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Preliminary Analysis of Impacts from Future Potential FTL Regulatory Changes for EMS

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MANAGING RISK
DNV

Preliminary analysis of impacts from future potential
FTL regulatory changes for EMS
for

EASA

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MANAGING RISK

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Executive Summary

Introduction

A rulemaking task (hereafter referred to as RMT.0346) has started at the beginning of 2012 for the development of Flight Time Limitations and rest requirements (FTL) for Emergency Medical Services (EMS). As part of this task a Regulatory Impact Assessment (RIA) has to be developed. Under framework contract EASA.2010.FC06, EASA has requested that DNV/Circadian conduct some preparatory data collection and preliminary impact analysis to assist the future work on the RIA.

The focus of this report has been on the safety, economic and social impacts of potential future rule changes for EMS. It addresses aeroplane and helicopter EMS (AEMS and HEMS).

Method

For the safety impact analysis the approach has been as follows:

- Relevant fatigue hazards have been identified for HEMS and AEMS (preliminary – this will need to be reviewed during the related rulemaking task process);
- Key issues relating to the hazards which may form part of future FTL regulatory changes have been considered from a safety perspective; and
- These considerations have been based on scientific literature, if available, and the use of Circadian's CAS model to see how key parameters (e.g. shift duration) impact on fatigue levels.

For the economic and social impact analyses, we have:

- Identified what are considered likely to be potential FTL changes with the most significant economic and social impacts;
- Described the effects qualitatively and listed factors which are likely to affect the size of the economic and social impact; and
- For selected impacts illustrated a process that would allow estimates of the scale of the impacts once more robust data have been gathered.

Conclusions

EMS operations have certain higher risk characteristics relative to other aircraft operations such as time pressures to reach and transport patients and flights made at short notice with potentially challenging topographical features and weather conditions. In addition there are aspects of flight time limitations and rest provisions that could lead to fatigue and increased risk, e.g. requirements to extend a duty period to respond to an emergency.

It is difficult to draw firm conclusions about the actual record of controlling fatigue risk in EMS operations in Europe due to potential under-reporting of fatigue as a causal factor of accidents/ incidents. The scientific literature and the modelling described in this report indicate that operating to the extremes of the national FTL ranges[1] currently allowable in Europe could have a significant impact on fatigue and alertness. Hence harmonisation of FTL provisions is likely to have safety impacts; in particular if the higher risk bounds of the ranges are reduced there will be positive safety impacts.

With respect to economic and social impacts a large number of potential FTL changes have been considered including harmonisation of:

- Maximum shift/ FDP durations
- Flexibility for shift/ FDP extensions due to EMS events
- Block hours over different time periods
- Extended rest requirements following extended shifts/ FDPs
- Availability of relief crews for HEMS night shifts
- Number of consecutive HEMS shifts (day/night)
- Periodic increases in rest
- How standby contributes to FDP and cumulative duty hours
- Reduced rest provisions
- Augmented crew arrangements.

This report provides information and preliminary analysis to be considered for the RIA development for RMT .0346 on FTL for EMS with a view to assist in an overall balanced assessment of safety, economic and social impacts.

[1] The ranges in European EMS FTL provisions are described in tables in report D1. For AEMS, Table 3.2 presents the range of maximum FDPs with extensions which can exceed 18 hours under special conditions, Table 3.3 contains the range of rest arrangements and Table 3.5 presents in-flight rest arrangements and ranges of FDP durations with augmented crews. For HEMS, Table 3.6 indicates a wide range of basic maximum FDPs and duty durations, Table 3.7 presents the range of rest arrangements (basic, reduced and extended recovery) and Table 3.8 contains the range of cumulative duty and block hours limits. Further FTL details are available in Appendix 2 of report D1. These ranges are further described in Section 5 for HEMS and Section 6 for AEMS in this report.

1.0 Introduction

1.1 Background

In December 2010 the European Aviation Safety Agency (EASA) published the Notice of Proposed Amendment (NPA) No. 2010-14A on ‘Implementing Rules on Flight and Duty Time Limitations and Rest Requirements for Commercial Air Transport (CAT) with Aeroplanes’. Following extensive consultation the Comment Response Document (CRD) to NPA 2010-14A was published in January 2012. Within the CRD is a Draft Opinion of EASA, Annex III, PART-ORO (ORGANISATION REQUIREMENTS) covering Subpart — Flight and duty time limitations and rest requirements. Section 1 of this contains General FTL requirements and Section 2 is for Commercial Air Transport Operators. Also within the CRD is a Certification Specification (CS) for Commercial Air Transport by Aeroplane — Scheduled and Charter Operations, designated FTL 1.

The CRD has placeholders for Certification Specifications FTL 2, 3 and 4 covering Emergency Medical Services (EMS) by aeroplane and by helicopter, Air Taxi and Single Pilot Operations by aeroplane and other CAT operations by helicopters respectively.

A rulemaking task has started at the beginning of 2012 for the development of FTL for EMS. The rulemaking task for Air Taxi and Single Pilot will begin third quarter of 2012 and the one for other CAT operations by Helicopters is to follow in 2013.

To support the development of these rules EASA procedures require the preparation of Regulatory Impact Assessments (RIAs) similar to the one published in NPA 2010-14A. These RIAs will be undertaken with the support of the respective Rule Making Groups (RMGs).

Under framework contract EASA.2010.FC06 EASA has requested that DNV/Circadian conduct some preparatory data collection and preliminary impact analysis to assist the future work on the RIAs. Prior to the current report DNV/Circadian have produced Deliverable D1 which was a survey from eight European NAAs of FTL provisions used for EMS in their States.

1.2 Objectives of D2 Report

The main objective of this report, Deliverable D2, is to produce preliminary analysis of the impacts of potential future FTL regulations concerning EMS. This analysis is intended to assist the RMG on EMS in their future discussions, the development of potential regulatory options and the preparation of the RIAs.

1.3 Scope of D2 Report

The scope of this preliminary analysis is to study, in the context of future potential FTL proposals:

- Safety impacts;
- Economic impacts; and

- Social impacts.

In the future RIAs other impacts including environmental, the degree of proportionality between the proposed measures and the impacts and the impact on regulatory harmonisation will also need to be taken into account.

It is not the purpose of this report to develop options for regulatory changes – this will be undertaken in future RMT activities. Hence rather than analyse the impact of defined options, in this report we look at key issues/ parameters (e.g. the duration of Flight Duty Period, FDP) and analyse how safety, economic costs and social impacts will vary if this issue/ parameter is changed. This will assist the future choice and analysis of options.

No attempt is made in this report to combine the analysis of different impacts (e.g. safety and economics) via one of the accepted RIA methods such as multi-criteria analysis. This is to be completed as part of RMT .0346 activities.

This report addresses aeroplane and helicopter EMS (AEMS and HEMS). Future reports will cover:

- Air Taxi and Single Pilot Operations (Aeroplanes) – Deliverable D3.
- Other Commercial Air Transport Operations by Helicopters – Deliverable D4.

Ultra Long Range (ULR) operations are used by some AEMS operators in Europe but are considered ex-scope in this report. ULR operations will be subject to a separate Rule Making Task in the future. Also the combination of AEMS and Air Taxi operations are not analysed in this report.

This report considers EMS crew covered under FTL as pilots and technical crew members.

1.4 Structure of this Report - Deliverable D2

The rest of this report is structured as follows:

- Section 2 provides an overview of how the preliminary impact analysis has been conducted.
- Section 3 identifies and classifies HEMS and AEMS fatigue hazards.
- Section 4 is a literature review covering aviation references relevant to EMS and general industry references on shift work as this is considered particularly relevant to HEMS operations.
- Section 5 analyses the key HEMS hazards and the main issues related to these hazards.
- Section 6 analyses the key AEMS hazards and the main issues.
- Section 7 presents conclusions.
- Sections 8 and 9 provide references and acronyms.
- The Appendices contain supporting data namely:

- Appendix 1 – EMS Safety Data, descriptions of fatigue aspects of relevant accidents.
- Appendix 2 – Circadian Alertness Simulation (CAS) modeling description.
- Appendix 3 – EMS operational data on numbers of missions, aircraft, crew, operators etc. (partial, not a comprehensive, picture of Europe).
- Appendix 4 – example HEMS and AEMS working patterns.

1.5 Acknowledgements

Large amounts of information was provided by representatives of the eight surveyed NAAs, i.e. Czech Republic, France, Germany, Norway, Poland, Spain, Switzerland and the UK. In addition, when NAAs were not able to respond they provided details of operator personnel who were able to fill in gaps. We would like to thank all these people for their time and assistance.

2.0 Methods for Analysing Impacts

2.1 Analysing Safety Impacts

A direct method for analysing safety impacts from FTL regulatory changes would be:

- To estimate current safety risk levels in European EMS operations from appropriate accident/ incident data.
- To analyse how potential changes to FTL regulations would affect this historical risk estimate either based on relevant data or expert judgement.

A problem with this direct approach, as revealed in the NPA 2010-14 RIA (EASA, 2010) is that:

- The data are statistically insufficient to directly deduce potential benefits of rule changes;
- The data are statistically insufficient to detect current and future safety risks, especially as fatigue related events may be masked under "human factor-related incidents" or they are not reflected at all in these data.

Two European EMS accidents reports which refer to fatigue (or the possibility of fatigue) are described in Appendix 1 from public domain sources. In addition EASA's Safety Analysis Section conducted a search of the EASA copy of the ICAO ADREP data base. This uncovered one further European accident and 2 non-European EMS occurrences where fatigue appears to have been a factor. These 5 events equate to 1.3% of the 395 EMS occurrences in the data base. Four of these five events were fatal accidents. 28% of the 395 EMS occurrences in the data base were fatal accidents. Thus fatigue appears to be a contributory cause in 3.6% of fatal EMS accidents. These relatively low percentages for the contribution of fatigue to overall occurrence and accident rates should be treated with some caution for the reasons noted above; in particular reports may not identify fatigue even though it could have been a factor to some degree.

One event from 2005 in the UK (described in Appendix I) reveals the potential difficulty of pilots on home standby managing their rest so that they do not become excessively fatigued when they are called out, particularly at night. Another occurrence was also related to a pilot remaining awake all day before a helicopter nighttime shift.

Even with the caveats about under-reporting of fatigue as a causal factor it would appear from the occurrence data that the controls that have been in place to manage fatigue in European EMS have generally been effective . Compared to the social benefits from EMS operations in terms of patient safety and health (see below), the overall safety balance (flight safety v patient safety) is very positive.

Because of this lack of data relating to the exact contribution of fatigue a similar approach to that adopted in the NPA 2010-14 RIA has been adopted in this report, i.e.:

- Relevant fatigue hazards have been identified for HEMS and AEMS (preliminary – this will be reviewed during the RMT.0346 process);

- Key safety issues relating to each hazard which may form part of future FTL regulatory changes have been considered from a safety perspective;
- These considerations have been based on scientific literature, if available, the use of Circadian's CAS model (see Appendix 2) and Circadian's expertise in the field of fatigue.

The CAS software models alertness based on three physiological processes:

- circadian time of day;
- sleep-wake balance and sustained wakefulness; and
- sleep inertia.

Based on the hours worked, the CAS model estimates sleep duration and placement around these restrictions. Within the hours worked CAS can apply varying degrees of alertness decrease to emulate varying workloads. For fixed wing operations CAS assumed higher workload during the take-off and landing phase of the flight. For helicopter operations the entire flight was assumed to be more demanding and more fatiguing.

CAS then provides simulation results as either direct alertness averages per given time period (usually duty periods) or an aggregate Fatigue Score which summarizes the entire pattern into one number.

To establish a consistent basis for comparison between the multiple diverse duty-rest and scheduling options considered in this study the following assumptions have been made in the CAS settings used for this analysis.

1. The settings are based on the average working age person, and individual variations in circadian chronotype (e.g. morningness-eveningness, unrestricted sleep duration, sleep quality, adaptive flexibility of circadian sleep-wake pattern and napping propensity) are not considered. Thus actual fatigue scores and alertness levels may be higher or lower than estimated in this CAS analysis depending on the individual chronotype of each individual. Much of sleep science research has been based on college students, as a matter of convenience; but this population has a significantly different circadian sleep profile compared to the majority of working age (25-65 year old) subjects. We have based our modeling on data from this post-college age population.
2. It is assumed that no active fatigue risk mitigations are in place, and the individuals modeled act as a person not trained and or practicing sleep-alertness management. Thus with populations of individuals who are actively practicing fatigue risk management, this CAS analysis will overestimate the fatigue score and underestimate the levels of alertness.

The safety impact analyses are described in Section 5.0 for HEMS and Section 6.0 for AEMS.

2.2 Analysing Economic Impacts

2.2.1 Overall Scale of EMS Activity

Based on the data that could be collated, approximately 200,000 HEMS and AEMS missions are flown annually in Europe. There are over 360 HEMS helicopter bases in Europe with additional fixed-wing ambulance bases chiefly providing cross-border or inter-continental services such as medical repatriation. (http://www.ehac.eu/index.html).

Extra details about activity levels were sought from the eight States surveyed in D1 and this was supplemented by data available on public websites. Annual missions by State are summarized in Table 2.1 below. Not all the surveyed States were able to provide data. The values in Table 2.1 account for about 75% of the estimated 200,000 missions per year in Europe.

Table 2.1: Annual Missions By State (partial picture only)

State	HEMS	AEMS	Total	Comments
France	15000 private +11800 public			Minimum estimate for HEMS, AEMS data difficult to obtain
Germany	84671	1020	85691	Based on data from 3 operators
Netherlands	2100			Data based on only 1 operator. Assuming 2 flights = 1 mission.
Norway	10663	8988	19651	Data based on 1 operator and military missions. Another operator probably contributes about half as much again in Norway.
Poland	4417	327	4743	Assuming 2 flights = 1 mission.
Switzerland	10797	1052	11849	Data based on 1 operator. Two other operators in State.
UK	17500	1500	19000	Minimum value for AEMS
Total (rounded)	157000	13000	170000	

Appendix 3 has more details on numbers of aircraft, crew and operators.

2.2.2 Business Models

Appendix 3 shows that there are many different EMS operators in Europe. These operators have a variety of business models which affect their costs. The different EMS business models in Europe include the following options, sometimes in combinations:

- Government funded (via Civil and Military), examples include:
    - Scottish Ambulance Service is the UK's only government funded air ambulance service.
    - Poland's LPR is funded by the government through the Ministry of Health but run independently.

  - Helicopters operated by the Ministry of the Interior in Germany are staffed by German Police pilots performing emergency responses when required.
  - Royal Norwegian Air Force provides an air ambulance service.
  - Norwegian Luftambulanse is funded primarily by grants from four regional health authorities.
- Donation/ Charity based, e.g.:
  - The air ambulance service in England and Wales is funded by charities organized into regions.
  - REGA in Switzerland is non-profit receiving no government subsidies and obtains funds from patrons and donations as well as fees for service from insurance companies and liable parties.
  - The DRF's AEMS and HEMS operations in Germany are not completely covered by public health insurance and also need the support of sponsoring members and donations.
- Fee based – in this model operators charge fees for their EMS services. These fees can be covered by travel or health insurance companies, liable parties or public health services. Some organisations mix this model with additional donations as noted above.
- Independently supported – a business or outside organization can fund the EMS service. An example of this is ADAC, Germany's largest automobile club, which funds the operation of many air ambulances.
- Shared cost model – some EMS operators share aircraft, pilots and facilities with other organisations. Examples include the UK's Wiltshire and Sussex Air Ambulance services which part share their helicopter operations with the Police.

As well as the different business models there are other factors that will affect operating costs around Europe and between different operators:

- Different types of mission in different States (e.g. aiding a ski injury as compared to a road traffic accident);
- Different utilization of crews – in some locations close to a high density of people and roads for example pilots may fly more missions per unit time than a pilot based in a remote location;
- Whether medical staff are included within the overall personnel costs of an EMS operator or whether they are outside funded within health care services;
- Whether crew and facilities are shared with other operators (e.g. police) and whether crew are leased or are full time personnel.

2.2.3 Crew Cost Estimates

The main impacts of FTL and rest regulatory changes are likely to be on crew costs. Therefore the sections below focus on this and look at data on the percentage contribution to overall operating costs of crew costs. Crew costs cover salary and non-salary such as pensions. Any changes in crew numbers will also impact costs associated with recruitment, training and checking of crew.

Given the many business model variations and other factors listed above a range of operating costs is to be expected. The percentage contribution of crew costs to overall operating costs will also be expected to vary.

Estimates for this percentage contribution have been obtained directly from NAAs and operators. All 8 States were asked. Some States referred us to operators for this information.

Table 2.2: Estimates of Crew Costs As Percentage of Overall Operating Costs

State/ Operator	% contribution to overall operating costs from crew related costs	Comment
State 1	15%	Estimate for AEMS based on data from an operator and judged appropriate also for HEMS
Operator 1	20%	Estimate based on AEMS
Operator 2	32%	For HEMS
Operator 3	18% (range 12%-24%)	Estimated based on total personnel costs from Annual Report and assumptions about crew costs vs average personnel costs
Operator 4	20-25%	For HEMS
Operator 5	11%	For HEMS
Operator 6	14%	For AEMS

A number of annual reports from operators have been reviewed[2] but crew costs are not split out as a separate item in the accounts.

Another method of deriving crew related costs would be via pilot salary surveys. A comprehensive survey, covering many different types of operations including EMS was

[2] Including those of Norsk Air Ambulance, REGA, Scottish Ambulance Service and Yorkshire Air Ambulance

carried out in the US (Professional Pilot, 2011). However no equivalent European survey has been found.

It should be noted that there could also be other more subtle economic impacts associated with changes to FTL and rest requirements, e.g.:

- EMS crew jobs could be made less or more attractive, for example, by changing the number of rest days available, affecting the number of flying hours or leading to changes in salary.
- In areas where there is competition for helicopter crew, e.g. where EMS is competing with the offshore industry (where salaries are generally higher), this could lead to a shortage of crew for EMS with a consequent knock-on impact to EMS service provision.
- If there is a need for more crew arising from FTL changes it may be a challenge to find such crew from the immediate locality. It may be difficult for crew to travel from further afield depending on FTL constraints regarding travel times.
- The impact on the number of flying hours can also affect job satisfaction and how motivated/ bored personnel become.

In the absence of more robust data, these impacts are not considered explicitly in the sections below.

2.2.4 Analysis Method for HEMS and AEMS

It is not possible to analyse all possible economic impacts of all conceivable future FTL regulatory changes. Therefore the subsections under HEMS (Section 5.0) and AEMS (Section 6.0) have for the safety issues identified under each hazard:

- Identified what are considered likely to be those FTL changes with the most significant economic impacts;
- Described the effects qualitatively and listed factors which are likely to affect the size of the economic impact; and
- For selected impacts illustrated a process that would allow estimates of the scale of the impacts once more robust data have been gathered.

2.3 Analysing Social Impacts

As noted above, the overall social impact of EMS in Europe has been very large in terms of safety and health benefits to ill and injured persons. The detailed data from States and operators shows approximately 1 person treated/ transported per mission and hence the 200,000 missions per year translates into millions of patients attended and transported over the last 10 years in Europe. The literature (e.g. Taylor et al, 2010) indicates a widespread range (0% to 22%) in EMS effectiveness in terms of percentage of lives saved per mission. The studies of EMS effectiveness have lots of variations including:

- Location type such as dense urban infrastructure, rural infrastructure, etc. One of the studies that found 0% benefit was in London UK, another was in Nova Scotia, Canada.
- Patient groups – e.g. one US study focused on obstetric patients only whereas others looked across all patient types.
- Criteria – the study from Varkaus Finland quotes "HEMS attendance was 'life saving or beneficial' in 22% of patients – so 22% may be an overestimate for saving lives.

The paper by Taylor et al (2010) makes clear that it is very hard to compare these studies: "*Given the variation inherent in the health systems in which HEMS operate, synthesis and extrapolation of study findings across differing health environments is difficult. To address economic and clinical evidence in relation to HEMS, future research that is tailored to account for local system factors is required*."

If the average value for the percentage of lives saved per mission is taken to be the middle of the range above, 10%, it can be inferred that a very large number of fatalities have been averted through EMS.

Clearly, given this very large benefit in terms of patient safety, the impacts of proposed FTL changes on EMS service provision need careful analysis in future RMT activities. A proposal to improve flight safety via an FTL change could potentially cause a degradation in EMS service provision and reduction in the number of patients treated/ transported.

The analysis method for social impacts has been analogous to the one above for economic impacts, i.e.

