it becomes increasingly difficult to fall asleep or stay asleep as the circadian wake drive increases across the morning.[1] This can truncate the daytime sleep of night workers, including night cargo pilots.[7] It is also difficult to fall asleep when the circadian wake drive peaks in the few hours before usual bedtime (the 'evening wake maintenance zone'). This inhibits falling asleep earlier than usual and leads to truncated sleep with early duty report times.[8]

For comparing sleep opportunities in the second vs. the third rest break, flights in Fig. 2 that required augmentation ($N = 2614$) were grouped by their departure and arrival times, based on domicile time (i.e., acclimated time) as a surrogate measure of circadian phase, using the following assumptions.

1. For outbound flights that were the first in a trip sequence, acclimated time was assumed to be local time in the departure city.
2. For inbound flights after 1–2 d layovers, minimal circadian adaptation was assumed and acclimated time was assumed to be local time in the outbound departure city.
3. The WOCL was assumed to be between 02:00–05:59 domicile time.
4. For flights that occurred as the third or subsequent flight in a trip sequence ($N = 551$), there was no reliable method for estimating the time zone to which pilots were acclimated.

The remaining 2063 flights for which pilots' acclimated time zone could be estimated were grouped into five categories, based on their acclimated departure and arrival times. These are summarized in **Table II**.

Group 1 flights (blocks off after the WOCL, blocks on before 00:00) occur across the usual waking day and none of the rest breaks coincide with the optimal part of the circadian body clock cycle for sleep. On flights with arrivals later in the evening, the third rest break will at least partially overlap the evening wake maintenance zone, when it is difficult to fall asleep. The AMOC allows the pilot flying the flexibility to take either the second or third break, provided they are given at least one-third of the available rest time and not less than 1 h 45 min. This gives the crew the opportunity to make informed choices based on the specifics of the flight (airports, en route navigation, etc.), their operational experience, their knowledge of fatigue acquired through fatigue management training, and conditions on the day.

Group 2 flights (blocks off outside the WOCL, blocks on 00:00–01:59 or 06:00–08:00) begin and end outside the WOCL, but end at times when there is still relatively high risk of fatigue-related impairment at TOD. However, it is not clear that the third break will always contain more of the optimal part of the circadian body clock cycle for sleep than the second break. On flights arriving between 00:00-01:59, the sleep on both breaks may be affected by the evening wake maintenance zone. On flights arriving between 06:00-08:00, the increasing circadian wake drive is likely to be more problematic for sleep in the third rest break than in the second rest break.

On Group 3 flights (blocks off before the WOCL, blocks on after 08:00), the second rest break is likely to have more overlap with the optimal part of the circadian cycle for sleep than the third rest break, which will include more of the morning increase in wake drive from the circadian body clock.

All but one of the Group 4 flights are scheduled to depart

Table I. Estimated Time Awake at Top of Descent on the Shortest and Longest Flights in Fig. 2.*

	SHORTEST FLIGHT (7 h 2 min)	LONGEST FLIGHT (11 h 59 min)
Report time (blocks off − 1 h)	18:13	18:06
Blocks off	19:13	19:06
Start break 1 (blocks off + 1 h)	20:13	20:06
End break 1	21:54	23:26
Time awake at TOD† (end break 1 + 20 min)	4 h 11 min	7 h 29 min
Start break 2	21:54	23:26
End break 2	23:35	02:46
Time awake at TOD (end break 2 + 20 min)	2 h 30 min	4 h 9 min
Start break 3	23:35	02:46
End break 3 (blocks on − 1 h)	01:15	06:05
Time awake at TOD (end break 3 + 20 min)	50 min	50 min
TOD (blocks on − 0.5 h)	01:45	06:35
Blocks on	02:15	07:05
Off duty (blocks on + 0.5 h)	02:45	07:35

* These estimates assume that all breaks were of equal length and that pilots woke up 20 min before the end of the break.
† TOD: top of descent.