- Identified what are considered likely to be those FTL changes with the most significant social impacts;
- Described the effects qualitatively and listed factors which are likely to affect the size of the social impact; and
- For selected impacts illustrated a process that would allow future estimates of the scale of the impacts on patient safety.

The focus has been on patient safety and health. There could be other social impacts, e.g.:

- Working conditions for crew;
- Employment impacts (job creation/ losses), closely linked to economic impacts;
- Need for relocation or more/ less travelling as a result of FTL changes; and
- Impact on social life and work/ life balance.

These have been identified where relevant.

3.0 Hazard Identification

3.1 General Fatigue Factors and EMS Specifics

Fatigue is an impairment of mental and physical function manifested by a cluster of debilitating symptoms, usually including excessive sleepiness, reduced physical and mental performance ability, depressed mood and loss of motivation, which may result from a variety of causes including:

- **Sleep deprivation/circadian phase effects**: Fatigue develops as the result of an extended time awake (acute sleep deprivation), or reduced time asleep, or disrupted or poor quality sleep (partial sleep deprivation), time awake in the Window of Circadian Low (WOCL) or from the cumulative effect of multiple days with shortened or disrupted sleep such as may occur in jobs with extended work hours, irregular schedules or with night duty (chronic sleep deprivation).

- **Heavy stressful physical or mental effort:** Fatigue occurs as the result of extended hours of work with heavy muscular activity (e.g. marathon runner), continued stress or danger (e.g. combat fatigue) or intense mental exertion (e.g. EMS operations in challenging conditions) which occurs either during the task or as a rebound effect after the task, in proportion to the relative fitness (and/or prior training) of the individual.

- **Sleep disorders:** Fatigue manifested as excessive daytime sleepiness is the most common presenting complaint in sleep disorders, such as obstructive sleep apnoea, restless legs syndrome, narcolepsy or most of the other 85 different sleep disorders listed in the International Classification of Sleep Disorders (2005).

- **Illness or disease:** Fatigue is common in many diseases and illnesses (ranging from flu to cancer) which may occur as a direct result of the metabolic or other systemic pathophysiological disturbances of that disease, as a secondary consequence of sleep disturbances caused by other symptoms such as pain, nausea etc., or as the primary presenting complaint (e.g. chronic fatigue syndrome).

- **Therapeutic side-effect**: Fatigue is a commonly listed side-effect of prescription or over-the-counter pharmacological drugs, or may occur as the result of other therapeutic interventions (e.g. surgical procedure).

- **Stimulant drug usage:** Fatigue often occurs as a person rebounds after the initial euphoria, increased energy or “high” induced by illegal, over-the counter (e.g. Redbull, NoDoz etc.) or prescription stimulant pharmacological substances.

Unlike the engineering use of the word “fatigue” which is used to describe irreversible failure of a material as a result of stresses over an extended period of time, the medical definition of “fatigue” usually refers to a loss of physiological and psychological function as a result of extended wakefulness, heavy work, excessive stimulation, illness or stress which can usually be reversed in whole or in part by rest, sleep, treatment or recovery from the condition that caused it.

For this report we will use the ICAO definition of fatigue:

A physiological state of reduced mental or physical performance capability resulting from sleep loss or extended wakefulness, circadian phase, or workload (mental or physical activity) that can impair a crew member's alertness and ability to safely operate an aircraft or perform safety related duties.

In this report we have not considered sleep disorders, illness and disease, therapeutic side effects or stimulant drug usage. Workload is considered in terms of its direct effects on fatigue.

During sleep the human brain cycles through distinct stages, each characterized by changes in the electrical activity of the brain. When we are awake and alert, the electrical brain waves measured by electro-encephalography[3] (EEG) are fast (13 to 35 cycles per second) and random, but as we become drowsy the brain waves start to slow into a regular “alpha” pattern (of 8 to 12 cycles per second), which is exaggerated when we close our eyes. The first stage of sleep is when we start slipping into a semiconscious state, called stage 1 sleep, characterized by a further slowing of the brainwave rhythm to the “theta” range of 3 to 7 cycles per second, but in which we remain vaguely aware of our surroundings. We may even convince ourselves that we are still awake and in control of our consciousness - a dangerous misperception if we are on duty in a critical job.

From stage l we progress unknowingly into stage 2, a light level of sleep in which bursts of electrical activity called K-complexes and sleep spindles intrude into the EEG. Finally, after 30 to 40 minutes, we sink into the deepest stages of sleep (called stages 3 and 4) in which the brain waves slow down to 0.5 to 2 cycles per second and are magnified in their amplitude. These deep slow waves are called delta waves.

We do not linger for long in delta sleep. In fact, we tend to oscillate in a 90- to 100-minute cycle between the lighter and deeper stages of sleep interspersed with bouts of dreaming in which the brain waves suddenly speed up to an awake-like pattern and the eyes start moving rapidly from side to side. This stage, called rapid eye movement (REM) sleep, may occur four or times a night, building in duration as dawn approaches. Thus one may have four or five distinct dreams per night.

The stage of sleep from which you awake determines your condition on arousal. If you are in the deepest stages of delta sleep, you will feel groggy and disoriented on awakening, and suffer significant “sleep inertia” or impaired functioning for ten or twenty minutes or more. If you are in stage 1 or 2 sleep, you are much more likely to wake up alert and refreshed. Likewise you are more likely to remember a dream if you awake during a REM sleep stage.

Those factors which are most likely to affect sleep deprivation and circadian phase effects include:

[3] the recording of electrical activity along the scalp

1. Time of day according to the individual's own circadian phase

An individual's level of alertness and sleepiness varies over the course of the 24–hour day in a predictable circadian (approximately 24-hour) pattern with the greatest sleepiness in the early hours of the morning before dawn (typically 1AM-6AM), and a second lesser period of sleepiness in mid-afternoon (often referred to the "post-lunch dip" or the "siesta hour"). Numerous studies have shown that transportation and other accidents caused by fatigue have a peak time of risk relative to circadian phase around 1-6 AM and secondary time of risk approximately from 1-4 PM (Horne, 1995; Langlois, 1985).

It is not the clock time on the wall that determines these daily biological cycles of sleepiness and alertness. The time of day according to a person's circadian pacemaker (biological clock) is called the "circadian phase", which is shifted by exposure to light in other time zones or to a lesser extent during night duty activities. Even in people who are not travelling across time zones, an habitual early bed time and early arising time on both work days and weekends/rest days is associated with an earlier (or "advanced") circadian phase, and a pattern of maximum sleepiness and alertness that is shifted to earlier hours, as compared to someone who habitually stays up and sleeps in late, who will have a late (or "delayed") circadian phase.

2. Chronotype of the individual

Individuals vary considerably in their orientation to day and night on a morningness-eveningness scale and in their required sleep duration for recuperation (Duffy, 1999; Horne, 1976; Aesbach, 1999). Morning types tend to rise early and they feel and perform best during the morning hours. Evening types tend to rise late in the morning and they feel at their best late in the evening. It has been shown that these characteristics are genetic in nature, and independent of age, sex and ethnic heritage (Katzenberg,1999). As discussed earlier we have used default settings representing the average person in this analysis and have not simulated individual chronotypes.

3. Length of time since awakening from last sleep episode

When a person first wakes up from sleep there is a period of grogginess or sleepiness that resolves typically in less than half an hour. This is referred to as "sleep inertia". Once a person has fully recovered from the residual sleep inertia from his or her last sleep period the drive for sleep builds with time until the next sleep period occurs. Eventually the extended time spent awake results in a strong sleep pressure. This is referred to as the homeostatic drive to sleep. However, sleep propensity, or the likelihood of falling asleep, is determined by a combination of the homeostatic drive and the other factors listed here. As a result sleep propensity does not simply relate to the length of time awake which drove the original FDT regulations. In reality, the circadian and homeostatic drives to sleep interact. This produces peaks in relative alertness in mid-morning and early evening, separated by an early afternoon "post-lunch" dip in alertness or siesta hour. This circadian-homeostatic interaction also causes the precipitous drop in alertness after midnight when an employee begins his first night duty period following several days of night-time sleep and daytime wakefulness.

4. Duration of the previous consolidated sleep period

The effectiveness of a sleep period in quenching the level of sleepiness that an individual has accumulated over the previous day(s) is determined by the sleep period's duration, as well as by the quality of sleep obtained (see factor #6 below). The average adult needs 7-8 hours of sleep per day to maintain average levels of daytime alertness. However, there are considerable inter-individual differences, with some individuals needing as much as 9 hours per day, while others only need 6 hours. Significant increases in daytime sleepiness are found for most people when the nocturnal sleep length is reduced below 5 hours, or when reduced sleep duration occurs for two or more successive nights. In the CAS analysis we have used default settings representing the average person.

5. Timing of sleep episode

In addition to the duration of sleep, the timing of the sleep episode is a key factor. Due to the influence of circadian phase, sleep is more effective and its quality better at some times of the day than at others. As noted above, it is also important to consider the time of day according to a person's biological clock, (i.e. his or her "circadian phase") not only in predicting or assessing the level of sleepiness, but also in judging the duration and quality of sleep that is obtained by sleeping at a particular time of day.

Because of the strong effect of the circadian system, sleep duration is also highly dependent on the circadian time of day. For example, there are certain times of day when it is difficult to obtain more than four hours sleep, even under ideal conditions, after extended periods of time awake, and with the most highly motivated individual.

The studies of Akerstedt and Gillberg (1986) are particularly instructive. They studied working age subjects (comparable to EMS personnel) who were given an opportunity to sleep under ideal conditions (quiet comfortable bedroom) during rest periods which started at various times of day or night. When the rest period began at 11PM at the end of a normal day of 16 hours continuously awake, they slept on average for 8 hours, as one would expect given the unlimited sleeping opportunity. However the later the rest period began after 11PM, the shorter was the sleep duration as a result of the strong circadian time of day effect. Thus when the rest period began at 3 AM (after 20 hours continuously awake) they achieved only 6.5 hours sleep, when rest began at 7 AM (after 24 hours continuously awake) they obtained only 4.5 hours sleep; when rest began at 11 AM (after 28 hours continuously awake) they got only 4 hours sleep.

6. Quality of sleep in the previous sleep period

The quality of sleep at night also influences the sleepiness level on the subsequent day. When sleep is disturbed by deviations from typical sleep characteristics, this results in increased sleepiness the following day.

Many factors may influence these characteristics of sleep quality, including the time of day or night that sleep is attempted, the environmental conditions in which one is sleeping, and the existence of any clinical sleep disorders or other medical conditions.

To ensure adequate sleep, the sleeping environment should be both physically comfortable and psychologically conductive to sleep. People usually sleep better in their own bedroom than in an unfamiliar environment. One of the most important challenges many transportation employees face is the requirement to sleep away from home. In other words a transportation employee sleeping in their own bed on their regular nightly schedule and routine will have significantly higher sleep quality than the same person sleeping away from home in unfamiliar circumstances at an unusual time of day. In this analysis CAS takes into account the timing of sleep. It does not consider the effect of sleep disorders.

7. Cumulative effect of sleep duration and quality over the past week

A person's sleepiness level on a given day is most strongly influenced by the quality and duration of the last sleep episode. However, the sleep pattern during the preceding week will also affect sleepiness level. It is also well recognized that days-off, where there is no substantial restriction on the opportunity for unrestricted sleep, allow a person to recover fully from all accumulated sleep debt. The number of days required depends on the level of sleep deprivation, but in most circumstances two consecutive nights of sleep has been determined to be sufficient.

When a person follows a regular sleep-wake schedule, that is, going to bed and waking up at approximately the same hour every day, this helps to synchronize his or her sleep/wake and other circadian rhythms to that regular schedule.

Thus a regular daily pattern of bedtime and awake time, and a regular routine of exposure to light and dark will cause a person's circadian sleep-wake rhythm to become optimally synchronized to the time of day that they are going to bed – even if that time of day is not a typical or traditional time. This synchronization will promote optimal sleep quality and consequently minimize sleepiness at the time of the day the crew member wishes to be most alert.

In addition there are EMS specific factors that can impact on or combine with these fatigue factors:

- EMS operations are often time sensitive and crucial to getting a critically ill or injured patient to a medical facility as efficiently as possible which may influence a flight crew to fly under operational or fatigue related circumstances that they otherwise would not. It should be noted that the effect of adverse operational circumstances might be underestimated by a fatigued pilot.
- EMS operations are often conducted under challenging conditions, e.g. HEMS are at low altitudes and under varied weather conditions. Operations can be in rural or urban settings, in mountainous and non-mountainous terrain, during the day and night and in IFR and VMC conditions. Remote sites may be unfamiliar to pilots and for HEMS operations trees, buildings, wires and uneven terrain at remote sites can cause high workload.

The UK AAIB report (AAIB, 2006) into a 2005 AEMS accident states:

"*Air ambulance flights occupy a unique position within the public transport framework, and the operation of such flights may at times entail a greater level of overall risk. Although air ambulance flights are subject to the same regulations as other public transport flights, they are, by their very nature, more likely to have to operate under adverse circumstances. Fixed-wing air ambulance flights are also more likely to operate over the more remote areas of the United Kingdom, where aerodromes tend to be smaller and less well equipped, and where weather factors may be less favourable. Flights are often made at short notice outside of normal operating hours, and with an additional time pressure on crews which is not present with other types of operation*."

3.2 Helicopter EMS (HEMS)

The general characteristics of HEMS of relevance to fatigue and FTL are considered to be:

- On demand operations at very short notice
- Standby conducted at the HEMS base
- Multiple (very) short missions (could be as many as 20 short flights in a few hours)
- Mostly VFR operations often in unpredictable operational conditions to unknown landing sites and under time pressure
- Night flights involving use of Night Vision Imaging Systems (NVIS)
- HEMS bases operated typically with fixed duty hour shifts. The fixed duty hour shifts can depend on the latitude of the base as this influences daylight hours.
- Depending on emergency scenarios there may be a need to extend beyond the planned FDP/ shift duration
- Some HEMS bases are daytime operations only – others operate 24/7
- Significant variability on FDP, duty times and rest times across European States (see Report D1)

- Generally single pilot aided by additional crew member conducting navigation and other flight safety related tasks (could be a second pilot at night).

For more details on HEMS working patterns see Appendix 4.

Table 3.1 identifies hazards that appear relevant to HEMS. Potential mitigations have been identified. Comments based on the information supplied by NAAs and operators about the characteristics of HEMS have been included where relevant. These hazards and mitigations are preliminary and will be reviewed during the future RMT .0346 process.

Table 3.1: Preliminary HEMS Hazard Identification

Grouping	Hazards and Descriptions	Potential Mitigations	Comments
A. Time awake/ Duration of duty (relating to homeostatic process principally) See Literature Review in Section 4.1.	1. Duration of FDP/shift too long leading to fatigue (including EMS related extension) N.B. standby at HEMS base included in shift duration	a. Limits on maximum duration of HEMS shift/ FDP (including extensions) b. Limits on number of missions or daily flying time c. Requiring full rest before an extended shift d. Extended rest after a long duration shift/ FDP (after the event) e. Limiting the frequency of long extended shifts per week or per month (cumulative fatigue control) f. FRMS (general – applicable to all hazards) g. Relief pilot for single pilot operations when an extension is invoked h. Prohibiting combining EMS shift extension with extension due to split duty i. Limiting number of persons on aircraft during extensions j. Controlled napping and relaxation during ground breaks	Long (extended) shifts and FDPs are allowed in some States and are likely to be a potential peak fatigue issue. D1 shows significant variability between States. The impact of shift duration and the number of missions has been analysed in Section 5.1 and the impact of a break between missions. The impact of shifts encroaching the WOCL is considered in Section 5.2. Impact of controlled naps considered in Section 5.4.1.

Grouping	Hazards and Descriptions	Potential Mitigations	Comments
	2. PIC reacts to circumstances on the day to extend FDP/shift excessively leading to fatigue	a. Maximum limits on PIC extension (duration and frequency) b. A non-punitive process for a PIC to reduce a shift duration and/or increase rest in the case of fatigue c. Reporting to the NAA when the extension is above a certain threshold d. Guidance to the NAA on this subject e. Training on fatigue to support PIC in the decision process, e.g. the potential risks of PIC extensions, techniques for self-evaluation of fatigue, pressures likely to be encountered, etc. f. FRMS including awareness training for commanders	PIC discretion can be used to extend FDPs/ shifts, to finish a mission or return the helicopter to base. Could potentially lead to long duration duties. Considered in Section 5.5.
	3. On-ground break ("ad-hoc split duty") used to extend the FDP/shift excessively leading to fatigue	See Hazard A1 above + a. Establish minimum consecutive number of hours for break b. Establish how hours of the break contribute to daily shift duty time or FDP c. Suitable accommodation for the break d. Take account of split duty for subsequent rest calculation e. Limitation on number of missions after the split	Use of on-ground breaks is used in some States to justify extension of HEMS shift to durations considered in Section 5.1.
	4. Extended FDP/ shift due to in-flight rest leads to fatigue	Not relevant to HEMS	Not relevant to HEMS

Grouping	Hazards and Descriptions	Potential Mitigations	Comments
	5. Ground duties in addition to flight duties extend day's duties excessively.	a. Limitations on combined flight and ground duties (included in HEMS shift durations)	Included in HEMS shift duration analysis in Section 5.1.
B. Time of Day Effects (relating to circadian process principally) See Literature Review in Section 4.2.	1. Night shifts leading to fatigue	a. Napping before night shifts. b. Limiting shift/FDP hours. c. Limit number of missions (flying hours) per night shift. d. Training on how to manage night shift work (e.g. use of caffeine, meals, staying active, etc.) and when to recognize that one is fatigued (e.g. to be wary of relaxation after delivery of patient and ignoring level of fatigue). e. Availability of relief pilots to take over if a crew member realizes they are too fatigued or if flying hours limit is reached. f. Using two pilots at night. g. Controls over consecutive night shifts (see Cumulative Fatigue below). h. Additional rest	See Section 5.2. N.B. Early starts and late finishes are built into the shift patterns considered in Section 5.1
	2. Circadian disruption – mixing night and day shifts	a. Extended and recovery rest b. Limiting mixing of night and day duties	See Section 5.7.
	3. Time Zone de-synchronisation	Not relevant to HEMS	Not relevant to HEMS

Grouping	**Hazards and Descriptions**	**Potential Mitigations**	**Comments**
C. Cumulative See Literature Review in Sections 4.3 and 4.7.	1. Cumulative fatigue arising from consecutive day shifts	a. Limitations on consecutive days and weekly duty hours b. Longer term cumulative limits c. Minimum number of days off per month d. Rest periods periodically extended e. Spreading out duty as evenly as possible – difficult for on-demand EMS service	See Section 5.3. The impact of a variety of existing HEMS shift patterns are analysed to assess their impact on cumulative fatigue. Any working pattern leads to a combination of transient and cumulative fatigue.
	2. Cumulative fatigue arising from consecutive night shifts	See Hazards C1 + B1 for relevant mitigations + a. Special limits on consecutive night shifts	See Section 5.3.
	3. On-ground breaks during HEMS shifts not considered adequately in cumulative duty calculations	a. Take account of HEMS base standby time in cumulative duty and rest calculations	See Section 5.4.1.
D. Rest and Sleep Off Duty (relating to homeostatic process principally but affected by circadian process) See Literature Review in Section 4.4.	1. Lack of rest opportunity and rest at sub-optimal periods (in relation to basic rest and reduced rest)	a. Set minimum rest period and sleep opportunity between duties b. Set minimum duration for reduced rest (if used) c. Augmentation of rest and/or reduction in max. FDP/shift following reduced rest d. Limit frequency of reduced rest occasions e. Limit number of missions following reduced rest	See Section 5.4.2 Includes insufficient time to rest/ sleep in between shifts
E. Relaxation and Naps On Duty (relating to Sleep Inertia process principally) See Literature Review in Sections 4.5 and 4.6.	1. Overlong nap and insufficient time awake could lead to sleep inertia as mission begins	a. Awareness training about effect of length of nap on sleep inertia	Relaxation and napping mainly considered as a mitigation to hazard A.1 and analysed in Section 5.4.1. Role as a potential hazard considered in literature in Section 4.6.2.