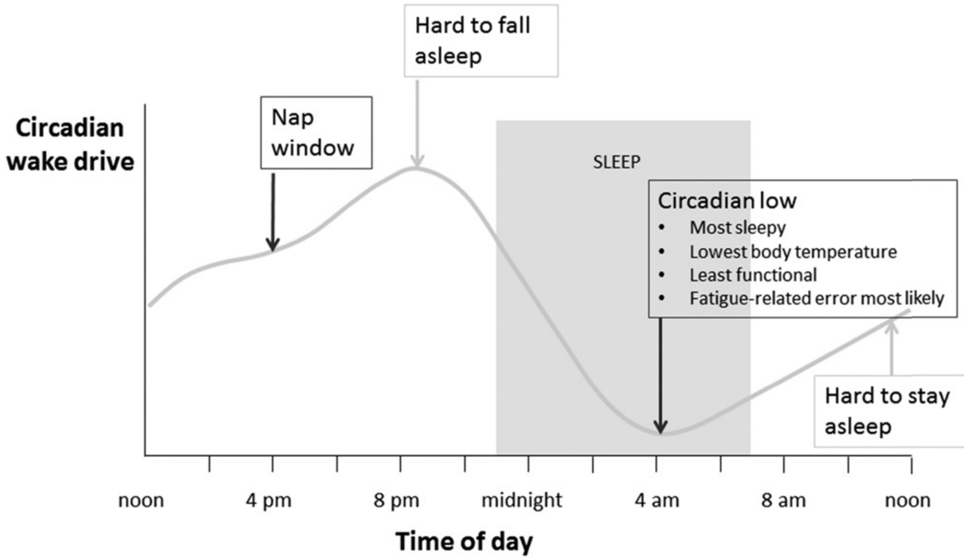

Fig. 3. Summary of the effects of the circadian wake drive on the ability to fall asleep and stay asleep (sleep propensity).

during the WOCL and arrive outside the WOCL (12:00–15:00 acclimated time). The exception is a flight with blocks off at 04:25 acclimated time and scheduled blocks on at 15:44 acclimated time (maximum flight time, 11 h 19 min). The early departure times mean that most pilots will have had their sleep truncated before these flights. This sleep restriction would be expected to increase sleepiness during the afternoon nap window, which may occur during some of the flights with later blocks on times. However, the third rest break, which ends about 1 h before arrival, overlaps late morning (acclimated time), when circadian wake drive is expected to be increasing while homeostatic sleep pressure remains relatively low (assuming that pilots obtained adequate sleep and had not been awake long before coming on duty). This combination of factors makes it difficult to fall asleep or stay asleep during this time period. Thus, the third rest break is not necessarily the optimal break for sleep on these flights.

Group 5 flights are scheduled to arrive during the WOCL, with scheduled departure times outside the WOCL (17:05 to 22:30). Unless pilots take preflight naps, they will have been awake for long periods when they start duty. Arrival times correspond with times of relatively low circadian wake drive and high risk of fatigue-related impairment at TOD. On these flights, the evening wake maintenance zone would interfere with sleep during the first break on all flights and with the second rest break on flights departing earlier in the group. The third break would be expected to provide a reasonable sleep opportunity on all flights.

Based on these considerations, it was argued that on these flights, the flexibility offered by the AMOC provides at least an equivalent in-flight sleep opportunity to 14 CFR Part 117, which requires pilots flying the landing to take the third rest break. Limited data were also available from two previous studies of three-pilot operations that predate the new prescriptive regulations. These are summarized in **Table III**. Sleep on all flights was measured by actigraphy.

The B747-400 flights in the first study occurred during complex 9–13 d trip patterns, with the Japan-Hawaii flights being the second, fourth, or sixth flights in the trip sequence, and the Hawaii-Japan flights being the third, fifth, or seventh flights. Because of their differing positions in the trip sequence, it was not possible to reliably estimate acclimated time for these flights.[12]

The Japan-Hawaii flights were night flights (median departure 21:10 local time) and only 3% of pilots did not attempt to sleep during their rest break. In contrast, the Hawaii-Japan flights were daytime flights (median departure 12:59 local time) and 23% of pilots did not attempt sleep during their in-flight rest break (32% who were allocated the third rest break did not attempt sleep). One contributing factor may have been the higher levels of cabin noise during daytime flights. Linear mixed models controlling for the variability within and between pilots indicated that total in-flight sleep did not vary between the first, second, and third rest breaks on either the Japan-Hawaii or the Hawaii-Japan flights. On the Hawaii-Japan daytime flights (but not the Japan-Hawaii night flights) more total in-flight sleep was an independent predictor of lower subjective fatigue and sleepiness at TOD. **Fig. 4** shows that pilots flying the landing used the third rest break on only 4% (1/26) of the Hawaii-Japan flights and none of the Japan-Hawaii flights.

The second study involved flights from Seattle-Japan which were followed by 7–12 d in Asia with short haul flight duties (crossing no more than one time zone per 24 h, with two-pilot crews) and then a return Japan-Seattle flight. The study concluded that there was complete adaptation to Japan time prior to the return transpacific flight.[13]

Table II. Flights Requiring Augmentation, Categorized by Acclimated Departure and Arrival Times.

GROUP	# FLIGHTS	# CITY PAIRS	SCHEDULED BLOCKS OFF	SCHEDULED BLOCKS ON
Group 1	299	11	after the WOCL*	before 00:00*,†
Group 2	623	22	outside the WOCL	00:00–01:59 or 06:00–08:00 (outside the WOCL)
Group 3	142	6	before the WOCL	after 08:00 (outside the WOCL)
Group 4	670	26	during the WOCL	outside the WOCL
Group 5	329	13	outside the WOCL	during the WOCL

* WOCL = window of circadian low defined as 02:00-05:59.
† Data from four-pilot crews[12] and the SAFTE model (Prof. Steve Hursh, personal communication; May 2014) suggest that after midnight, physiological fatigue risk begins to increase sharply.

Table III. Data from Two Previous Three-Pilot Studies That Predate 14 CFR Part 117.

ROUTE	MEDIAN FLIGHT DURATION (H)	TIME ZONES	POSITION AT LANDING		
			FLYING	MONITORING	RELIEF
B747-400 AIRCRAFT					
Japan (NRT, KIX)-Hawaii (HNL)	7.3 or 7.9	+ 5 h	16	28	21
Hawaii (HNL)-Japan (NRT, KIX)	7.8 or 8.6	- 5 h			
B757/767 AIRCRAFT					
U.S. West Coast (SEA)-Japan (KIX)	11.92	- 7 or - 8 h	7	7	1
Japan (KIX)-U.S. West Coast (SEA)	9.41	+ 7 or + 8 h	5	6	4

Fig. 4 indicates that pilots flying the landing used the third rest breaks on only 14% (1/7) of the Seattle-Japan flights and 20% (1/5) of the Japan-Seattle flights.

Having seen the risk assessment described above, the FAA requested a validation study to confirm that the third break does not consistently provide a better sleep opportunity than the second break. Participants completed one-page surveys on long-range flights to document their flight start and end times, break times, in-flight sleep duration and quality if they attempted sleep, and rated their fatigue and sleepiness at TOD. For the study, the rest break allocation provision in 14 CFR Part 117 was suspended so that landing pilots could take their preferred rest break. A full description of the study methods has been published elsewhere.[21] Data were analyzed from 280 surveys completed on flights landing in three 4-h domicile time bins (**Table IV**). Flights landing between 22:00–01:59 (Bin F) were significantly shorter than flights landing in the other time bins and were predominantly eastward, whereas flights in Bins A and B were predominantly southward or northward. The average durations of flights in Bins A and B were not significantly different.