Grouping	Hazards and Descriptions	Potential Mitigations	Comments
F. Positioning and Travelling (related to time awake and cumulative effects and homeostatic process principally)	1. Positioning before an FDP causing lack of rest and excessive time awake and hence fatigue	a. Inclusion of positioning immediately before flight duty in the FDP	See Section 5.6
	2. Positioning immediately after an FDP leading to excessively long duty periods with potentially a cumulative effect	a. Post-FDP positioning should be limited to prevent excessive duty day b. FDP and post-FDP positioning to be taken into account for subsequent rest period	See Section 5.6
	3. Excessive travelling time	a. Nomination of a home base for each crew member b. Ensuring a protected 8 hour sleep opportunity c. Counting travel time in excess of a limit (e.g. 60 minutes) as duty time (or positioning).	See Section 5.6

3.3 Aeroplane Emergency Medical Services (AEMS)

The AEMS operations in Europe appear to be split into two broad types in terms of key characteristics of relevance to fatigue and FTL.

1. **Home standby**. This appears to be the most commonly used form in Europe with the following characteristics:
   - Short call standby
   - Possibly intercontinental flights
   - Potentially long multiple sectors in FDP
   - Potentially ULR (ex-scope in this report)
   - Consequent use of augmented crews and in-flight rest
   - Flight crews acclimatized to local time of departure zone
   - AEMS pilots called out for duty on 25 - 60% of home standby days
   - Flying (block) hours and duty time could be relatively low compared to that of air taxi or airline pilots.

2. **Airport standby**. In a few locations AEMS is effectively providing a "HEMS-type" service in areas where HEMS coverage is not practical because of the remote location and large distances that need to be covered (e.g. Norway). It can be characterized by:
   - Short response times
   - Shorter, primarily domestic, flights
   - Varied shift patterns, different numbers of consecutive days and shift hours.

For both these types of standby the AEMS service:

- Is on demand operation upon short notice
- Can be multiple sectors
- Depending on emergency scenarios, may need to extend beyond planned FDP.

For more AEMS working pattern details see Appendix 4.

Table 3.2 identifies hazards that appear relevant to AEMS. Potential mitigations have been identified. Comments based on the information supplied by NAAs and operators about the characteristics of AEMS have been included where relevant. As with HEMS these hazards and mitigations are preliminary and will be reviewed during the future RMT .0346 process.

Tables 3.1 and 3.2 also show where the hazards are covered in the report.

Table 3.2: Preliminary AEMS Hazard Identification

Grouping	Hazards and Description	Potential Mitigations	Comments
A. Time awake/ Duration of duty (relating to homeostatic process principally) See Literature Review in Section 4.1.	1. Duration of FDP too long leading to fatigue (including EMS related extension)	a. Limits on maximum duration of FDP (including extensions) b. Modifying FDP according to number of sectors and/ or limits on daily flying time c. Requiring full rest before an extended FDP d. Extended rest after a long duration FDP (after the event) e. Limiting the frequency of long extended FDPs per week or per month (cumulative fatigue control) f. FRMS (general – applicable to all hazards) g. Relief pilot for single pilot operations when an extension is invoked h. Prohibiting combining EMS shift extension with extension due to split duty i. Limiting number of persons on aircraft during extensions j. Controlled napping and relaxation during any ground breaks	Long (extended) FDPs are allowed in some States and are likely to be a potential peak fatigue issue. D1 shows significant variability between States. The impact of FDP duration and WOCL encroachment have been analysed in Section 6.1 and the impact of a break between missions.

Grouping	Hazards and Description	Potential Mitigations	Comments
	2. PIC reacts to circumstances on the day to extend FDP excessively leading to fatigue	a. Maximum limits on PIC extension b. A non-punitive process for a PIC to reduce a shift duration and/or increase rest in the case of fatigue c. Reporting to the NAA when the extension is above a certain threshold d. Guidance to the NAA on this subject e. Training on fatigue to support PIC in the decision process, e.g. the potential risks of PIC extensions, techniques for self-evaluation of fatigue, pressures likely to be encountered, etc. f. FRMS including awareness training for commanders	PIC discretion can be used to extend FDPs, to finish a mission or return the aircraft to base. Could potentially lead to long duration FDPs. Considered in Section 6.5.

Grouping	Hazards and Description	Potential Mitigations	Comments
	3. Extended FDP due to in-flight rest (augmented crew) leads to fatigue	a. Maximum duration of FDP with augmented crew (including extensions) dependent on type of onboard rest facilities and number of additional crew carried b. Setting minimum standards for in-flight rest facilities c. Minimum rest period onboard required d. Specifying minimum rest durations at destination and home e. Additional compensation time at home over and above the standard rest time f. Sleep opportunities at home base after long missions (to mitigate home travel risks) g. Promote and pay for use of public transport after long missions h. Limiting the frequency of such extended FDPs with augmented crew i. Limiting the number of sectors.	See Section 6.2.
	4. On-ground break used to extend the FDP excessively leading to fatigue	a. Establish minimum consecutive number of hours for break b. Establish how hours of the break contribute to FDP c. Suitable accommodation for the break d. Take account of split duty for subsequent rest calculation e. Limitation on number of missions after the split	Survey data (see Appendix 4) indicated that split duty is either never used by AEMS operators or very infrequently. However, on-ground breaks have been modeled in Section 6.1 and on-ground breaks considered in HEMS shift durations (Sections 5.1 and 5.4.1).

Grouping	Hazards and Description	Potential Mitigations	Comments
	5. Standby at home followed by FDP leads to excessive time awake Unpredictability of home standby can cause difficulties in being fully rested before FDP	a. Take account of standby time in maximum FDP b. Limit on standby duration c. Standby management procedures so operator avoids placing crew on repeated 24 hr duration standbys, and preferential use of persons on standby who should be better rested. d. FRMS and crew's individual management of rest during standby – a FRMS can help raise crew's awareness of the importance of napping, avoiding heavy home working tasks, etc.	See Sections 6.1 and 6.4. N.B. Airport standby much less common for AEMS compared to HEMS (HEMS issues under Section 5.4.1).
	6. Ground duties in addition to flight duties extend day's duties excessively.	a. Limitations on combined flight and ground duties (included in HEMS shift durations)	AEMS pilots generally called out from home standby. For AEMS based on airport standby, see analysis of shift duration including ground duties in Section 5.1.
B. Time of Day Effects (relating to circadian process principally) See Literature Review in Section 4.2.	1. WOCL encroachment	a. Limiting maximum FDP duration based on WOCL encroachment	See Sections 6.1 and 6.3.
	2. Circadian disruption – mixing duty transitions between early/ late/ night duties	a. Extended and recovery rest b. Limiting mixing of night and day flights	See Section 5.7.

Grouping	Hazards and Description	Potential Mitigations	Comments
	3. Time Zone de-synchronisation	a. Duty restrictions and rest (home and away) based on number of time zones b. Limit max FDP according to day time and degree of acclimatization c. Minimum time set before a crew would be considered time zone acclimatized d. FRMS of particular importance to take account of time zone specifics and specific route patterns of a long range AEMS operator e. Limiting number of alternating east-west rotations per month and providing additional rest when these happen	Even for AEMS missions involving multiple time zone crossings, pilots will generally stay acclimatised to home base time as mission will involve either back to back flights or minimum time at destination to ensure patient is brought back as soon as possible.
C. Cumulative See Literature Review in Sections 4.3 and 4.7.	1. Cumulative fatigue / sleep debt builds up Includes effect of FDPs on consecutive days/ nights (even though unlikely to extend to several days due to on-demand nature of service)	a. Limitations on consecutive days and weekly duty hours b. Longer term cumulative limits c. Minimum number of days off per month d. Rest periods periodically extended e. Spreading out duty as evenly as possible – difficult for on-demand EMS service f. Providing additional rest if frequency of FDPs encroaching WOCL exceeds a certain limit g. Limiting the frequency of WOCL encroached FDPs – again potentially difficult for on-demand EMS service	See discussions in Section 5.3; although in context of HEMS, build-up of fatigue over consecutive days/ nights working and longer term cumulative limits in Section 5.3 are also of relevance to AEMS. N.B. States surveyed in D1 showed adherence to Subpart Q on cumulative hours for AEMS. Annual hours for AEMS pilots are generally significantly lower than for scheduled airline pilots.
	2. Home standby not considered adequately in cumulative duty calculations	a. Take account of home standby time in cumulative duty and rest calculations	See Section 6.4.

Grouping	Hazards and Description	Potential Mitigations	Comments
D. Rest and Sleep Off Duty (relating to homeostatic process principally but affected by circadian process) See Literature Review in Section 4.4.	1. Lack of rest opportunity and rest at sub-optimal periods (in relation to basic rest and reduced rest)	a. Set minimum rest period and sleep opportunity between duties b. Set minimum duration for reduced rest (if used) c. Augmentation of rest and/or reduction in max. FDP following reduced rest d. Limit frequency of reduced rest occasions e. Limit number of missions following reduced rest	See discussions in Section 5.4.2; although in context of HEMS, analysis of basic rest and reduced rest patterns in Section 5.4.2 are of relevance to AEMS as well.
E. Relaxation and Naps On Duty (relating to Sleep Inertia process principally) See Literature Review in Section 4.5 and 4.6.	1. Overlong nap and insufficient time awake could lead to sleep inertia during flights	a. Awareness training about effect of length of nap on sleep inertia	Role as a potential hazard considered in literature in Section 4.6.2.
F. Positioning and Travelling (related to time awake and cumulative effects and homeostatic process principally)	1. Positioning before an FDP causing lack of rest and excessive time awake and hence fatigue	a. Inclusion of positioning immediately before flight duty in the FDP	See Section 5.6
	2. Positioning immediately after an FDP leading to excessively long duty periods with potentially a cumulative effect	a. Post-FDP positioning should be limited to prevent excessive duty day b. FDP and post-FDP positioning to be taken into account for subsequent rest period	See Section 5.6

Grouping	Hazards and Description	Potential Mitigations	Comments
	3. Excessive travelling time	a. Nomination of a home base for each crew member b. Ensuring a protected 8 hour sleep opportunity c. Counting travel time in excess of a limit (e.g. 60 minutes) as duty time (or positioning).	See Section 5.6

4.0 Fatigue Risk in HEMS and AEMS Operations: Literature Review

This section reviews the peer-reviewed research literature in operator fatigue with a special emphasis on aviation operations, and on HEMS and AEMS operations where relevant studies are available. The main contributors to operator/crew fatigue and their interactions are discussed in the following sections.

4.1 Duration of Duty Shift and Time Awake

4.1.1 Overview

The relationship between duty length and fatigue is complex, and cannot be reduced to a simple formula, as it is complicated by circadian phase, time awake since last sleep, chronotype and the other factors discussed in Section 3.1.

The length of duty directly impacts the accumulation of fatigue whilst on duty since it goes along with "time awake" which is directly related to fatigue. This "time awake" also explains that the length of duty has to be looked at in conjunction with "time of day" since for night duties sleep often ends hours before the duty start, whereas for day duty pilots usually start with "freshly charged batteries" in terms of recent sleep. The length of duty also determines at what time of day the opportunity for rest and sleep occurs. This is important since sleep outside the window of circadian low is usually of lower quality and less beneficial.

When evaluating duty or shift duration, it should be noted that longer shifts not only affect time on duty, but also may reduce the amount of time off between shifts, and impact sleep duration and recovery. The amount and distribution of time off between both consecutive work days and blocks of work days is an important factor of the shift system. Accumulated sleep deprivation (i.e. a "sleep debt") can occur during blocks of consecutive shifts. This requires that individuals are provided with an opportunity to recover from the work set, and have adequate unrestricted time for sleep to recover from any accumulated sleep debt.

There are a series of factors that should be taken into account when analyzing duty or shift duration in aviation operations, including the influence of number of sectors, augmented crews and the possibility of in-flight rest (Section 4.6) and time of day effects (Section 4.2). Because HEMS operations are often based around shifts, the literature from other industries concerning shiftwork is reviewed below in addition to aviation specific literature.

4.1.2 Shift Duration Literature Across All 24/7 Industries

The main issue with shift duration is whether fatigue risk (and the associated risk of incidents and injuries) increases with increased shift length. A review of the scientific literature shows that most studies found increased fatigue with longer duty periods, and a number of studies have shown an increased risk of accidents at the end of the shift. However, the increase is not linear, and usage of breaks within a shift has been shown to be effective in decreasing accident risk during that shift as described below in section 4.1.2.2. Moreover, other studies have found that there is also increased risk at the beginning of the shift, and within 2-4 hours of the start of a shift.

4.1.2.1 8-Hour versus 12-Hour Shift Comparisons

Most of the scientific literature on shift duration is focused on the comparison between 8-h and 12-h shifts, since these shift lengths are the most common in most shiftwork environments. While in some studies shifts up to 12 hours have been shown not to affect performance negatively (Smith et al. 1998), most studies have found an increased level of fatigue and sleepiness, especially during the final few hours of the shift (Rosa and Bonnet 1993, Rosa 1995, Fisher et al. 2000, Son et al. 2008).

However, there is agreement that, in most circumstances, shift durations up to 12 hours do not represent a significant risk increase, compared to 8- h shifts provided the total hours worked per week is the same. This is because the completion of weekly work hours in a fewer number of days means that there are more off-duty days per week on 12 hour shifts, and this allows more time to recover from any accumulated sleep debt as compared to the fewer number of days off-duty on 8 hour shifts.

4.1.2.2 Accident Risk and Shift Length

Some scientific studies have indicated that there is an increased risk of incidents in the 9th to 12th consecutive hour of work (Spencer et al., 2006). However, other studies have found that the relative frequency of incidents does not increase linearly from the first to the last hour of the shift. Furthermore, often there is an increased risk not only at the end of the shift, but also during the first or second hour (Hanowski et al., 2009; Folkard, 1997) until the operator gets focused. A review of shiftwork studies analyzing the relative incident risk over time on duty found a slight increase from the second to the 5th hour, a decrease in the 6th hour and then risk increased in an approximately linear fashion with time on duty, and in the 12th hour was more than double than during the first eight hours (Folkard and Tucker, 2003). The authors also suggested that a more comprehensive evaluation of the risk associated with time on duty should take into account the effect of breaks. Their study analysed the effects of breaks on injuries in an industrial setting and found that breaks reduced accident risk, and that risk increased substantially and almost linearly between successive breaks, both during day and night shifts. The authors concluded that different factors need to be considered in combination when evaluating risk associated with night work, and for example, a 12-h night shift that included frequent rest breaks might be safer than an 8-h shift with only a single, mid-shift break (Folkard and Tucker, 2003).

4.1.2.3 Shifts Exceeding 12 hours

Schedules with shifts longer than 12 hours are less common across a range of industries (except in the trucking industry, where drivers are allowed to be on duty up to 14 hours per day, and a 10-hour rest before the following shift is enforced) and generally not recommended on a regular basis.

The safety of 14 consecutive hours on duty in a safety-critical position was endorsed by the FMCSA in the trucking Hours of Service regulations (Department of Transportation Report 2003). After much research (US Federal Register, 2005) and consultation, these U.S. trucking industry regulations, introduced in 2004, allow drivers to be on duty a maximum of

14 consecutive hours per day. However it should be noted that these regulations also enforce a minimum of 10 hours rest after each 14-hour duty period. This is also the pattern for FTL in the US for CAT operations.

Shifts of 16 hours or longer are unusual, except in emergency situations. For instance, the U.S. Nuclear Regulatory Commission (2001) sets the limit at 16 h in a 24-h period, provided that this is an occasional event. The international FRMS standard for the oil industry (American Petroleum Institute, 2010) states that extended shifts (greater than 14 hours) shall occur only to avoid unplanned unmanned safety critical positions or accomplish unplanned safety critical tasks. It also states that in the case of 14-16 hour shifts, a minimum of 8 hours off before next shift is required, and for shifts greater than 16 hours, a minimum of 10 hours off before the next shift. It also requires that extended shifts shall in no case exceed 18 hours and that that there should be not more than 1 extended shift longer than 14 hours per work set. Some studies have found that 16-hour shifts may be worked without significantly increasing fatigue, provided that adequate countermeasures are taken during and after the shift, such as allowing a nap during the shift and scheduling at least one day off after the shift (Takahashi et al., 1999).

4.1.3 Review of Aviation Scientific Literature: Duration of FDP in Non-Augmented Crews

In the aviation industry, duty periods of 12 hours and longer are becoming increasingly common in commercial aviation. In recent years the introduction of Ultra-Long-Range flights (in excess of 16 hours flight time) have become more frequent. In addition, extended duty periods may also occur in EMS operations. Many studies in the aviation industry (e.g. Samel et al (1997), Spencer and Robertson (1999), Goode (2003)) have found that extended duty periods in non-augmented operations are associated with elevated fatigue levels and increased accident risk at the end of the duty period.

The risk of aviation accidents increases with time of duty. A large U.S. study analysed human factors related accident data over a period of 21 years for which a 72-hour history of pilot activities prior to the accident was available. The distribution of these pilot work schedules was compared to a large reference sample of all pilot work patterns. The data showed that for duties of 10-12 hours the relative risk of an accident was 1.7 times higher than for all duties, and for duties of 13 hours or more, the relative risk was over 5.5 times higher. In addition, while 20% of human factors accidents occurred to pilots who had been on duty for 10 hours or more, only 10% of pilot duty hours occurred during that time (Goode, 2003). As noted in Section 4.1.1 the relationship between duty length and fatigue risk is complex; in particular in the context of the Goode 2003 paper the rest requirements under Part 121 will have influenced the fatigue risk as well as the duty lengths and hence the relationships derived in this paper need to be treated with caution when the rest requirements are significantly different from those applicable to this study.

NTSB investigations have found that long duty days (over 13 hours) are associated with a disproportionate amount of accidents, compared to duty periods of less than 13 hours. The longer the crews are awake, the more errors they commit, especially cognitive errors such as decision making (NTSB, 1994).

Limited use of 18-h shifts has been studied in HEMS. Thomas et al. (2006) evaluated sleep and cognitive performance of helicopter rescue flight nurses, comparing 12-hour versus 18-hour shifts during a 72-hour duty schedule: either three consecutive 12-hour night shifts or two consecutive 18-hour (0700 to 0100) shifts separated by a 24 hour rest period. The data showed that provided that adequate daily sleep (at least 7 hours per day) is obtained, there was no difference or decline in the cognitive function of the nurses working 12-hour or 18-hour shifts during a 72-hour schedule.

There is some agreement that FDP limits should be 12-14 hours, with recommendations for specific situations. An early study (Dinges, 1996) recommends that an extended cumulative flight duty period should be limited to 12 hours within 24 hours (in the context of a 10-hour max FDP recommendation) and that it should be accompanied by additional restrictions and compensatory off-duty period. The Paper for the European Transport Safety Council (ETSC) states that there is no objection to an FDP of 12 hours during the day, but does not support FDPs as long as 14 hours for early starts (Akerstedt, 2003). The Moebus Aviation report (Moebus, 2008) recommends that a single maximum daily FDP should never exceed 13 hours (and then only under specific favourable conditions) and that extension provisions above this should be excluded. However, in the report there is no account taken of the increased rest period required by Subpart Q in case of an extension of 1 hour to an FDP (2 hours before + 2 after or 4 hours after the extended FDP).

4.1.4 Influence of Number of Sectors

There is consensus that multi-segment flights are a major contributor to fatigue. However, there is still controversy on when fatigue countermeasures, such a reduction of maximum FDP, should be implemented and on the magnitude of the reduction.

A number of studies have shown that fatigue increases with the number of sectors (Powell et al., 2007; Spencer and Robertson, 2000; Bourgeois-Bougrine et al., 2003a&b). Prolonged duty periods (multi-segments flights over a sequence of 4 to 5 days) was cited as a major contributor to fatigue by 53% of short-haul pilots completing a questionnaire assessing perceived causes of fatigue (Bourgeois-Bougrine et al., 2003a&b). In a study that evaluated fatigue in two-pilot operations with no overnight duties pilots were asked to complete a questionnaire and validated fatigue and sleepiness scales at top of descent on the last sector of the duty. The most important factors affecting fatigue were length of duty and number of sectors, which increased fatigue in a linear fashion (Powell et al., 2007).

The need to decrease the FDP if there are a significant number of sectors is confirmed by many scientific studies. The Subpart Q requirement on maximum allowable FDP is based on a 30-minute reduction after the second sector.

However, the scientific literature does not give a uniform answer to the question of at which sector number should the reduction begin. For example, while Spencer (2000) finds no difference with respect to fatigue between one and two sectors, Powell (2008) states that fatigue increases from the second sector.

There is no agreement on how large should be the reduction. While some studies have recommended a reduction of 45 minutes per sector (Spencer, 2002), other studies recommend shorter reductions.

4.2 Time of Day Effects and Night Duty

4.2.1 Overview

There is extensive data on the increased risks associated with night duty shifts across multiple industries. For example, the relative incident risk across different shifts found that risk increased in an approximately linear fashion across shifts. Compared to the morning shift, the increased risk was 18.3% for the afternoon shift and 30.5% on the night shift (Folkard and Tucker, 2003).

There is consensus that overnight flights and night duty are especially vulnerable to severe fatigue, since flying time occurs during the WOCL, the circadian phase with lowest alertness and performance. In addition, these effects are compounded by the sleep deprivation associated with working during the night and sleeping during the day. The detrimental effects of sleep deprivation, time since sleep, and the WOCL can lead to severe fatigue with increasing time on task. Furthermore, fatigue during homebound flights is often exacerbated in unacclimatised crews, who had during layovers a sleep shorter and of poorer quality than at home.

Another issue to be taken into account is the time of departure of the flight. Early start flights present a challenge, since they usually result in shorter sleep before the flight, mainly due to the fact that pilots do not advance bedtime to compensate for the early wake up time. Over the 24 hour day, there are two periods when alertness is high, during the morning and early evening. These periods are called "sleep forbidden zones", because it is difficult to fall asleep at these times. This makes it difficult to advance bedtime. There is agreement that early starts are associated with sleep deficit and increased fatigue, especially in the case of consecutive early starts.

4.2.2 Overnight Flights and Night Duty

4.2.2.1 Increased Fatigue and Accident Risk During Night Duty

Many studies have documented the increased risk of fatigue in overnight aviation operations. Field studies of single-sector two-crew operations have shown that some crews were having difficulty remaining awake during overnight duties of 11 hours or more (Samel et al., 1997a; Spencer & Robertson, 1999). A survey of long-haul pilots found that pilots reported night flights as a major contributor to fatigue by 59% of pilots, especially schedules involving overnight outbound and inbound flight with daytime layovers (Bourgeois-Bougrine et al., 2003). Another study assessing pilots' fatigue using a validated scale found that fatigue ratings were greater on longer trips (except where mitigated by adding an extra pilot) and on overnight sectors (Powell et al., 2011). The Moebus Aviation report (Moebus, 2008), based on a review of scientific studies, notes that during night hours fatigue increases and vigilance decreases more markedly with ongoing duty hours than during the day.

4.2.2.2 Night Operations and Pilot Error

The negative impact of night duties was clearly demonstrated in a study analyzing the hours of the day when pilots working in a commercial airline made the most errors (de Mello et al., 2008). Errors were analysed using data from flight operation quality assurance systems, including the following errors: operational deviations and/or errors, procedural errors and maintenance faults and mistakes in procedures. The data showed that the risk of pilot errors increased by almost 50% in the period from 0:00 to 5:59, relative to the morning period 6:00-11:59.

Several studies have focused on HEMS and accident risk at different times of the day. An extensive review and risk assessment of HEMS accidents highlighted the increased risk of overnight operations. The study found that even though 38% of HEMS flight occur at night, 49% of accidents occurred during night-time hours (NTSB, 2006). An evaluation of human-error-related HEMS accidents in the US (1990-2003, accidents that occurred during en-route, transport and repositioning) showed that night-time accidents were twice as likely to be associated with fatalities as daytime accidents, 44.7% compared to 22.9% (Boquet et al., 2006). The NTSB, 2006 report states that fatigue (lack of rest, extended hours) could be a causal factor. It should be noted that factors other than fatigue will be important risk contributors at night including visibility.

Based on data from scientific research, some experts have suggested that FDT limits could be different for daytime and night-time duties, with longer duty period during daytime (although a single FDP should never exceed 13 hours) than during overnight duties, depending on the start time and the amount of sleep obtained and acclimatization to local time (Samel et al., 1997, Spencer and Robertson, 2007). An early study (Dinges, 1996) recommended that there be no extended flight duty period that encroached on any portion of circadian low. Spencer and Robertson (1999) strongly supported that non-augmented duty overnight should not exceed 10 hours, and suggested that 12 hours is acceptable for 2-crew operations during daytime.

4.2.2.3 Factors Contributing to Increased Fatigue During Night Duties

Longer periods of wakefulness before duty: One of the factors contributing to increased fatigue in overnight flights is an increased period of wakefulness before duty, especially if crews are not able to take an afternoon nap. A study of a simulated ULR flight found that pilots who departed at night, after being awake for at least 13.5 hours, had significantly reduced reaction times compared to pilots who departed during the morning hours, after about 3.5 hours of wakefulness. Pilots in the overnight flights were especially impaired during the first half of the flight, due both to sleep and circadian factors that were promoting sleep. However, towards the end of the flight, with increased hours of continued wakefulness, performance decrements were seen in both morning and night departure groups (Caldwell et al., 2006).

Consecutive night duties: The risk associated with overnight flights may increase with recurrent night duties because studies show that shift workers seldom obtain the same amount of sleep during the day they would normally obtain when sleeping at night (Folkard et al., 2005).

Duration of duty period and number of segments: A study evaluating fatigue in two-pilot operations flying 1-2 sectors duties that ranged from 3 to 12 hours total duty time asked pilots to complete a questionnaire and validated fatigue and sleepiness scales at top of descent on the last sector of the duty. The strongest influence on fatigue was time of day, with the highest levels during the WOCL (02:00-06:00). Fatigue also increased with length of duty and number of sectors. Moreover, the study found that time of day also affected level of fatigue at start of duty and the rate at which fatigue levels increased. For example, fatigue level after 12 hours for duties starting between 06:000 and 12:00 was already exceeded after 3 hour on duty for duties starting between 00:00 and 03:00 (Powell et al., 2008).

Thus the scientific literature strongly supports the need for reducing the maximum FDP for WOCL encroachment. This supports the approach taken in Subpart Q and in the CRD 2010-14.

4.2.3 Early Start Flights

Time of day effects occur not only on overnight duties. Early start flights also present a challenge, since they usually result in shorter sleep before the flight.

With shift start times before 6:00 a.m., achieving the required seven to eight hours of sleep can be difficult for most people, and these shifts have great potential for contributing to workers' sleep deprivation (Kecklund & Akerstedt, 1995). This results in increased fatigue and consequently increases the risk of errors and accidents during the morning shift. One reason for reduced sleep before an early morning shift is that, irrespective of what time the shift starts, many people go to bed at their usual bedtime (Moores, 1990). However, the main reason is that it is difficult to fall asleep in the early evening. Lavie (1986) described a "sleep forbidden zone," during the evening, related to the circadian rhythm of alertness, which results in making it very difficult to fall asleep at that time.

The effect of early start times on sleep and alertness in short-haul pilots has been confirmed by several studies. For example, a survey found that for short-haul pilots, successive early wake-ups was cited as a major contributor to fatigue by 41% of pilots (Bourgeois-Bougrine et al., 2003). Spencer and Montgomery, (1997) found that time of day was the most important factor affecting sleep duration and quality. The mean duration of sleep episodes starting between 21:00 and 01:00 was greater than 7 hours. As start of sleep was progressively delayed, its duration decreased to 2.5 hours with starts between 17:00 and 18:00. When a duty period started before 09:00 the duration of the preceding sleep period was reduced.

The sleep loss amounted to approximately 30 minutes for every hour that the duty period advanced between 09:00 and 05:00. Subjective sleep quality was also reduced for duty periods starting before 07:00. During schedules involving consecutive early starts, the sleep deficit accumulated and alertness tended to deteriorate. Another study showed that the duration of sleep prior to an early start was reduced by almost one hour for report times between 07:00 and almost two hours for report times between 05:00 and 06:00. The subsequent sleep deficit had a clear effect on fatigue. Duties starting before 09:00 were associated with increased fatigue throughout the following duty period, and that fatigue also increased during schedules that included several consecutive duties starting at 08:00 or earlier (Spencer and Robertson, 2002). A recent study found that the lowest amount of sleep was obtained prior to duty periods starting between 04:00 and 05:00 (5.4 hours), and the greatest for duty periods starting between 09:00 and 10:00 (6.6 hours). The data indicate that approximately 15 minutes of sleep are lost for every hour that the start of duty is advanced prior to 09:00. Moreover, self-rated fatigue at the start of duty was highest for duty periods starting between 04:00 and 05:00 and lowest for duty periods starting between 09:00 and 10:00 (Roach et al., 2012).

4.2.4 Day-Night Shift Transitions

Another important factor is the number of day-night transitions, that is, from sleeping at night and being active during daytime to sleeping during the day and being active at night.

The underlying issue is that physiological rhythms do not shift immediately when transitioning from day to night shift and vice versa. Research studies have shown that circadian rhythms can shift approximately one hour per day when working night shifts, but coming back to the daytime routine the adjustment is faster, about two hours per day. During the transition, there is a misalignment of the circadian rhythms, which translate into malaise and increased fatigue. Earlier studies found that the change from night to day shift may cause as much discomfort as a change in the other direction (Akerstedt et al 1977). Recent studies have confirmed these results. For example, a study conducted on off-shore oil rigs evaluated adaptation and re-adaptation to night shifts and day shifts, and found that the return to day shift led to an increase in sleepiness and worsening of sleep, but they improved gradually during the week (Bjorvant et al. 2006).

Several research studies have studied the transition from day to night shift without rest days in between and found that in these circumstances, the first night shift is the most difficult shift in a sequence of consecutive shift. The studies showed that the impairment in the ability to sustain focus, decrease in subjective alertness and decrease in visual search sensitivity were more pronounced during the first night shift than in subsequent shifts (Santhi et al 2007). Thus, increasing the number of transitions may result in increased frequency of problems.

4.3 Cumulative Effects of Multiple Consecutive Duty Shifts

There is contradictory data on the effects of consecutive duty shifts on fatigue and performance. The results of the studies are not conclusive: while some studies found increased accident risk over consecutive nights, other studies found lower risk and improved performance over the first few days, and some did not find any significant changes across consecutive nights. There are multiple factors that explain the divergent results including the amount of sleep individuals obtain between shifts, the time on task (length of shift), and the time of day of the shift. These factors are considered below.

4.3.1 Review of Cumulative Fatigue Across All Industries

The effects of consecutive day and night shifts on fatigue involve different sets of factors and are therefore considered separately.

Day shifts: An early study (DERACHS, 1999) showed a gradual increase in subjective fatigue that occurs over seven consecutive work days. The increase in fatigue was much more pronounced with an early starting time (6 am) than with a late start (9am) (75% increase compared to 40% increase). Workers reported that they needed 1 day off to recover from working 3 consecutive shifts with an early start, and 2 days off to recover from 5 consecutive early shifts. However, other studies suggested that risk is not substantially greater with up to seven consecutive 12-h day shifts (Persson et al. 2003, 2006a&b). The results from these studies suggest that for day shift, an early shift start has more impact on fatigue than time on duty. In addition, early starts, which are likely to be associated with greater sleep deprivation, require longer rest periods (days off between blocks of shifts) to recover from the cumulative fatigue.

Night shift: A more significant concern relates to the number of consecutive night shifts, since they are usually associated with higher levels of fatigue than day shifts (Akerstedt, 1995). Working too many consecutive night shifts can cause an accumulation of sleep deficit, which can cause both health and safety issues (Knauth, 1997). This accumulation of sleep debt over consecutive periods of shortened day time sleep is counterbalanced by the adaptation of the sleep/wake cycle after working several consecutive night shifts. The adjustment of the circadian physiological rhythms to night work among individuals working consecutive night shifts is seldom complete, and permanent night shift systems are unlikely to result in sufficient adjustment in most individuals to benefit health and safety (Folkard, 2008).

This counterbalance between accumulated sleep debt and partial circadian adaptation either results in an increased risk over successive night shifts if sleep is not well managed, or decreases risk if good sleep management practices are followed. As a result the literature contains data which reaches apparently contradictory sets of conclusions. To avoid the cumulative effects of sleep deprivation the best practice is to train the employees on optimal sleeping strategies and provide opportunities for sleep (appropriate time and facilities for sleep). In this way the accumulated effects on performance can be minimised.

1. Studies showing increased risk over successive nights. A series of studies have found increased risk over consecutive night shifts. A review of seven studies (mainly of 8-h shifts) found an increased risk from the first to the fourth night. One study found a continuous deterioration of performance during five consecutive night shifts (Tilley et al., 1982). Another study showed that overall, there was a gradual increase in fatigue over 5-6 nights (DERACHS, 1999). A review of shiftwork studies analyzing the relative incident risk over successive shifts found that, compared to the first night shift, on average, risk was 6% higher on the second night, 17% higher on the 3rd night and 36% higher on the 4th night. Studies evaluating the risk on day/morning shift also found an increased risk over consecutive shifts, but the increase was substantially smaller than over night shifts (Folkard and Tucker, 2003). A meta-analysis of several studies of operations without an FRMS indicated that accident and injury risk can increase over consecutive night shifts (Folkard & Lombardi, 2006).

2. Studies showing decreased risk over successive nights. However, under optimal sleep conditions, the sleep debt that accumulates during consecutive night shifts is relatively small and does not exacerbate decrements in night-time performance resulting from other time-of-day factors. Based on laboratory studies, as well as field studies, it has been reported that for employees with diurnal patterns (active during daytime, sleeping at night), the first night shift after days off is the most difficult (Santhi et al., 2007; Lamond et al., 2004; Baker, 1995), and that alertness and performance is increased on subsequent nights. One study, evaluating four consecutive 11-h shifts, found three different patterns of fatigue on consecutive night shifts, reflecting the loads of the reticular activating system, musculoskeletal, and central nervous system respectively. While the musculoskeletal fatigue increased over consecutive night shifts, the other two patterns showed significant improvement over consecutive night shifts (Kubo et al., 2008). When sleep loss is minimised, employees' performance adapts as their circadian rhythms adapt (Lamond et al., 2003). One study found that performance in the night shift increased from the first to the third night shift, probably reflecting an adjustment of circadian rhythms. However, there was a decrease of productivity toward the 5th shift, which is most likely due to an accumulation of sleep deficit. A different study found an increase on production quality from the first to the 5th night shift, while another found an increase in human error from the first to the 6th night shift, and a lower error rate on the 7th shift (Knauth, 1995). Other studies (Vinogradova et al. 1975, Wagner 1988) analyzing longer spans of consecutive night shifts reported a decrease in risk from the 4th to the 5th night, which was maintained until the 7th and final night shift.

4.3.2 Review of Aviation Scientific Literature on Cumulative Fatigue

The same opposing conclusions on the effects of successive nights of duty have been shown in aviation studies. When the normal pattern of sleep is disrupted, aviation studies have found that the development of cumulative fatigue tends to increase during consecutive periods of duty, especially for long duties, early starts, late finishes and overnight duties, (Spencer and Robertson 2000, Spencer and Robertson 2002). However one of the few studies so far carried out of cargo operations where aircrew is experienced at routinely operating at night found that fatigue levels on the first night were higher than on nights two, three and four (Spencer MB et al 2004),. This was in contrast to the results of a study on passenger charter flights, which showed a slight increase over three consecutive nights (Spencer MB & Robertson KA, 2000).

The Moebus Aviation report (Moebus, 2008) notes that the development of cumulative fatigue tends to be increased during consecutive periods of duty, especially for long duties or when early starts, late finishes or overnight duties are involved that disrupt the normal pattern of sleep. It suggests that it is sensible therefore to limit the number of duties and/or reduce the maximum FDP of these duties when they run consecutively, especially where they are close to maximum FDP limits. Following a sequence of consecutive duties mitigating strategies could involve scheduling a rest day including one local night. The author proposed additional limits to those in Subpart Q, i.e. a duty hours limit over 14 consecutive days and a block hours limit per 12 consecutive months. Limits on these (slightly modified from those proposed in the Moebus Aviation report) are included in CRD 2010-14 although, as noted in NPA 2010-14 (EASA, 2010) there is a lack of scientific evidence and the limits are rather based on judgements of what appears “reasonable”.

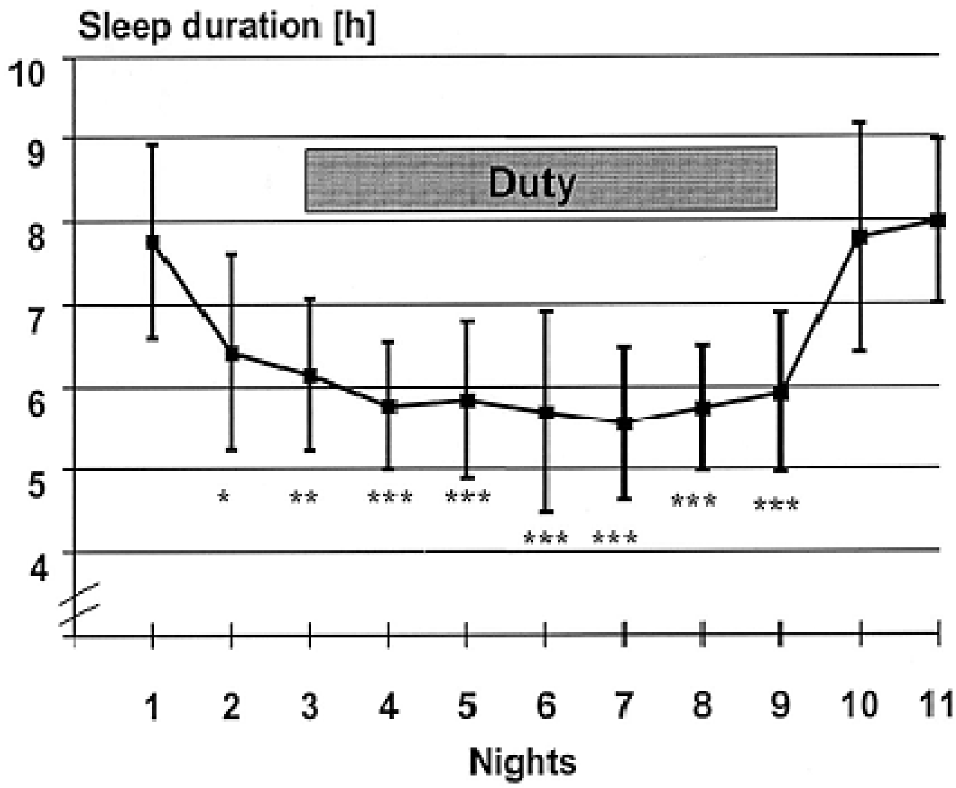
Helicopter operations: There are only a few studies on sleep and fatigue during consecutive days of pilot duty in helicopter operations. For example Gander et al (1998) evaluated helicopter crews operating during daytime in the North Sea (4-5 day trips). Crews reported a reduction in sleep duration by nearly 1 hour on duty days. On duty days, crews reported higher overall fatigue and greater fatigue by the end of the day, compared to pre-trip days. The higher overall fatigue levels on post-trip could reflect an accumulation of subjective fatigue across the 4-5 day trips. Crews also reported lower activation and poorer mood at the end of duty days than at the end of pre-tip days, and staying on duty longer increased the effect.

HEMS: A detailed study of sleep deficit and cumulative fatigue was carried out of HEMS crew in Germany (Samel et al, 2004). Helicopter-based emergency medical services in Germany can be required to operate from sunrise to sunset, requiring up to 15.5 hours of continuous duty during the summer months for pilots, who could work for seven consecutive days. Over the 7-day duty period there was an increase of sleep deficit and stress:

- Mean sleep duration was found to decrease from 7.8 h to 6 h or less, resulting in a cumulative sleep loss of about 15 h over the 7-day period.
- Sleep latencies (time that it takes to fall asleep) decreased progressively, reflecting increased fatigue and need to sleep.
- The need for sleep was rated higher on duty days 2 to 6.
- Workload ratings increased progressively.
- The secretion of stress hormones (adrenalin, noradrenalin, and cortisol) increased significantly by 50 to 80%.
- Cortisol and noradrenalin excretion also remained elevated for the two post-duty days.

The authors concluded that the shortness of rest times with the progress of a duty period of 7 days consequently resulted in reduced sleep times and that this was the main reason for increased strain and stress. They concluded that the workload from the flight operations generally did not contribute to the increased strain and stress to the same extent as the cumulative sleep deprivation.

Figure 4.1: Sleep duration during 11 day study period for EMS pilots, including 7 days of consecutive duty (from Samel at al., 2004)



4.4 Sleep and Rest

In a shift based system such as used widely for HEMS, the duration of a rest period between consecutive work periods is related to the duration of the shifts. Consequently, longer work periods result in shorter rest periods (for example, 12-h off between consecutive 12-h shifts, compared to 16-h off between consecutive 8-h shifts). Research studies have found a high correlation between the duration of the rest period and the amount of sleep obtained during it. This is important because one of the key factors to mitigate fatigue is to obtain adequate sleep during time off.