There was a clear preference for pilots flying the landing to take the second rest break (94.9% of flights), and for pilots monitoring at landing to take the third rest break (94.4% of flights). The same proportion of pilots (91%) reported obtaining sleep during the second and the third rest breaks. Within each time bin, there were no differences between rest breaks in rest break duration, total sleep duration, sleep quality, sleepiness ratings at TOD, or fatigue ratings at TOD (Mann-Whitney *U*-tests, all $P > 0.1$).

Analysis of covariance of combined data from all three time bins indicated that rest break number was not an independent predictor of sleep duration [model structure: second vs. third rest break; flight duration (continuous variable)]. For every 1-h increase in flight duration, sleep duration increased by 12.3 min. This finding using self-reported sleep duration is consistent with a previous study with actigraphic sleep monitoring (237 pilots in 4-pilot crews, 730 flight segments), which found 10 min of additional sleep for each additional hour of flight duration after controlling for flight direction, domicile departure time, and crew position (landing vs. relief crew).[10]

In the 3-pilot validation study, fatigue and sleepiness ratings at TOD did not differ after taking the second vs. the third rest break. On flights that landed in domicile time Bins A (02:00–05:59) and B (06:00–09:59), fatigue and sleepiness ratings at TOD did not differ from those of four-pilot crews with compliant rest break allocations on flights landing in the same 4-h time bins.

Having reviewed these findings, the FAA requested that equivalence testing be undertaken comparing sleep duration in the second and third rest breaks. In general, equivalence testing is a useful statistical technique when safety cases are required to demonstrate that an AMOC can provide an equivalent level of safety to operating within the prescriptive regulations. However, equivalence testing comparing sleep in the second and third rest breaks in the three-pilot validation study created challenges because: 1) sleep durations in the second and third rest periods were not normally distributed (they were bimodal, due to the shorter flight times in Bin F); and 2) equivalence testing requires defining 'practical equivalence', i.e., the largest difference in total in-flight sleep that would not produce a meaningful difference in fatigue at TOD. There were no appropriate data from laboratory or field studies to estimate practical equivalence for total sleep durations of the lengths reported (mean for the third rest break = 85 min).

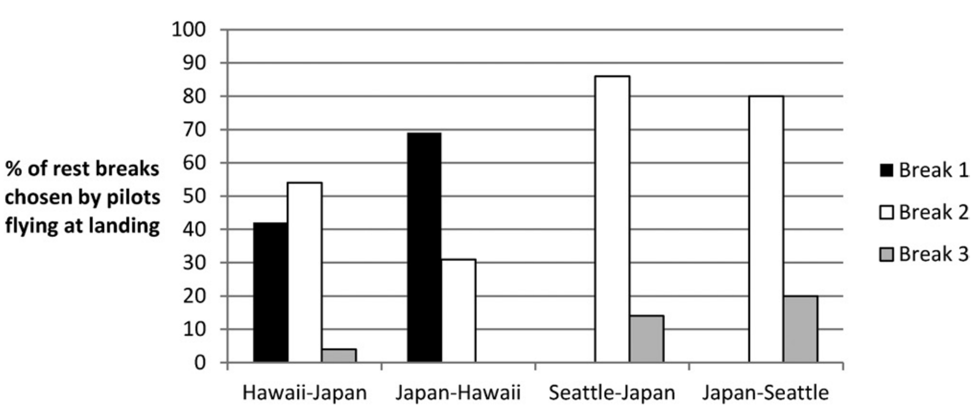

Fig. 4. Percentage of rest breaks chosen by pilots flying at landing in two earlier studies of three-pilot flights that predate implementation of the new prescriptive requirements on rest break patterns.