Scientific data demonstrated that shortened sleep every day (less than 7-8 hours) for one or two weeks (Belenky et al., 2003; van Dongen et al., 2003) produced significant cognitive decrements. Limiting sleep to six hours or less over successive nights resulted in a cumulative dose-dependent deficit in performance. Individuals who obtained less than four hours of sleep per night showed increased lapses in performance and reduced speed and accuracy when completing performance tasks, while those who obtained seven or more hours of sleep were able to maintain adequate levels of performance over 14 consecutive days. Other studies have documented the negative impact on health, mood, and safety of chronic sleep deprivation (Oginska & Pokorski, 2006; Leproult et al., 2003; Garbarino et al., 2002).

A single day with a shortened sleep in a person who otherwise has been obtaining adequate sleep can be tolerated without excessive fatigue risk. However, the number of days when these short sleep episodes occur must be strictly limited because shortened sleep episodes over consecutive days results in chronic sleep deprivation. Four hours of sleep has been suggested as the minimum amount of sleep required to sustain adequate performance levels during a single day (Belenky et al., 2003), although performance levels are lower than in people able to sleep for eight hours. Insufficient sleep, poor sleep quality and long work hours have been found to be both independently and synergistically associated with workplace injury risk (Nakata, 2011). An epidemiological study (Lombardi et al., 2010) showed the impact on health and safety of the combination of chronic sleep deficit and extended working hours. Using 7-8 hours of sleep as reference, the adjusted injury risk increased gradually with shorter sleep duration (from an odds ratio of 1.4 for 6-7 hours of sleep to an odds ratio of 2.7 for less than 5 hours of sleep).

The rest period between shifts should provide enough time for obtaining adequate sleep. A series of studies have shown that rest periods of 10 hours or less between consecutive shifts result in short sleep episodes, sometimes only 3-5 hours of sleep. It should be taken into account the time of day of the rest period, since rest between work periods that occur during daytime result in less sleep than rest at night (Kurumatani et al.,1994; Wylie et al., 1997).

Roach et al (2003) evaluated the effects of duration (12, 16 and 24 hours) and timing of rest periods between consecutive shifts, as well as the interaction between these two factors. The study participants (locomotive engineers) worked irregular rosters, with work episodes having an average duration of 8.4 hours. 44% of work periods started between 04:00 and 12:00, 34% between 12:00 and 20:00, and 22% between 20:00 and 04:00. Overall, the results showed that total sleep increased with longer rest periods. For 12-h and 16-h rest periods more sleep was obtained during rest periods that occurred during nighttime. For 24-h rest periods, longer sleep was obtained for rest periods starting 04:00-06:00 and 10:00-12:00. This is because individuals who finished a shift in the morning and started another shift the following morning (that is, that changed from night to day shift) often were able to fit two sleep episodes in the 24-h rest period (one after the work shift and another before the day shift).

One means of mitigating the effects of a long (extended) FDP, post-event, is to provide a longer rest afterwards. Clearly this does not help during the extended FDP, but it can mitigate subsequent effects. An early study (Dinges, 1996) recommends that the required off-duty period should be extended by the same duration of the flight duty period extension.

There may be occasions when EMS operations may require reduced rest. The Moebus Aviation report (Moebus, 2008) notes that any reduced rest arrangement is likely to result in increased fatigue levels following the reduced rest. The report recommends that reduced rest is only allowed as part of a comprehensive FRMS, and that the FRMS would need to take account of a wide range of factors including both the time spent commuting and the influence of the body clock on sleep duration. In addition, it recommends that any reduced rest that is less than 12 hours long should include the entire WOCL period, and that consideration should be given to ensuring that the subsequent flight duty is not too onerous and to specifying an absolute minimum reduced rest period, even in the presence of an FRMS.

4.5 Standby

4.5.1 Standby at Base/ Airport

There are differing approaches to how airport standby should be treated with respect to FDP and duty time contributions. Moebus (2008) notes that there is no scientific evidence to suggest that airport standby should be considered as any less fatiguing than flight duty and that further research is needed in this area. It concludes that time spent in airport standby should normally count 100% as flight duty when calculating the maximum FDP. It further recommends that standby count as 50% FDP if adequate rest facilities are provided, and FRMS is in place. However, detailed scientific justifications are not provided in this report on this issue and there is a general lack of scientific evidence about the impact of different airport standby facilities.

The Principles and guidelines for duty and rest scheduling in Commercial Aviation 'NASA Study' (Dinges, 1996) in contrast recommends that airport standby should be considered as duty but does not provide a rationale for this.

This uncertainty is reflected in the range of European States' provisions covering HEMS described in D1.

For HEMS key issues covering standby at base are how relaxation and napping during on-ground breaks can mitigate fatigue during shifts and how naps could lead to sleep inertia impacting missions. Sleep inertia refers to the fact that it takes a certain amount of time to fully wake up after sleeping. Sleep inertia is associated with impaired alertness and performance. Usually sleep inertia would dissipate in 10-15 minutes, but it may take longer if the person wakes up from deep sleep or is sleep deprived. Only a few studies have analysed napping in helicopter pilots. These studies found that helicopter pilots took naps only rarely during their on-call duty (Samel at al., 2004; Gander et al., 1998). This could be related to the difficulty of napping when fully kitted and the need to attend missions at short notice. However, it is noteworthy that in the EMS helicopter pilots study, naps were more frequent on duty days 5 and 6. Moreover, the average nap duration increased during the work week, from 6 minutes on duty day 2 to 30 minutes on duty day 7 (Samel at al., 2004).

The benefits and hazards of napping are further considered in section 4.6.2.

4.5.2 Standby at Home and Elsewhere

Short call home standby (may lead to an assignment without an intervening rest period) is used by many European AEMS operators (see Appendix 4). Long call home standby (at least 10 hours before start of an assigned duty) is not considered below as safety impacts are not considered so significant and is not so relevant to EMS on-demand operations.

The Principles and guidelines for duty and rest scheduling in Commercial Aviation 'NASA Study' (Dinges, 1996) does not consider 'on call reserve status' as duty, but recommends that 'a …. 8 hour sleep opportunity' should be protected from interruption by assignment to a flight duty period.

Crew Factors in Flight Operations XI: A Survey of Fatigue Factors in Regional Airlines Operations (Co, E., 1999) notes that the nature of flying on reserve means that crewmembers must respond when called for duty, thus creating unpredictability in their schedules. This unpredictability can lead to sleep loss, for example, when a call for duty occurs when a sleep period was planned. As evidence that sleep loss occurred, crewmembers reported getting 5.6 h of sleep before duty on average—2.3 h less than their normal average sleep.

Very little other scientific research covers this topic. However, Akerstedt/Gillberg (2003) have shown that there is a direct effect on being on standby and the lowered quality of recuperative sleep.

4.6 In-Flight Rest and Flightdeck Napping

This section evaluates separately in-flight rest and controlled napping in the cockpit.

4.6.1 In-flight Rest

Augmented crews allow pilots to use in-flight rest and obtain sleep in order to maintain alertness and reduce fatigue. Numerous studies noted below have shown that both objective physiological measures and subjective ratings of alertness demonstrate improvement following an in-flight rest taken during periods of sustained wakefulness and that in-flight rest can also reduce or delay expected performance decrements.

A number of studies have evaluated frequency and duration of in-flight sleep. For example, a study of in-flight rest during trans-Atlantic flights compared two and three-pilot crews. It found that sleep duration was longer in augmented crews: 38 minutes in outbound flights, and 1 h 06 minutes in homebound flights, compared to 26 min and 54 minutes respectively in non-augmented crews. Shorter in-flight sleep was associated with lower performance at top-of-descent for 2-pilot crews (Eriksen et al., 2006).

There is some debate on how much in-flight rest is used and the quality of sleep obtained. Roach and colleagues have conducted a series of studies on these issues. They estimated that in-flight sleep provides pilots with 70% as much recovery as duration-matched bed sleep (Roach et al., 2010). In a subsequent study, they evaluated frequency of in-flight sleep. Their data showed that pilots obtained 1.8 hours of sleep (27% of rest time) during duty periods with low fatigue likelihood and 3.7 hours of sleep (54% of rest time) during duty periods with extreme fatigue likelihood. The results indicated that pilots obtain more sleep during periods when fatigue is likely to be high (Roach et al., 2011).

There seems to be some controversy in how much of the time spent in the bunk is actually sleep. For example, while TNO considers that 75% of the time spent in a bunk may be counted as actual sleep, an FAA report (AC No: 120-100 Basics of Aviation Fatigue AFS-200, 2010) states that flight crews who had a 7 hour sleep opportunity obtained, on average, only 3 hours 25 minutes of bunk sleep.

The TNO report "Extension of flying duty period by in-flight relief" (Simon, 2007) recommends to allow an extension of the FDP based on the duration of the rest period available to the pilot and on the environment which is available for rest. It also concludes that the allowable extension should depend on whether the crew is acclimatised. These conclusions are reflected by the Moebus Aviation report (2008).

The TNO report also recommends that if augmentation is only by one additional pilot, the maximum FDP should be 16 hours. Finally, the TNO report proposes to give no credit to rest in an economy seat, although no data are available concerning onboard sleep in a normal economy class seat. However, based on laboratory data and ergonomic considerations, sleep in an economy seat is considered to be degraded to 0% of bunk/Class I seat because:

- The seat does not recline more than 40 degrees and has no adequate foot and leg rest which diminishes the probability of recuperative sleep;
- Space around the seat is not sufficient to create adequate separation from passengers or guarantee any privacy;
- A majority of passengers are unable to sleep at all in an economy seat. Some succeed in obtaining some sleep, but they often feel a general malaise after sleeping in a cramped position.

4.6.2 Controlled Napping

Brief structured nap breaks during extended-hour work shifts have been shown to be an effective operational strategy. Timing and duration of naps can be designed for optimal impact on alleviating fatigue. As with in-flight rest, napping will be most efficient when sleep occurs during the WOCL. An important consideration in terms of scheduling is the duration of the beneficial effects obtained. Studies suggest that a nap can maintain or improve subsequent performance and physiological alertness from 2 to 12 hours following the nap. Experiments have examined naps of varying lengths, and there seems to be a dose-dependent effect: more sleep is associated with greater beneficial effects.

However, some studies suggest that shorter naps can be just as or more effective than longer ones; recommendations range from 20- to 60-minute duration. Shorter naps (10-20 minutes) are also less likely to be associated with the phenomenon of sleep inertia (a short period of impaired alertness upon awakening). This is because in this amount of time, the individual will usually remain in light sleep and would not reach deep sleep. It is easier to wake up from light sleep and the individual will regain full alertness faster than waking up from deep sleep. In the case of long naps, sleep periods of approximately 90 minutes allow the completion of a full sleep cycle, and the individual wakes up from light sleep or REM sleep, which minimizes sleep inertia. On the other hand, naps of 40-60 minutes would result in the individual waking up from deep sleep, and that will result in more severe and long lasting sleep inertia. Sleep inertia can be associated with a performance decrement lasting for a few minutes to 35 minutes, though effects usually seem to dissipate in about 10 to 15 minutes (Robertson and Stone, 2002, Rosekind et al 1994).

A series of studies have proved the effectiveness of napping as a fatigue countermeasure in the aviation industry, and ICAO has stated that controlled napping is a valuable mitigation strategy that can temporarily relieve the symptoms of sleep loss (ICAO, 2011).

A joint study by the National Air and Space Administration (NASA) and the Federal Aviation Administration examined the effect of a planned cockpit rest period during long-haul flights. Two crews flying the same sequence of four scheduled flights were compared. One group was allowed a 40-minute nap opportunity (one crew member at a time), whereas the other group followed their normal activities. Pilots slept on 93% of the opportunities, falling asleep in 5.6 minutes on average and sleeping for 25.8 minutes on average. Crew assigned to the nap group showed better performance and higher physiological alertness on objective measures during the last 90 minutes of the flight (critical descent and landing phases of the flight) than did the control group (Rosekind et al, 1994).

The FAA authorises in-flight rest for flight crews if there is an augmented crew, so that two pilots are on the flight deck when the augmented crew is resting. The FAA does not authorise naps in the cockpit, however, other carriers and authorities do.

4.7 Periodic Extended Rest

How much rest an individual needs between blocks of working days is related to the number, timing, and length of consecutive shifts he or she works. Allowing more time off after extended blocks of night shifts is important because night shifts are more fatiguing, and sleep debt more prevalent, than with day shifts. There is agreement that a 24-h period including one single night is usually not enough to fully recover from a series of consecutive work days, and that the number of consecutive days off should increase with consecutive work days.

Several studies have found that two full nights of sleep were usually enough to recover from sleep deprivation and return to baseline levels of sleep structure and waking performance and alertness (Carskadon & Dement, 1979). Shiftwork researchers have shown that at least two unrestricted sleep episodes are needed to recover after a series of shifts and that at least 3 days, including 3 overnight sleep episodes, are necessary to recover from 7 consecutive night shifts (Knauth, 1997). Another study (Totterdell et al., 1995) showed that alertness and performance were more impaired on the first three days back at work following a single rest day, as compared to two or three rest days.

It is thus usually recommended that time off between blocks of work days should allow two days with nocturnal sleep (Health and Safety Executive, 2006; Knauth,1997). This is due to the fact that night-time sleep occurs at the time when circadian rhythms are conducive to sleep, and thus sleep episodes are longer and more restorative. An off-duty period of 36 hours after daytime shifts and 48 hours after night shifts are required to allow shiftworkers to obtain these two nocturnal sleep episodes.

Folkard (2000) recommends that having worked two or three consecutive night shifts it is important that staff are able to have sufficient sleep to fully recover. This requires two full nights' sleep after the consecutive night shifts, without an early start after the second night. In order to ensure this is achieved (and commuting time does not leave too short a period for rest), it is considered optimum that 54 hours or more should elapse between the end of the consecutive night shifts and the next shift.

The Principles and guidelines for duty and rest scheduling in Commercial Aviation 'NASA Study' (Dinges, 1996) recommends that if two or more flight duty periods within a 7-day period encroach on all or any portion of the Windows of Circadian Low, then the standard off-duty period (36 continuous hours within 7 days) be extended to 48 hours recovery.

5.0 HEMS Analysis

The following fatigue factors and hazards from Table 3.1 are addressed in this section:

5.1 Duration of duty (including extensions) – hazard A1, duration of FDP/ shift too long leading to fatigue

5.2 Time of day effects – hazard B1, night shifts and WOCL encroachment

5.3 Cumulative effect of multiple consecutive shifts – hazard C1, consecutive day duties and C2, consecutive night duties

5.4 Relaxation and napping on-duty (5.4.1) relating to hazard E1 and as a mitigation to hazard A1 and sleep and rest off duty (section 5.4.2) covering hazard D1

5.5 Pilot in Command (PIC) discretion – hazard A2, PIC discretion leading to too long an FDP/ shift

5.6 Positioning and travelling – hazards F1, F2 and F3.

5.7 Circadian disruption due to mixing night and day duties – hazard B2

5.1 Duration of Duty Including Extensions

HEMS operations are generally based around duty time restricted shifts. Examples are given in Appendix 4. Some States have FDP restrictions whereas others restrict the duty time at the base (see D1). The analysis below is based on the modeling of shift duty time. Implications for FDP can be derived from the modeling assumptions concerning when the first flight starts and last flight ends in the shift.

5.1.1 Safety Impacts of Changes of Duty Duration and Extensions

The key issues associated with hazard A1 from Table 3.1 are considered to be:

i. Duration of shift and fatigue level
ii. Day shift v night shift (encroachment of the WOCL) – see Section 5.2
iii. Duration of extended rest after an extended shift and impact of breaks during a shift – see Section 5.4
iv. Impact of number of missions/ flying time

Additional mitigations associated with this hazard are summarized in Table 3.1.

5.1.1.1 Duration of Shift and Fatigue Level

Literature Review

The relationship between duty length and fatigue is complicated by circadian phase, time awake, chronotype and the other factors discussed in Section 3.1. The literature in Section 4 from across industries indicates that shifts up to 12 hours are not necessarily higher risk than 8 hour shifts if appropriate mitigations are put in place. Shifts longer than 12 hours are relatively rare across industries. The limited evidence from EMS nursing staff of 18 hour shifts operated for short periods indicated that they did not impact on cognitive function. However, 15.5 hour daytime shifts operated by EMS pilots over 7 days did lead to evidence of cumulative fatigue (see Section 5.3). From the airline industry there appears a consensus that daytime FDPs exceeding 12-14 hours will lead to increasing fatigue and risk. The number of sectors in an FDP and WOCL encroachment (night duties) will be important fatigue contributing factors.

CAS modeling

Crew operating HEMS shifts experience quite different fatigue issues from airline pilots. Helicopter flying involves a different task workload from fixed wing operations. The shift patterns are very different from airline flight patterns in terms of times of day. Therefore some modeling using CAS was considered useful.

CAS has not been validated for helicopter operations in the same manner as it has for fixed wing operations (see Appendix 2). However, with this caveat some modeling is considered useful as it provides relative insights.

The crew workload has been modeled as equivalent to take off and landing for a fixed wing aircraft all through the helicopter flight. The following 5 scenarios have been modeled.

1. **Duty Shift 07:00 – 17:00 (10 hours):** flights starting one hour after beginning the shift - 20 x 15 minute missions spaced evenly throughout the shift.
2. **Duty Shift 07:00 – 17:00 (10 hours):** flights starting one hour after beginning the shift - 5 x 15 minute missions spaced evenly throughout the next 3 hours of the shift (termed “Flight Sequence 1”) and another 5 x 15 minute missions spaced evenly throughout the final 3 hours of the shift (termed “Flight Sequence 2”).
3. **Duty Shift 07:00 – 19:00 (12 hours):** flights starting one hour after beginning the shift - 5 x 15 minute missions spaced evenly throughout the next 3 hours of the shift and another 5 x 15 minute missions spaced evenly throughout the final 3 hours of the shift.
4. **Duty Shift 07:00 – 21:00 (14 hours):** flights as above.
5. **Duty Shift 07:00 – 23:00 (16 hours):** flights as above.

Scenarios 1 and 2 look at the influence of different numbers of flying hours during the shift and scenarios 2-5 investigate the influence of shift length in the range 10-16 hours and finish time.

The graph in Figure 5.1 shows the alertness at the end of the two flight sequences (Flight Seq. 1 and Flight Seq. 2) for scenarios 2-5 and the alertness at the end of the last flight for Scenario 1.The alertness at the end of Sequence 1 is unchanging as expected as it occurs at the same time of day (11:00) after the same workload (number of missions). The alertness at the end of Sequence 2 shows little change up to 12 hours and then decreases significantly. The effect of flying 10 or 20 flights of 15 minutes during day is not that strong in the context of a 10 hour shift but this finding should be treated with caution as HEMS workload modeling is less well understood/ validated. Alertness at the end of the longest shift (18hrs, 7:00-23:00) is just below the point where people would generally choose to go to sleep.

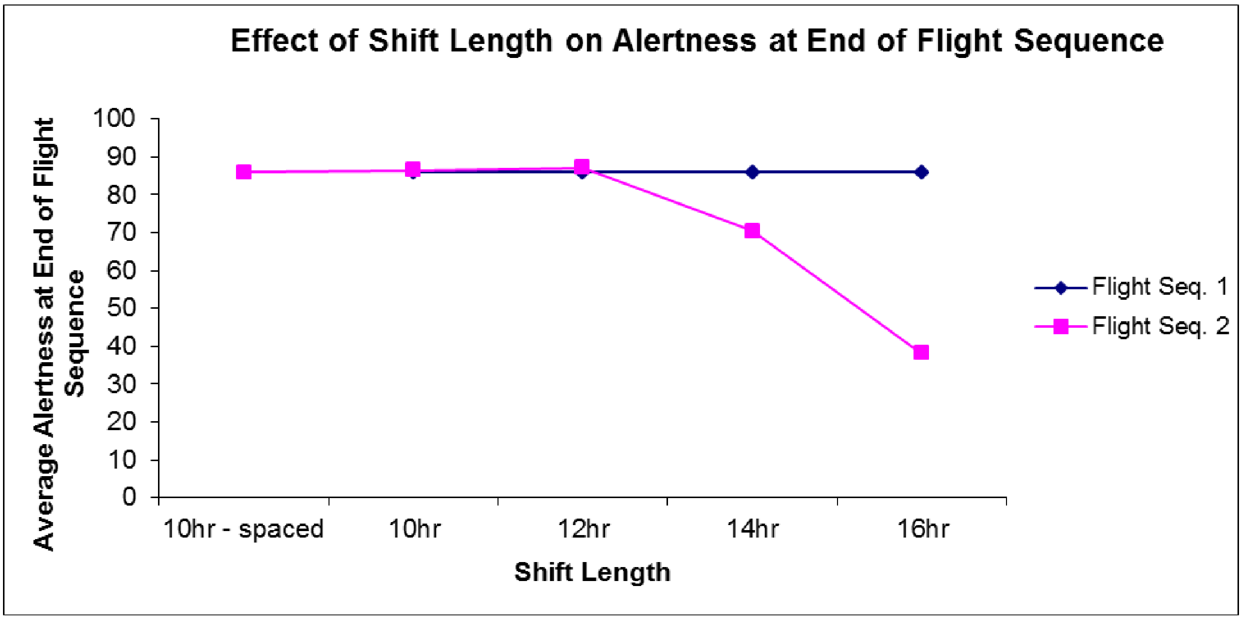


Figure 5.1 – *End of shift alertness is lower with shifts over 12hours.* *Alertness is shown at the end of either the first or second sequence of flights. See text above for scenario descriptions.*

The results from the CAS modeling looks broadly in line with the literature. Moving significantly above 12 hours shift duration does introduce extra fatigue and risk and would generally be undertaken only with good reason, e.g. responding to an emergency late in the shift (see D1 survey).

5.1.1.2 Impact of Number of Missions/ Flying Time

Another factor affecting fatigue is number of missions or amount of flying time. Unfortunately it is difficult to translate the literature, which is mostly aimed at the influence of the number of sectors on airline pilot fatigue, to the HEMS field. The need to decrease FDP if there are a significant number of sectors is confirmed by many studies (see Section 4.1.4). The Subpart Q requirement on maximum allowable FDP is based on a 30-minute reduction after the second sector.

Because of the on-demand nature of EMS, the numbers of missions in a shift could vary widely. One would expect increased HEMS flying hours to cause increased fatigue, other factors being equal. However, the strength of that dependence is difficult to derive from the literature or modeling.

In terms of current national provisions some States do have daily flying limits applicable to HEMS (e.g. UK and France < 8 hours per 24 hours, see D1 for others). Presumably these limits have been set based on accumulated operational experience.

5.1.1.3 Other Potential Mitigations/ Factors

In addition to limits on shift/ FDP duration and daily flying hours other potential mitigations could be incorporated into the FTL options. These may include:

- Extended rest after a long duration FDP/ shift (see Section 5.4.2.2)
- Limiting the frequency of long extended shifts per week or per month
- Requiring full rest before the extended shift
- FRMS (general – applicable to all hazards)
- Relief pilot for single pilot operations when an extension is invoked
- Prohibiting combining EMS shift extension with extension due to split duty
- Controls over extensions due to split duty/ on-ground breaks, e.g. minimum consecutive number of hours for break before it can lead to an extension, etc.
- Limiting number of persons on aircraft during extensions
- Controlled napping at base.

5.1.2 Economic Impacts of FTL Changes for Duty Duration and Extensions

Those economic impacts which are judged likely to be most significant following proposed regulatory changes are tabulated below (Table 5.1).

Table 5.1: **Economic Impacts Associated with Potential Changes to Duty Durations and Extensions**

Potential change	**Reference situation in Europe**	**Identification of generic economic impacts**	**Factors which will affect size of impacts**
Harmonisation of basic maximum duty length in Europe for HEMS	Based on the survey of 8 States in Europe (D1) HEMS duty shift lengths vary from 9.5 to 13 hours and FDPs vary from 8 to 12 hours depending on State, number of pilots, duty start time and consecutive number of days duty.	Changes to basic maximum shift length arising from harmonization could feed into changed pilot costs assuming that service levels are to be maintained.	The change in shift length/ maximum FDP proposed relative to current practice in each State/ operator will determine the size of the economic impact. As a hypothetical extreme example a decrease in average shift length from 12 hours to 8 hours would translate into a 50% increase in crew costs assuming there was no spare capacity for filling the extra shift.

Potential change	Reference situation in Europe	Identification of generic economic impacts	Factors which will affect size of impacts
Restricting flexibility to extend shifts/ FDPs to meet medical emergencies	Based on the survey of 8 States in Europe (D1) extensions vary from 0 up to 4 hours depending on State and type of emergency.	Operators with 24/7 bases in normal circumstances will have enough crew to cover shifts. The main reason for extending a shift is if a helicopter is in the middle of a mission and is in a better position to continue and bring a patient back to hospital for example rather than have a new crew get ready and proceed from the base. Therefore any changes in this flexibility would not necessarily have any significant impact on crew numbers or economic impacts (except for extended rest requirements described below).	Social impacts probably more significant.
Harmonisation of flying hours per day	Based on the survey of 8 States in Europe (D1), flying hours per day vary from 5 to 8 hours depending on State, number of pilots and time of day of duty start.	If limits are placed on flying hours per day which are more or less restrictive relative to the current flying patterns this could impact the number of crew required to maintain EMS service levels.	The size of the economic impact of changing the maximum allowable daily flying hours will depend on the demand compared to the proposed regulatory limits. For example if crew currently never fly more than 5 hours per shift, then reducing the limit from 8 hours to 7 hours would have no effect. If crew, however, frequently experience daily flying hours in the range 7-8 hours this change could have a significant impact on the requirement for extra crew or else impact service provision.
Harmonisation of required extended rest after an extended shift/ FDP	Based on the D1 survey the required rest after an extended FDP/ shift can vary from = FDP/ duty length up to 48 hours depending on State.	Changes to the amount of rest following an extended shift will affect crew availability. If a new requirement for extended rest following an extended shift is introduced then extra crew may need to be made available to cover such an event.	The percentage of shifts that get extended beyond proposed regulatory change. How much spare crew capacity operators have to cover such events currently.

Given the range of potential mitigations and options that the future RIA may develop there could be more economic impacts than identified in the table above.

An indication of the process for determining the economic impacts of proposed changes is illustrated by the following example relating to flying hours per day:

- Assume a regulatory change harmonises daily flying to Z hours.
- Assume that for an operator X% of shifts involve flying in excess of Z hours.
- Assume that effectively the last Y% of affected shifts are curtailed as a result of this change.
- As a simple estimate the amount of increased crew cover will need to be about X/100 × Y% to maintain service levels although the knock-on effects may be greater especially for smaller operators with less capacity for covering contingencies. This might in the extreme lead to changes in the whole shift pattern.
- Based on information from Section 2.2 it is estimated that crew costs are about 20% of total operating costs (although there appears quite a significant range from 15% to over 30%).
- Thus the impact on overall operating costs from this change with the simple assumptions above would be approximately 20/100 × X/100 × Y% increase. Clearly if the whole shift pattern needs to be changed, the cost impact could be greater.

Under AEMS, Section 6.1, there is an additional example calculation relating to regulations requiring changes to extended rest following extended shifts/ FDPs.

5.1.3 Social Impacts of FTL Changes for Duty Duration and Extensions

Those social impacts which are judged likely to be most significant following proposed regulatory changes are tabulated below (Table 5.2).

Table 5.2: **Social Impacts Associated with Potential Changes to Duty Durations and Extensions**

Potential change	**Reference situation in Europe**	**Identification of generic social impacts**	**Factors which will affect size of impacts**
Harmonisation of basic maximum duty length in Europe for HEMS	Based on the survey of 8 States in Europe (D1) HEMS duty shift lengths vary from 9.5 to 13 hours and FDPs vary from 8 to 12 hours depending on State, number of pilots, duty start time and consecutive number of days duty.	For any changes it seems reasonable to assume that, if practical, the aim will be maintain service levels with minimal impact on patient safety and health. If the economic impacts are very severe in a negative sense this could consequently cause negative impacts on the EMS service to the public. Economic impacts could lead to jobs created or lost.	N/R unless there are significant economic impacts.
Restricting flexibility to extend shifts/ FDPs to meet medical emergencies	Based on the survey of 8 States in Europe (D1) extensions vary from 0 up to 4 hours depending on State and type of emergency.	If changes lead to reduction in this flexibility then it could take longer to reach and transport patients in events which occur close to shift duty/ FDP limits. No other social impacts considered significant.	The percentage of shifts/ FDPs that get extended beyond proposed regulatory change. The percentage of these extended shifts/ FDPs that do actually “save lives” – would expect this percentage to be high as event needs to be urgent to justify shift/ FDP extension.
Harmonisation of flying hours per day	Based on the survey of 8 States in Europe (D1), flying hours per day vary from 5 to 8 hours depending on State, number of pilots and time of day of duty start.	As above, for any changes it seems reasonable to assume that, if practical, the aim will be maintain service levels with minimal impact on patient safety and health. If the economic impacts are very severe in a negative sense this could consequently cause negative impacts on the EMS service to the public.	N/R unless there are significant economic impacts, e.g. if uneconomic to arrange cover, might need to close HEMS base after pilot has reached daily flying hours limit.

Potential change	Reference situation in Europe	Identification of generic social impacts	Factors which will affect size of impacts
Harmonisation of required extended rest after an extended shift/ FDP	Based on the D1 survey the required rest after an extended FDP/ shift can vary from = FDP/ duty length up to 48 hours depending on State.	Some missions may not be possible and patient health could be affected directly. If extra rest days cannot be covered due to economic constraints then service levels would be affected indirectly. Economic impacts could lead to jobs created or lost.	The size of the change in required extended rest compared to current provisions. The frequency of extended shifts/ FDPs. The amount of crew cover an operator has to accommodate extended rests.

An indication of the process for determining the social impacts of proposed changes is illustrated by the following example relating to restricting duration of extended shifts/ FDPs:

- Assume that a regulatory change leads to a reduction in extensions from X hours maximum shift to Y hours maximum shift.
- Assume that an operator currently experiences extended shifts between X and Y hours duration Z per year.
- Assume that for 10% of these events the extension allowed a patient's life to be saved (see Section 2.3).
- The social impact of this regulatory change for this operator would be approximately Z × 10/100 extra patient fatalities per year.

5.2 Time of Day Effects and Night Duty

5.2.1 Safety Impacts of FTL Changes for Night Duty

Literature Review

Night duties present a special challenge, since flying time occurs during the WOCL, the circadian phase with lowest alertness and performance. In addition, these effects are compounded by the sleep deprivation associated with working during the night and sleeping during the day (Samel et al., 1997, Spencer & Robertson, 1999). The detrimental effects of sleep deprivation, time since sleep, and the WOCL can lead to severe fatigue with increasing time on task.

CAS modeling

The caveat from above about lack of model validation for helicopter operations should again be highlighted. However, modeling is considered helpful for a relative comparison between day and night shifts. Scenario specific assumptions are as follows:

- Day shift (scenario 3 in Section 5.1.1.1) – 12 hours duration from 0700 to 1900. 2 sequences of 5 missions each between 0800 and 1100 and 1600 and 1900.
- Night shift – 12 hours duration from 1900 to 0700. 2 sequences of 5 missions each between 2000 and 2300 and 0400 and 0700.

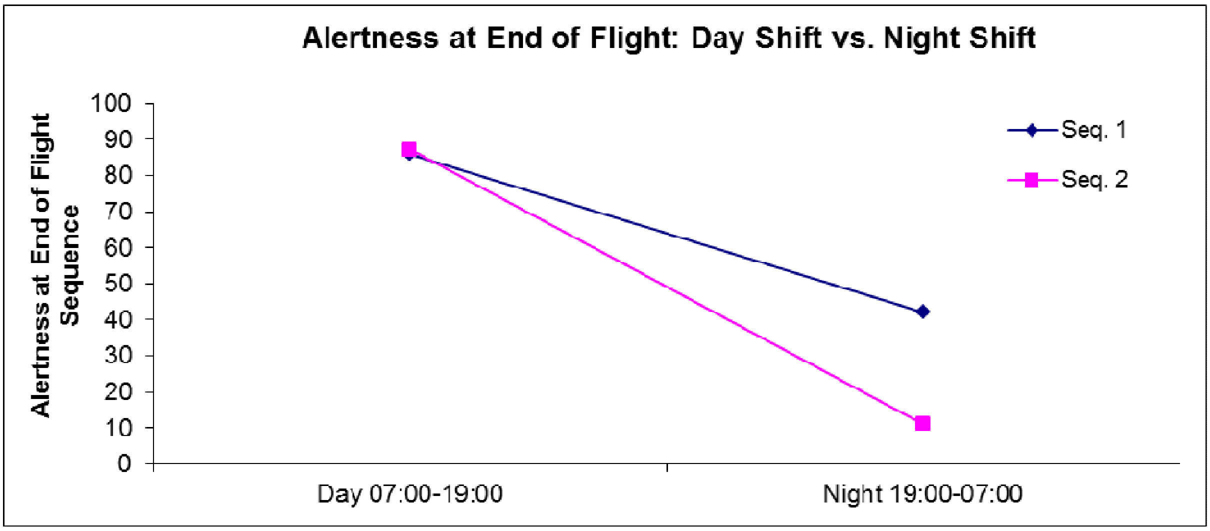


Figure 5.2: Alertness is lower at the end of Flight Sequence 1 and 2 during night shifts. Alertness is shown at the end of the first and second sequence of flights. Flight sequence 1 begins 1hr after shift start, and consists of five evenly distributed 15min flights in 3hr. This is followed by a 5hr break where is the pilot is expected to be awake. Flight sequence 2 consists of five evenly spaced 15min flights in 3hr ending at the end of the shift.

The graph in Figure 5.2 indicates that:

- The second flight sequence around the time of the WOCL for the night shift has a very low alertness score.
- HEMS operations during the night appear to present key fatigue challenges based on this modeling.
- Fewer missions during the night than the day are probably to be expected and hence a comparison between day and night with the same numbers of missions is probably rather unrealistic – however the broad findings are still considered relevant.

Figure 5.3 below presents another graph showing the percentage of time spent fighting sleep while flying. This emphasizes the potential fatigue challenge of night duties.

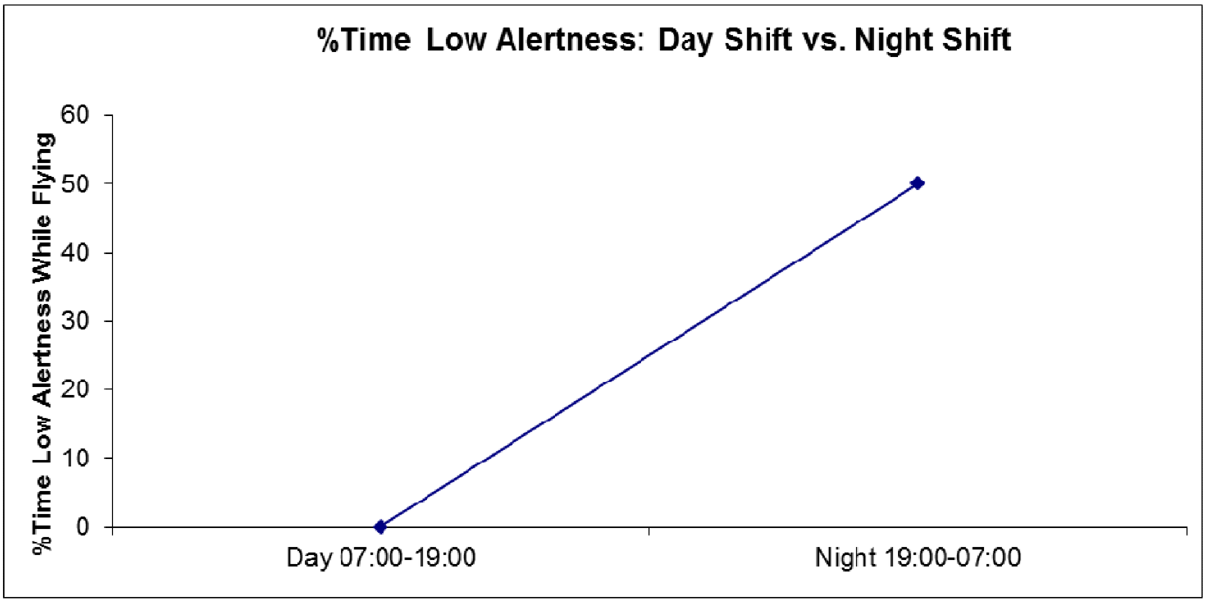


Figure 5.3 – Pilots spend more time experiencing low alertness during night shifts. Pilots flying the night shift spend 50% of their time in low alertness. This corresponds to the entire length of Flight Sequence 2.

This modeling ties in with the literature reviewed in section 4.2.2.2 which indicated a disproportionally high rate of HEMS accidents at night. Section 3.1 refers to transportation studies that show peaks risks around 1-6 AM.

Potential mitigations in addition to limiting duty hours for night shifts could include:

- Napping before night shifts;
- Training on how to manage night shift work and when to recognize that one is fatigued (e.g. to be wary of relaxation after delivery of patient and ignoring level of fatigue);
- Limiting the number of missions (or flying hours) per night shift (if the limit is reached, the pilot would have to be relieved by a pilot on home standby);
- Availability of relief pilots to take over if a crew member realizes they are too fatigued or a flying hours limit is reached;
- Controls over consecutive night shifts (see Section 5.3 below for safety analysis);
- Using two pilots at night;
- Additional rest.

5.2.2 Economic Impacts of FTL Changes for Night Duty

Those economic impacts which are judged likely to be most significant following proposed regulatory changes are tabulated below.

Table 5.3: Economic Impacts Associated with Changes to Night Shift Provisions

Potential change	Reference situation in Europe	Identification of generic economic impacts	Factors which will affect size of impacts
Harmonisation of the maximum number of consecutive night shifts	The typical number of consecutive night shifts appears to vary from 3 – 7 (see Appendix 4).	Changes could alter the ratio of rest days to working days and affect crew productivity.	Depends how different proposed regulations are from current practices and what impact there is on ratio of rest days to working days. For smaller operators impacts could be proportionally larger.
Specifying a requirement for availability of relief crew to take over at night for fatigued colleagues (who have reached a defined limit or who declare themselves too fatigued)	Current situation in Europe not known.	Likely to lead to changed requirements for crew cover and impact crew numbers and costs directly.	The current amount of cover that an operator typically carries. If an operator has a lot of cover already there might be a low economic impact. Alternatively an operator could shut a base until the next shift starts (see social impacts below).
Harmonisation of the maximum duration of night shifts	Typical durations currently set at 12 hours (see Appendix 4).	See Table 5.1 above for impact of duty shift duration changing.	See Table 5.1 above

5.2.3 Social Impacts of FTL Changes for Night Duty

Those social impacts which are judged likely to be most significant following proposed regulatory changes are tabulated below.

Table 5.4: Social Impacts Associated with Changes to Night Shift Provisions

Potential change	Reference situation in Europe	Identification of generic social impacts	Factors which will affect size of impacts
Harmonisation of the maximum number of consecutive night shifts	The typical number of consecutive night shifts appears to vary from 3 – 7 (see Appendix 4).	Provided operator can still cover all the shifts, service provision levels should not be affected. Working patterns of crew may be altered which could affect travel time/ time at home if they typically stay at the base for the whole sequence of shifts.	Depends how different proposed regulations are from current practices.

Potential change	Reference situation in Europe	Identification of generic social impacts	Factors which will affect size of impacts
Specifying a requirement for availability of relief crew to take over at night for fatigued colleagues (who have reached a defined limit or who declare themselves too fatigued)	Current situation in Europe not known.	If insufficient relief crew, base may need to close if crew reports too fatigued.	Frequency of such events.
Harmonisation of the maximum duration of night shifts	Typical durations currently set at 12 hours (see Appendix 4).	See Table 5.2 above for impact of duty shift duration changing.	See Table 5.2 above

5.3 Cumulative Effect of Multiple Consecutive Duty Shifts

5.3.1 Safety Impacts of FTL Changes Related to Cumulative Fatigue

The key issues associated with this hazard are:

i. Number of consecutive days/ hours in week
ii. Cumulative sleep deprivation, e.g. cumulative shift hours overlapping with WOCL
iii. Other cumulative limits
iv. Other potential mitigations

5.3.1.1 Number of Consecutive Days/ Hours in Week and Cumulative Sleep Deprivation

Literature Review

The scientific research on the links between fatigue and the subsequent risk of accident and injuries over consecutive work days is reviewed in Section 4.3. The development of cumulative fatigue tends to increase during consecutive periods of duty, especially for long duties, early starts, late finishes and overnight duties, when the normal pattern of sleep is disrupted (Spencer and Robertson 2000, Spencer and Robertson 2002).