The FAA proposed that equivalence could be defined proportionally to total in-flight sleep duration. We had previously proposed that a 30-min difference in total in-flight sleep (15%) was a conservative estimate of practical equivalence on ULR flights with mean total in-flight sleep of 3.35 h (measured by polysomnography).[20] A 52-min difference in total in-flight sleep between command and relief pilots did not produce a significant difference in mean PVT response speed at TOD on these ULR flights. For

Table IV. Available Surveys and Average Flight Duration for Each Domicile Arrival Time Bin.

	NUMBER OF SURVEYS				
ARRIVAL TIME	**BIN A* 02:00–05:59**	**BIN B* 06:00–09:59**	**BIN F† 22:00–01:59**	***N* FLYING AT LANDING**	***N* MONITORING AT LANDING**
N, 2nd break	63	39	35	130	7
N, 3rd break	61	43	39	8	135
	AVERAGE FLIGHT DURATION (h)				
	9.03	8.87	8.05		

* Sleepiness and fatigue at TOD were expected to be high in Bins A and B.
† Flights arriving in Bin F traverse the evening wake maintenance zone, which is expected to make in-flight sleep more difficult.

the 3-pilot validation study, 15% of mean total in-flight sleep in the third rest break (85 min) is 13 min. Using this criterion, total in-flight sleep was equivalent in the second and third rest breaks, with 90% confidence intervals of −7 min to +8 min (pooled method with two one-sided *t*-tests for between-group samples). However, this conclusion needs to be treated with caution, given the nonnormal data distributions and in the absence of empirical support for the definition of practical equivalence.

It was concluded that the validation study found no evidence to indicate that the third rest break provided a better sleep opportunity than the second rest break in these 3-pilot operations.

Risk management. All pilots involved in the operations covered by the AMOC have undergone fatigue management training that meets FAA requirements.[5] This is covered in five training sessions (two 45-min basic courses and three 15-min refresher courses) that they are paid to work through outside of duty time. Schedulers and others involved in the management of the operations covered by the AMOC undergo a 45-min fatigue management training session that outlines why pilot fatigue is a safety concern, explains the physiology behind fatigue symptoms, discusses the role of scheduling in pilot fatigue, and reviews the purpose and processes of the airline FRMS.

Additional risk management strategies already implemented include the provision of a third pilot on flights that can legally be flown with two pilots (36.7% of the flights covered by the AMOC), thereby enabling pilots to take breaks and obtain sleep in flight. As mentioned previously, this is the result of the airline's policy of augmenting both the outbound and inbound flights between a city pair if either flight requires augmentation. As a mitigation to reduce the workload of the pilots flying and monitoring at landing, the airline has developed procedures whereby the relief pilot performs all ancillary and administrative duties from TOD. This allows the pilots flying and monitoring to focus on the actual operation of the aircraft.

Monitoring. As part of the airline's FRMS, all pilots on flights covered by the AMOC have received specific training on fatigue reporting mechanisms. They are advised that, if they encounter a situation that they consider to be a present or future fatigue concern, they are responsible for making management aware of the situation and, if appropriate, removing themselves from duty or refusing an assignment to duty. Different report forms are required if fatigue represents a flight safety concern vs. when it is not a direct flight safety concern. If a crewmember chooses to call in too fatigued for duty, they are required to:

- call the Crew Scheduler, if it is prior to sign-in; or
- call Crew Tracking, if is after sign-in; or
- call the Duty Pilot/Chief Pilot Support Centre;
- inform the Dispatcher (if applicable); and
- file an Aviation Safety report or alternatively an Aviation Safety Action Program report (if the event meets the requirements of the FAA) if they wish to have their report reviewed in a de-identified format.

If Flight Operations personnel encounter a situation that they consider may cause a fatigue-related risk, it is their responsibility to notify the appropriate supervisor or manager.

All fatigue reports are acknowledged and feedback is provided to the pilot group on a regular basis. The airline's Pilot Fatigue Program Director and the Fatigue Safety Action Group carefully evaluate and discuss any fatigue reports associated with the operations covered by the AMOC. They are also responsible for using FRM processes (Fig. 1) to act on fatigue reports when appropriate.