A wide variety of HEMS operating patterns is shown in Appendix 4 with respect to consecutive days working and rest days. A high level modeling approach is adopted below.

CAS modeling

The following shift patterns were modeled for 5 consecutive days, all shifts starting at 07:00, 10 x 15 minute missions in each shift all evenly spaced throughout:

- 10 hours duty and 14 hours rest (7.5hrs sleep)

- 12 hours duty and 12 hours rest (7.5hrs sleep)
- 14 hours duty and 10 hours rest (7.5hrs sleep)
- 16 hours duty and 8 hours rest (6hrs sleep)
- 18 hours duty and 6 hours rest (4hrs sleep)

Figure 5.4 indicates that for shifts up to 14 hours, the fatigue score stays at a relatively low level over this 5 day period. The fatigue score is calculated as a weighted sum of 11 individual factors including the average alertness on duty, number of recovery breaks per week, hours on duty per week, number of time zone crossings and others. A number of these factors are sensitive to cumulative fatigue. Figure 5.4 indicates that cumulative fatigue rises rapidly as shift length exceeds 16 hours consistent with the scientific literature.

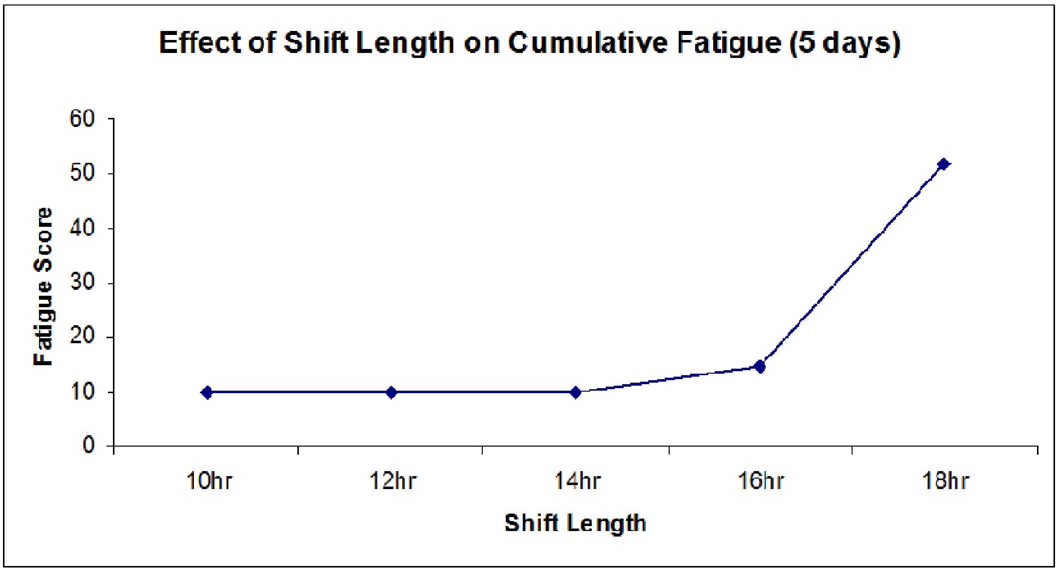


Figure 5.4 – Cumulative fatigue is highest after 5 consecutive 16 or 18hr shifts. *Shift length and time-of-day factors combine to make 16-18hr shifts more challenging than 10-14hr shifts.*

A nighttime shift pattern of 12 hours duty beginning at 19:00 running for 7 consecutive days with 10 x 15 minute missions in each shift was also modeled. Figure 5.5 shows the alertness at the end of shift for days 1 to 7. The alertness at the end of the shifts actually increases slightly from Days 1 to 4 and then levels off to Day 7. Cumulative effects of fatigue are likely obscured in this modeling scenario by 1) time of day effects and 2) a “floor effect”. Floor effects are seen when it is unlikely for alertness (for example) to go much lower. CAS assumes that the subject being modeled will not fall asleep on the job, however subjective feelings of alertness may be lower at shift end over the course of the seven days. However, all these alertness values at the end of shift are low. It should be noted that the average alertness across all the shift hours is at about 40-45, i.e. significantly above the end of shift values in Figure 5.5.

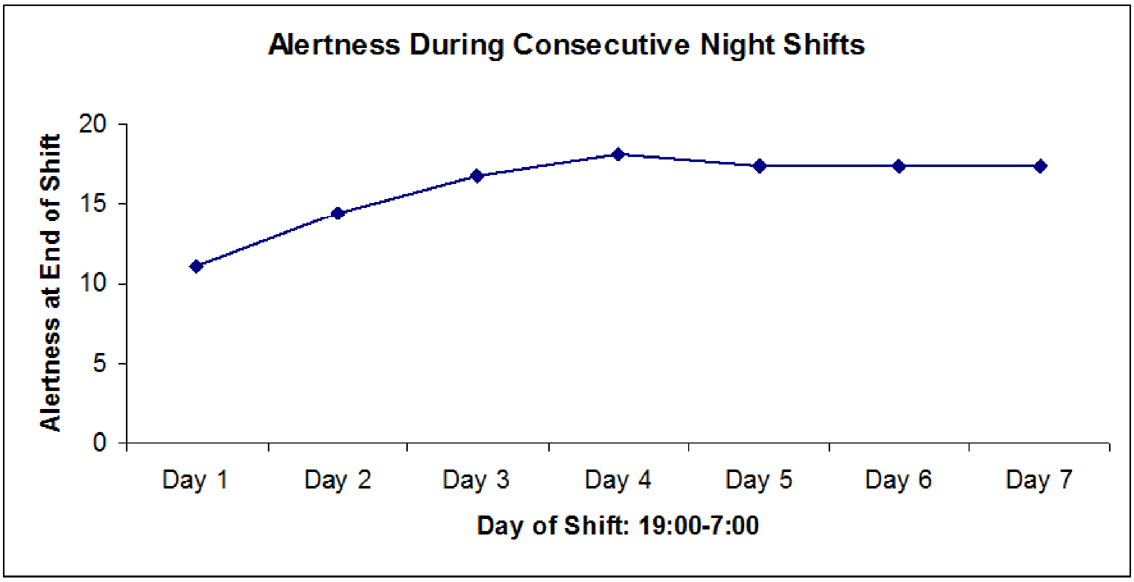


Figure 5.5 – Alertness improves slightly then levels off during consecutive night shifts. However, all scores are low. *Pilots fly seven consecutive 12hr night shifts with 10 x 15min flights spaced evenly throughout the entire shift.*

5.3.1.2 Other Cumulative Limits

Monthly and annual limits are generally built up from weekly limits with rest days added in. It is very difficult to relate cumulative fatigue to longer term limits either from scientific literature or modeling.

Moebus Aviation's report (Moebus, 2008) proposed additional limits to those in Subpart Q, i.e. a duty hours limit over 14 consecutive days and a block hours limit per 12 consecutive months. Limits on these (slightly modified from those proposed in the Moebus Aviation report) are included in CRD 2010-14 although, as noted in NPA 2010-14 (EASA, 2010) there is a lack of scientific evidence and the limits are rather based on judgments of what appears "reasonable". Operational experience with respect to EMS will be important to allow filling in the gaps from the scientific literature and modeling.

5.3.1.3 Other Potential Mitigations

Other potential mitigations could be incorporated into the options for managing cumulative fatigue. These may include:

- **Minimum number of days off per month** – there is a lack of scientific evidence regarding the impact of this measure on cumulative fatigue. There are a variety of provisions for HEMS in Table 3.7 of Deliverable D1. The Working Time Directive requires a minimum of 7 days off per month.

- **Spread out duty as evenly as possible** – good practice but difficult to apply in EMS.

- **Rest period increased periodically** – while various scientific studies highlight the benefit of two nights of recovery sleep to resume baseline levels of sleep structure and waking performance and alertness, HEMS patterns can be quite varied (see Appendix 4 and Table 3.7 of D1). One of the cycles in France for example can have 12 consecutive days of onsite standby followed by 6 days' rest.

5.3.2 Economic Impacts of FTL Changes Related to Cumulative Fatigue

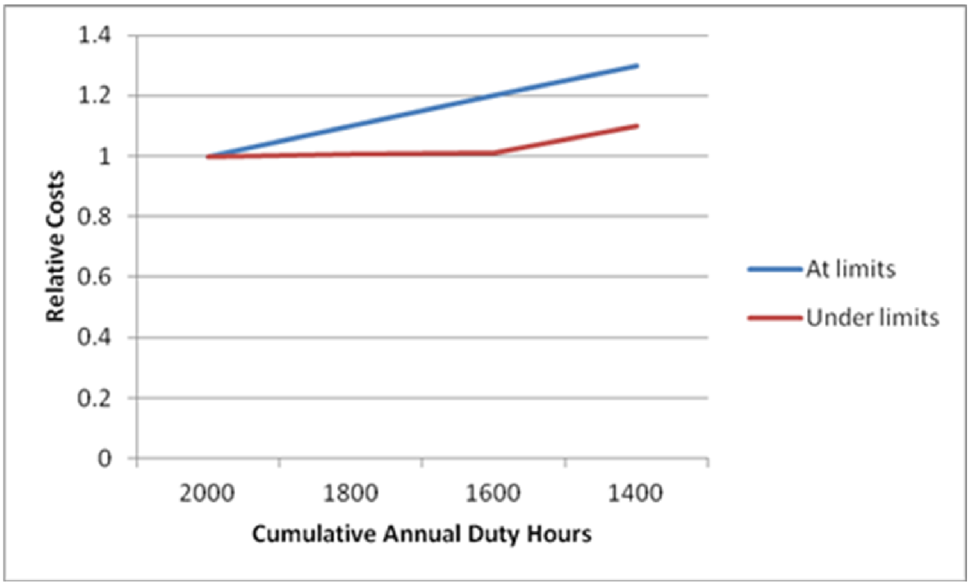
Those economic impacts which are judged likely to be most significant following proposed regulatory changes are tabulated below.

Table 5.5: Economic Impacts Associated with Potential Changes to Cumulative Limits

Potential change	Reference situation in Europe	Identification of generic economic impacts	Factors which will affect size of impacts
Harmonised limits on weekly, monthly, annual duty/ flying hours	As per Subpart Q with some national additions (see Table 3.8, D1)	New regulations on cumulative limits, if different from current practices, will lead to crew reaching limits more quickly/ slowly and impacting the productivity and costs of crew.	Depends on how current hours compare to whatever new limits are proposed. For smaller operators with less crew, effects are likely to be proportionally larger. See illustrative graph Figure 5.6 below.
Harmonisation of minimum number of rest days per month and/ or periodic rest period increases	Large national variations in rest days per month and periodic increases in rest periods (see Table 3.7, D1)	New regulations on minimum number of days off, if different from current practices, will directly impact crew productivity and required crew numbers to maintain EMS service level.	Size of impact will depend on difference between proposed regulations and current practice. See AEMS Section 6.1 for illustrative example of impact of changing number of rest days.

Figure 5.6 illustrates how the impact of cumulative limit changes could be different for operators working at or close to the cumulative limits ("At limits") already and those who have some slack in the cumulative hours their crews are working ("Under Limits"). For those working at existing limits, e.g. 2000 duty hours per year, a rule reduction in this limit will directly lead to increased crew costs. For an operator whose crew are on average at 1600 duty hours per year, for example, Figure 5.6 below illustrates how it is only when the limit reduces to this level that costs will increase significantly.

Figure 5.6: Illustrative Graph of Impact of Cumulative Limit Changes on Operating Costs



5.3.3 Social Impacts of FTL Changes Related to Cumulative Fatigue

Those social impacts which are judged likely to be most significant following proposed regulatory changes are tabulated below.

Table 5.6: Social Impacts Associated with Potential Changes to Cumulative Limits

Potential change	Reference situation in Europe	Identification of generic social impacts	Factors which will affect size of impacts
Harmonisation on limits on weekly, monthly, annual duty/ flying hours	As per Subpart Q with some national additions (see Table 3.8, D1)	For any cumulative limits changes it seems reasonable to assume that service levels will be maintained, if practical, with minimal impact on patient safety and health. If economic impacts are severe, this could affect EMS service levels and could affect job security. In addition crew members work/ life balance could be affected by changes.	Depends how different proposed regulations are from current limits.
Harmonisation of minimum number of rest days per month and/ or periodic rest period increases	Large national variations in rest days per month and periodic increases in rest periods (see Table 3.7, D1)	As above	As above

5.4 Sleep/ Rest Off-Duty and Relaxation/ Napping On-Duty

5.4.1 On-Duty HEMS base standby

5.4.1.1 Safety Impacts of FTL Changes

The key issues associated with this hazard are:

i. Value to be given to standby/ on-ground breaks within duty hours or FDP
ii. Quality of relaxation/ napping while on standby (relates to available facilities)

Given that HEMS operations are usually based on duty hours restricted shifts the issues of maximum base standby duration and rest following standby are part of shift duty duration (covered in Section 5.1) and rest following duty shifts (covered in Section 5.4.2 below).

Value to be given to standby/ on-ground breaks within duty hours or FDP

In those States surveyed where the regulations are based on daily duty time limits, there are examples of the standby time at base being counted 100% towards duty (e.g. France) and where it is counted 50% towards duty (e.g. Czech Republic).

In those States surveyed where regulations/ provisions use FDP limits for HEMS, there are examples where all the standby time at base for immediate readiness counts to the FDP (e.g. UK), where the FDP is interrupted when there is a break exceeding 1 hour (e.g. Switzerland) or exceeding 2 hours in suitable accommodation (e.g. Germany).

As discussed in the Literature review (Section 4.5) there are contradictory recommendations concerning how airport standby should be treated with respect to FDP and duty time contributions. Moebus Aviation (2008) notes that there is '*no scientific evidence to suggest that airport standby should be considered as any less fatiguing than flight duty and that further research is needed in this area*'. It concludes that '*time spent in airport standby should normally count 100% as flight duty when calculating the maximum FDP'*. The Principles and guidelines for duty and rest scheduling in Commercial Aviation 'NASA Study' (Dinges, 1996) contradicts Moebus Aviation's conclusions and recommends that '*airport standby should be considered as duty*'.

This uncertainty is reflected in the range of European States' provisions covering HEMS.

Relaxation/ napping while on base standby

If taken between flights, a brief nap can benefit alertness and performance. The nap should be limited to 15-20 minutes, or 90 minutes, and allow 10-15 minutes recovery from any potential sleep inertia. The potential benefits of a nap in improving alertness and performance during routine operations, with a resulting increase in safety margin, may outweigh the potential negative effects of a short period of sleep inertia.

A potential negative consequence is that the nap can theoretically disrupt the duration or quality of a later sleep period. Providing fatigued employees with an opportunity for a nap before driving home at the end of a shift will theoretically decrease the risk of accidents while driving fatigued.

This topic has been explored further using CAS modelling applied to naps during HEMS standby. The following scenarios were modeled to investigate in-shift naps:

- Scenario 5 from Section 5.1.1.1 – i.e. 16 hours shift duration from 0700 to 2300. 2 sequences of 5 missions each.
- Scenario 9 = Scenario 5 but with a nap inserted into the middle of the shift. The nap was placed between the two flight sequences, it was 90min long, and occurred between 14:00-15:30. That is probably the best time to take a nap, since it occurs during the "post lunch dip", when the threshold to fall asleep is lower.

The results are shown in Figure 5.8 below. This graph indicates that the 90 min mid-shift nap is effective in raising alertness for the second half of the shift. It should be noted however, that a nap of 90 min is probably on the high side – naps of 30 minutes or less will be more common and additional modeling of 30 minute naps indicates less benefit than the 90 minute naps (data not shown).

5.4.1.2 Economic Impacts of FTL Changes to HEMS Base Standby

Those economic impacts which are judged likely to be most significant following proposed regulatory changes are tabulated below.

Table 5.7: Economic Impacts Associated with Potential Changes to Base Standby Provisions

Potential change	Reference situation in Europe	Identification of generic economic impacts	Factors which will affect size of impacts
How airport standby time contributes to cumulative duty time	In some States in D1 survey standby at base contributed 100% to cumulative duty time whereas for Czech Republic it counts as 50% contribution.	If a regulatory change leads to airport standby contributing 100% instead of 50% to cumulative duty time (for example) this could lead to crew reaching cumulative duty time limits more quickly, thereby reducing average crew availability.	Depends on amount of airport standby and how current cumulative hours compare to limits. For those operators so affected this could be significant.

Potential change	Reference situation in Europe	Identification of generic economic impacts	Factors which will affect size of impacts
How airport standby time contributes to FDP and shift duty time	In some States in D1 survey standby at base contributed 100% to FDP and shift duty time, in others with breaks between missions of 1-2 hours there was a 0% contribution with suitable crew facilities.	For those States/ operators allowing breaks in missions of a certain length and quality to interrupt/ extend the FDP or shift, if this provision were removed, effective FDP/ shift duration would be reduced.	The significance of this would depend on current patterns of missions/ breaks and how much benefit operators are currently deriving from this flexibility. May be more of a social impact for some operators who only use these breaks to extend shift when there is a critical mission need.
Quality of airport standby facilities	No data obtained so far.	If a proposed regulation required operators to upgrade facilities, this would have a direct impact in terms of capital costs and possibly extra running/ maintenance costs for the facilities.	Scale of impact will depend on proposed regulatory requirements compared to existing facilities and number of bases affected (N.B. approximately 360 HEMS bases in Europe).

5.4.1.3 Social Impacts of FTL Changes to HEMS Base Standby

Those social impacts which are judged likely to be most significant following proposed regulatory changes are tabulated below.

Table 5.8: Social Impacts Associated with Potential Changes to Base Standby Provisions

Potential change	Reference situation in Europe	Identification of generic social impacts	Factors which will affect size of impacts
How airport standby time contributes to cumulative duty time	In some States in D1 survey standby at base contributed 100% to cumulative duty time whereas for Czech Republic it counts as 50% contribution.	If crew members reach their cumulative limits earlier or later that will impact the number of pilots required. If this leads to a need for more pilots and there are not sufficient pilots available, or they cannot be afforded economically, then service provision may decrease.	Depends how different proposed regulations are from current practices. Depends also on amount of airport standby and how current cumulative hours compare to limits.

Potential change	Reference situation in Europe	Identification of generic social impacts	Factors which will affect size of impacts
How airport standby time contributes to FDP and shift duty time	In some States in D1 survey standby at base contributed 100% to FDP and shift duty time, in others with breaks between missions of 1-2 hours there was a 0% contribution with suitable crew facilities.	If FDPs/ shifts are effectively shortened, there may be a reduction in times for which certain HEMS bases can be open if extra crew cover cannot be provided economically or there may be extra delays in responding to certain missions.	The significance of this would depend on current patterns of missions/ breaks and how much benefit operators are currently deriving from this flexibility.
Quality of airport standby facilities	No data obtained so far.	It seems reasonable to assume that service levels will be maintained, if practical, with minimal impact on patient safety and health	N/R unless significant economic impacts

5.4.2 Sleep and Rest Off-Duty

This subsection addresses the following hazard groupings:

- Lack of rest opportunity associated with basic rest and reduced rest
- Lack of extended rest following an extended FDP/ shift

5.4.2.1 Safety Impacts of FTL Changes to Basic and Reduced Rest

Literature Review

How much rest an individual needs between blocks of working days is related to the number, timing, and length of the consecutive shifts he or she works. Allowing more time off after extended blocks of night shifts is important because night shifts are more fatiguing, and sleep debt more prevalent, than with day shifts. There is agreement in the literature that a 24 hour period with one single night is usually not enough to fully recover from a series of consecutive work days. Instead, two consecutive days and nights off (48hrs) with unlimited sleep opportunity is usually enough to dissipate any cumulative sleep debt (see Section 4.7).

CAS Modeling

To indicate the potential impact of 2 periods of reduced rest within a week's shift pattern CAS modeling has looked at the following sequence of day shifts (60 hours duty in week total):

- 10 hours duty and 14 hours rest at home
- 15 hours duty and 9 hours rest at base in suitable accommodation
- 10 hours duty and 14 hours rest at home
- 15 hours duty and 9 hours rest at base in suitable accommodation
- 10 hours duty and 14 hours rest at home

Figure 5.7 shows the alertness at the end of shift for the 5 days. The average alertness across all hours is high for these day shifts. The modeling indicates very little difference between alertness at the beginning of the shift on days 1-5 with the fatigue score varying from 76 to 79. The predicted sleep periods are as follows:

Day	1	-	work	07:00-17:00,	sleep	22:15-6:00
Day	2	-	work	07:00-22:00,	sleep	23:00-6:00
Day	3	-	work	07:00-17:00,	sleep	22:30-6:00
Day	4	-	work	07:00-22:00,	sleep	23:00-6:00
Day	5	-	work	07:00-17:00,	sleep	22:30-6:30

On the normal duty days (3 and 5) of 10 hours, alertness at the end of the shift has recovered from the previous reduced rest days. This assumes that the crew has managed 7 hours sleep at the base on days of reduced rest. This appears sufficient in this scenario to prevent significant cumulative fatigue. However, the data from Samel et al (2004) with HEMS crew in Section 4.3.2 shows what can happen if sleep drops below 6 hours per night for consecutive days.