DISCUSSION

Performance-based regulatory approaches for managing operator fatigue are expanding across all modes of transport.[6] These often place a requirement on companies to provide safety cases in support of the systems they propose to implement to manage operator fatigue, but there is little detailed guidance on how to prepare such safety cases. This paper proposes an approach with four key elements that map to the ICAO fatigue risk management processes loop.[14] The aim of the paper is to stimulate discussion around best practice for making a scientifically based argument for equivalent levels of safety for operations covered by an alternative means of compliance, compared to operations remaining within the prescriptive requirements.

Safety cases need to be explicit and detailed about the scope of the requested AMOC, and well-supported by analyses of both scientific and operational data. The regulator needs to be confident that the risk management and monitoring processes in the operator's FRMS are fully functional and able to deliver an equivalent level of safety to that achieved by operating in compliance with the prescriptive fatigue management regulations.

The three-pilot in-flight rest allocation safety case described here sought to allow pilots flying the landing to choose either the second or third in-flight rest break on shorter flights, as opposed to the prescriptive requirement for them to take the third break. The risk associated with this AMOC was assessed based on: a review of previous field studies monitoring pilots in augmented crews (which included primarily four-person crews in aircraft with Class 1 rest facilities); limited data available from three-pilot operations in the airline prior to the new prescriptive rules; estimates of the maximum time awake at TOD for the shortest and longest of 4151 monthly flights that would be covered by the AMOC; and an evaluation based on scientific principles of the sleep opportunities offered by the second vs. the third rest period, grouping flights according their domicile arrival times. These analyses concluded that the third rest break does not consistently provide a better sleep opportunity or result in less fatigue at TOD, compared to the second rest break.

The FAA requested a prospective validation study on flights covered by the AMOC to confirm this conclusion and provided an exemption to enable the study to be conducted. Subjective reports ($N = 280$) of in-flight sleep duration and quality, as well as fatigue and sleepiness ratings at TOD, confirmed that the third rest break did not consistently provide a better sleep opportunity or less fatigue at TOD compared to the second rest break.

The safety case also described how operations covered by the AMOC are subject to routine fatigue monitoring, risk assessment, and hazard identification via the airline's fatigue risk management processes, and the multiple fatigue mitigation strategies that are in place. The AMOC was approved by the FAA in 2014.

In this example, the need for the AMOC arose from an unintended consequence of new prescriptive fatigue risk management regulations. The requested exemption in fact allowed the continuation of customary practice, i.e., the preference of pilots flying the landing in three-pilot crews to take the second in-flight rest break. Other successful safety cases using this approach have addressed extensions beyond the daily flight time and duty time limits in unforeseen circumstances, and the certification of bunks for Class 1 rest facilities.[4]

FRMS implementation in commercial aviation is expanding, but many regulators and operators are still on a steep learning curve. The standard of evidence currently required by the FAA in safety cases is high, reflecting a conservative approach that is appropriate, but that may evolve as experience builds. The required complexity of a safety case should be commensurate with the complexity of the operations that it addresses and the expected level of fatigue risk. This same principle applies to the required complexity of an FRMS.

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REFERENCES

1. Czeisler CA. Measuring the passage of brain time. Science. 2016; 353 (6300):648–649.
2. Federal Aviation Administration. Flight crewmember duty and rest requirements. FAA-2009-1093; Amendment Nos. 117-1, 119-16, 121-357; 2011. [Accessed May 2017.] Available from http://www.gpo.gov/fdsys/pkg/FR-2012-01-04/pdf/2011-33078.pdf.
3. Federal Aviation Administration. 14 CFR Parts 117, 119, and 121: Flightcrew Member Duty and Rest Requirements. Washington (DC): FAA; 2012.
4. Federal Aviation Administration. Advisory Circular 117-1: Flightcrew Member Rest Facilities. Washington (DC): FAA; 2012.
5. Federal Aviation Administration. Fatigue education and awareness training program. FAA AC 117-2; 2012. [Accessed May 2017.] Available from https://www.faa.gov/regulations_policies/advisory_circulars/index.cfm/go/document.information/documentID/1020336.
6. Gander PH. Evolving regulatory approaches for managing fatigue risk in transport operations. Reviews of Human Factors and Ergonomics. 2015; 10(1): 253–271.
7. Gander PH, Gregory KB, Connell LJ, Graeber RC, Miller DL, Rosekind MR. Flight crew fatigue IV: overnight cargo operations. Aviat Space Environ Med. 1998; 69(9, Suppl.):B26–B36.
8. Gander PH, Gregory KB, Graeber RC, Connell LJ, Miller DL, Rosekind MR. Flight crew fatigue II: short-haul fixed-wing air transport operations. Aviat Space Environ Med. 1998; 69(9, Suppl.)B8–B15.
9. Gander PH, Mangie J, van den Berg MJ, Smith AAT, Mulrine HM, Signal TL. Crew fatigue safety performance indicators for fatigue risk management systems. Aviat Space Environ Med. 2014; 85(2): 139–147.
10. Gander PH, Mulrine HM, van den Berg MJ, Smith AAT, Signal TL, et al. Pilot fatigue: relationships with departure and arrival times, flight duration, and direction. Aviat Space Environ Med. 2014; 85(8): 833–840.
11. Gander PH, Mulrine MA, van den Berg MJ, Smith ATT, Signal TL, et al. Effects of sleep/wake history and circadian phase on proposed pilot fatigue safety performance indicators. J Sleep Res. 2015; 24(1): 110–119.
12. Gander P, Mulrine HM, van den Berg MJ, Wu LJ, Smith AAT, Signal TL. Does the circadian clock drift when pilots fly multiple transpacific flights with 1-2 day layovers? Chronobiol Int. 2016; 33(8):982–994.
13. Gander P, van den Berg M, Mulrine H, Signal TL, Mangie J. Circadian adaptation of airline pilots during extended duration operations between the USA and Asia. Chronobiol Int. 2013; 30(8):963–972.
14. International Air Transport Association, International Civil Aviation Organisation, International Federation of Airline Pilots' Associations. Fatigue Management Guide for Airline Operators, 2nd edition 2015. Montreal (Canada): International Air Transport Association; 2015.
15. International Civil Aviation Organisation. Fatigue management-related excerpts from Annex 6 to the Convention on International Civil Aviation. Montreal (Canada): ICAO; 2011.

16. International Civil Aviation Organisation. Manual for the oversight of fatigue management approaches, 2nd ed. Montreal (Canada): International Civil Aviation Organisation; 2016.
17. Pascoe PA, Johnson MK, Montgomery JM, Robertson KA, Spencer MB. Sleep in rest facilities onboard aircraft: questionnaire studies. Farnborough (UK): RAF Institute of Aviation Medicine; 1994. Report No.: IAM Report No. 778.
18. Rosekind MR, Gregory KB, Co EL, Miller DL, Dinges DF. Crew factors in flight operations XII: a survey of sleep quantity and quality in on-board crew rest facilities. Moffett Field (CA): NASA Ames Research Center; 2000.
19. Signal TL, Gander PH, van den Berg MJ, Graeber RC. In-flight sleep of flight crew during a 7-hour rest break: implications for research and flight safety. Sleep. 2013; 36(1):109–115.
20. Signal TL, Van den Berg M, Travier N, Gander PH. Phase 3 ultra-long-range validation: polysomnographic sleep and psychomotor performance: final report. Wellington (New Zealand): Massey University Sleep/Wake Research Centre; 2004.
21. van den Berg MJ, Wu LJ, Gander PH. Subjective measurement of in-flight sleeps, circadian variation, and their relationship with fatigue. Aerosp Med Hum Perform. 2016; 87(10):869–875.