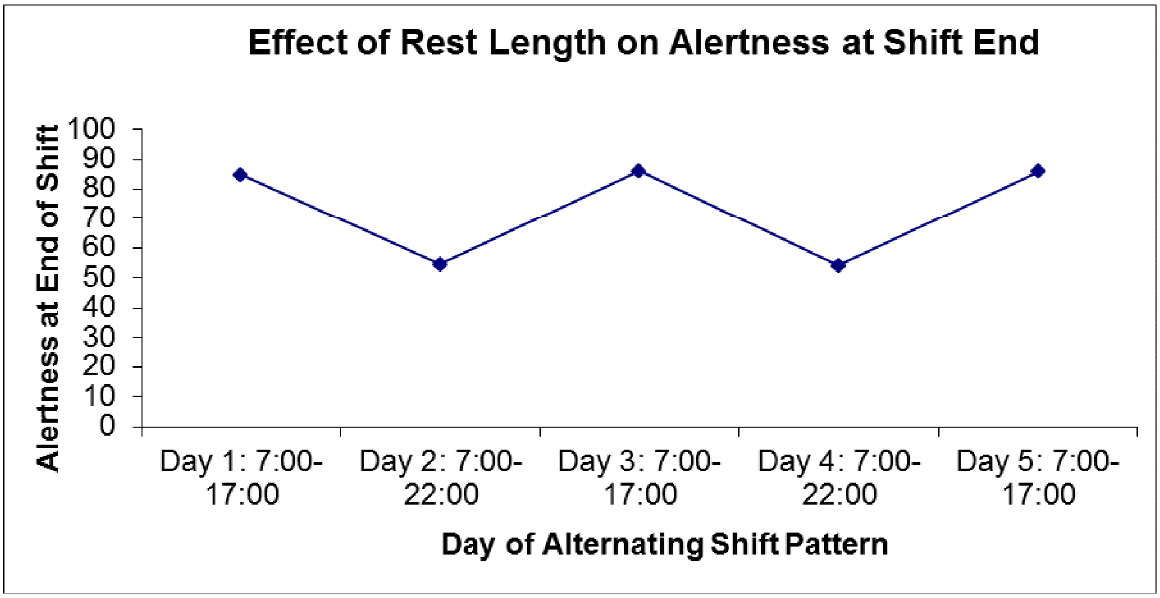


Figure 5.7 – Alertness at end of shift shows that two periods of reduced rest in week do not have significant cumulative effects in this scenario . *Pilots fly five consecutive day shifts with 15min flights spaced evenly throughout the shifts. Shift length on days 1, 3, and 5 is 10hr, allowing 14hr rest at home. Shift length on Days 2 and 4 is 15hr, allowing 9hr rest taken at the base in sleeping accommodation.*

5.4.2.2 Safety Impacts of FTL Changes Related to Extended Rest Following Extended FDP/ Shift

One means of mitigating the effects of a long (extended) shift, post-event, is to provide a longer rest afterwards. Clearly this does not help during the extended shift, but it can mitigate subsequent effects.

In terms of the scientific literature, The Principles and guidelines for duty and rest scheduling in Commercial Aviation 'NASA Study' (Dinges, 1996) recommends that '*the ….. required off-duty period should be extended by the same duration of the flight duty period extension*'.

In the UK at least 48hrs must elapse between the end of one extended HEMS air ambulance FDP and the start of another.

CAS modeling

The following scenarios were modeled to investigate post shift extended rest:

- Scenario 5 in Section 5.1.1.1 – 16 hours duration from 0700 to 2300. 2 sequences of 5 missions each.
- Running scenario 5 for 2 consecutive days
- Running scenario 5 twice but with an additional 24 hour rest in between.

Figure 5.8 indicates that:

- Having two long shifts on consecutive days does lead to a reduction in alertness at the end of day 2 compared to the end of day 1.
- An extra 24 hours rest brings alertness levels at the end of the second long day back up to the levels at the end of the first day. So in this scenario an extra 24 hours rest is an effective mitigation for an extended HEMS shifts.

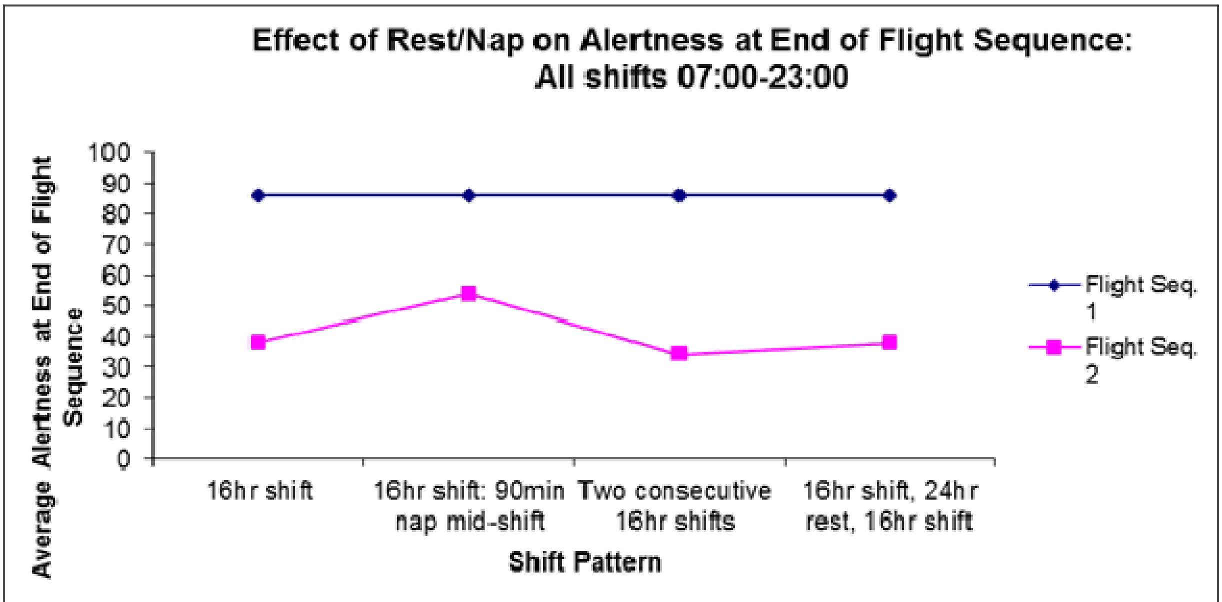


Figure 5.8 – Alertness during a 16hr shift is improved by a nap mid-shift, and marginally by 24hr extra rest between shifts. *Alertness is shown at the end of either the first or second sequence of flights. Flight sequence 1 begins 1hr after shift start, and consists of six evenly*

distributed 15min flights in 3hr. This is followed by a 9hr break where is the pilot is expected to be awake. Flight sequence 2 consists of six evenly spaced 15min flights in 3hr ending at the end of the shift. 16hr Shift is a single 16hr shift from 7:00-23:00. 16hr shift: 90min nap mid-shift is a single 16hr shift with a 90min nap in the middle of the 9hr break. Two consecutive 16hr shifts refers to two consecutive 16hr shifts with no naps. 16hr shift, 24hr rest, 16hr shift is two 16hr shifts with no naps and a 24hr additional rest between them.

5.4.2.3 Other Potential Mitigations:

In addition to setting minimum rest periods and limits on reduced rest, other potential mitigations for lack of rest that could be considered are:

- Augmentation of rest period following reduced rest
- Reduced maximum FDP/ shift following reduced rest
- Limiting the frequency of reduced rest occasions
- Limiting the length and number of missions after reduced rest (probably not practical for HEMS).

5.4.2.4 Economic and Social Impacts of FTL Changes to Off-Duty Rest

Those economic impacts which are judged likely to be most significant following proposed regulatory changes are tabulated below.

Table 5.9: Economic and Social Impacts Associated with Potential Changes to Off Duty Rest Provisions

Potential change	**Reference situation in Europe**	**Identification of generic impacts**	**Factors which will affect size of impacts**
Removing possibility for reduced rest	Minimum reduced rest varies from 8 hours to 11 hours depending on State. (N.B. 6 hours has been set in Switzerland as minimum time to get "enough" sleep between flights on a 48 hour shift period – but not officially classed as reduced rest. See Table 3.7, D1.)	May need extra pilots to ensure bases are open on time next day. Alternatively base may need to stay shut while pilots catch up with their full rest affecting service provision and impacting patient safety and health.	Frequency with which reduced rests are currently taken. Whether base is daytime only or 24/7 and current level of contingency crew cover.
Setting minimum hours for reduced rest	As above.	If the proposed regulatory minimums are significantly different from current national rules, the impacts could be similar to row above.	As above.

5.5 Pilot in Command Discretion

5.5.1 Safety Impacts of FTL Changes to PIC Discretion

The facility for the PIC to extend an FDP or shift is considered in the ranges of shifts modeled above (see Section 5.1.1.1). As well as providing maximum limits on this extension other potential mitigations could be:

- A non-punitive process for a PIC to reduce a shift duration and/or increase rest in the case of fatigue
- Training on fatigue to support PIC in the decision process (part of FRMS)
- Reporting to the NAA when the extension is above a certain threshold
- Guidance to the NAA on this subject.

5.5.2 Economic Impacts of FTL Changes to PIC Discretion

The main impact would be related to the duration of the extension period that is under the PIC's discretion. The economic impact of changing extended FDP/ shift limits is considered already above in Section 5.1.

Other economic impacts will be related to the setting up and administration of any new or updated processes related to training, reporting and guidance.

5.5.3 Social Impacts of FTL Changes to PIC Discretion

See Section 5.1 for social impacts of reducing flexibility for extensions.

5.6 Positioning and Travelling

The relevant hazards are:

- Positioning before an FDP/ shift which could lead to excessive time awake towards the end of a mission
- Positioning immediately after an FDP/ shift which could lead to excessively long duty periods with a cumulative effect
- Excessive travelling time

For HEMS operations, positioning will be relatively infrequent. Positioning to another base to cover for staff shortage might be an example. When it does occur then the following mitigations are relevant:

- Counting position duties as FDP when immediately prior to FDP
- Rest being based on the duty hours which counts positioning in full

These mitigations appear consistent with current provisions in Europe.

The potential for excessive traveling times is relevant to HEMS as for other operations. The following mitigations are likely to be relevant:

- Nomination of a home base for each crew member
- Ensuring a protected 8 hour sleep opportunity
- Counting travel time in excess of a limit (e.g. 60 minutes) as duty time (or positioning).

Depending on the current situation in terms of HEMS crew travel times and what changes are proposed there could be significant impacts. If many crew are travelling significantly greater than a chosen limit (e.g. 60 minutes) then introducing such a limit could have economic impacts in terms of increasing duty hours and hence rest requirements. If this causes movement of crew closer to bases there could also be social impacts. Hence a clearer picture in terms of current crew travel to and from HEMS bases would be valuable to assess potential impacts.

5.7 Circadian Disruption Due to Mixing Night and Day Shifts

As noted in Section 4.2.4 transitioning from day to night shifts and vice versa can cause problems. During the transition there is a misalignment of the circadian rhythms which leads to malaise and increased fatigue. Research studies (Santhi et al 2007) have studied the transition from day to night shift without rest days in between and found that the first night shift is most problematic with impairment in the ability to sustain focus, decrease in subjective alertness and decrease in visual search sensitivity more pronounced than in subsequent shifts.

A number of the European States surveyed in D1 have provisions for rest days between series of shifts. In France for example a set of 7 consecutive day shifts would be followed by 7 consecutive rest days before a series of night shifts would be undertaken. For other States see Appendix 2 of D1. The provision of rest days in between these transitions is an important mitigation for this cause of circadian disruption. Limiting the frequency of such transitions would also be a mitigation but may be difficult to achieve depending on operational factors and crew resources.

6.0 AEMS Analysis

The following fatigue factors and hazards from Table 3.2 are addressed in this section:

6.1 Duration of FDP and Extension for non-augmented crew – hazard A1, duration of FDP too long leading to fatigue, including A2, A4, A5 as possible causes of long periods awake

6.2 Duration of FDP and Extension for augmented crew – hazard A3, extended augmented crew FDP leads to fatigue

6.3 Time of Day Effects and Night Duty – hazard B1, WOCL encroachment

6.4 Home standby – how the unpredictability of home standby can contribute to long periods awake, hazard A5, and how it could contribute to cumulative fatigue, hazard C2

6.5 Pilot in Command Discretion – hazard A2, PIC discretion leading to too long an FDP

6.1 Duration of FDP and Extension – Non Augmented Crews

6.1.1 Safety Impacts of FTL Changes for FDP Duration and Extensions

The key issues associated with hazard A1 are:

i. Length of FDP and fatigue level
ii. Length of extended rest after an extended FDP
iii. Encroachment of WOCL (see section 6.3)
iv. Impact of number of sectors
v. Other potential mitigations.

6.1.1.1 Length of FDP and Fatigue Level

Literature Review

See Section 5.1.1.1.

CAS modeling

As some States and AEMS operators make use of extended FDPs that are significantly longer than those allowed in Subpart Q, modeling of longer FDPs is considered useful to future rule making discussions.

FDPs in the range 11 to 20 hours have been considered with <u>non-augmented crews</u>. The scenario specific assumptions are:

- Two sectors of 5 hours each, first flight starting 30 minutes after start of FDP and second flight ending at end of FDP, with half hour post flight duties
- Full rest before FDP
- Pilots assumed to stay awake during gap in 2 sectors
- No time-zone complications for this scenario

Three different finish times for the FDP have been selected, 0600 (worst case in terms of alertness), 13.00 and 21.00. The graph below shows alertness at the end of the last flight for these 3 different finish times with the different FDP durations.

Figure 6.1 indicates that:

- Alertness at the end of the last flight is heavily dependent on circadian time-of-day as expected.
- For the finish time where alertness is highest (2100) there is a large variation in alertness depending on FDP length between 11 hours (score of 76) and 20 hours (score of 32). Above 13 hours duration the alertness score starts to decrease steadily.
- For the other two end times of 0600 and 1300 there is less variation with FDP duration. In the case of 0600 the alertness is very low (<10 “bottomed out”) for all the durations modeled. A combination of FDP greater than 11 hours flown with an unaugmented crew and ending at 0600 will lead to low levels of alertness. Additional mitigations may be applied by crew in such circumstances, such as controlled napping when sanctioned. For 1300 the alertness varies from 38 to 27.

These findings seem broadly consistent with the literature in Section 4 indicating significant increases in risk as FDP begins to exceed 12-14 hours. The combination of literature and modeling shows that if EMS extensions are granted beyond 13 hours, flight safety risks are likely to increase. This needs to be balanced in some way with the medical benefits to patients and the public of extended EMS FDPs.

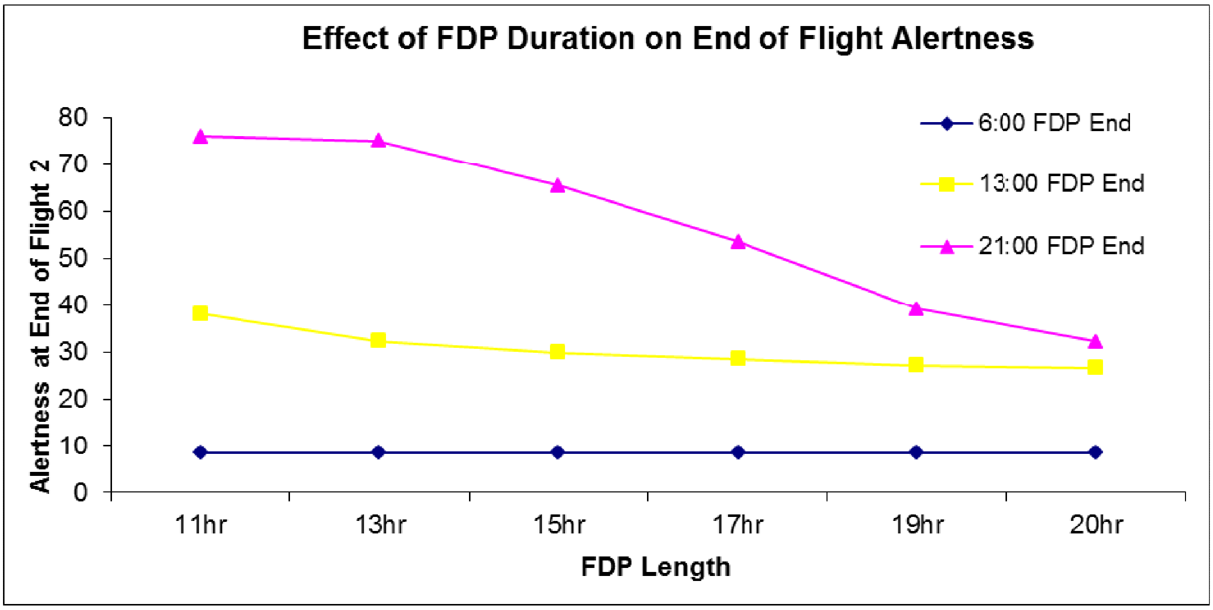


Figure 6.1 – Alertness at end of FDP depends on FDP length and time-of-day of FDP end.
Alertness is shown at the end of Flight 2. Flight 1 is a 5hr flight starting 30min after shift start. This is followed by a break of varying lengths where the pilot is expected to stay awake. Flight 2 is a 5hr flight that ends at the end of the shift. FDPs of 11, 13, 15, 17, 19, and 20hr end at either 6:00, 13:00, or 21:00 and start at varying times accordingly.

6.1.1.2 Length of Extended Rest After an Extended FDP

One means of mitigating the effects of a long (extended) FDP, post-event, is to provide a longer rest afterwards. Clearly this does not help during the extended FDP, but it can mitigate subsequent effects.

In terms of the scientific literature, The Principles and guidelines for duty and rest scheduling in Commercial Aviation 'NASA Study' (Dinges, 1996) recommends that '*the ….. required off-duty period should be extended by the same duration of the flight duty period extension'*. Other literature in Section 4 notes the importance of two nights sleep to recover from peak fatigue.

In the UK at least 48hrs must elapse between the end of one extended air ambulance FDP and the start of another. Pilot can fly 3 air ambulance extended FDPs in any 28 consecutive days. In France, if the FDP is greater than 14 hours, subsequent rest must be at least 24 hours including a local night except if reduced rest provisions are applied. In Norway a FDP of up to 17 hours (maximum) would be followed by a rest of at least 17 hours.

In one of the Swiss EMS operators there is the concept of Compensation Time added on top of the obligatory rest period. This is calculated using formulae which take account of the extended FDP duration, the number of crew members and whether the FDP included part or all of the night. The Compensation Time on top of the standard rest time can vary from 3 hours to 48 hours depending on these factors.

6.1.1.3 Impact of Number of Sectors

The need to decrease the FDP if there are a significant number of sectors is confirmed by many scientific studies (see Section 4.1.4). The Subpart Q requirement on maximum allowable FDP is based on a 30-minute reduction after the second sector. AEMS pilots can fly multiple sectors and it is reasonable to believe that this will have a similar effect on them as for scheduled and charter pilots. A reduction of FDP based on the number of sectors is part of some national provisions and Subpart Q is applicable to AEMS in many States as described in D1.

6.1.1.4 Other Potential Mitigations

In addition to limits on FDP duration, extended rest and modifying maximum FDP depending on numbers of sectors, other potential mitigations for long duration FDPs could be incorporated into the RIA options. These may include:

- Requiring full rest before the extended FDP (assumed in modeling above)
- FRMS (general for all hazards)
- Relief pilot for single pilot operations when an extension is invoked
- Prohibiting combining EMS operations FDP extension with extension due to split duty

- Controls over extensions due to split duty/ on-ground breaks, e.g. minimum consecutive number of hours for break before it can lead to an extension, etc.
- Ensuring that the most strict limits apply when extensions are used for mixed operations (e.g. air taxi and EMS)
- Limiting number of persons on aircraft during extensions
- Limiting the frequency of such extended FDPs
- Controlled napping and relaxation during any ground breaks between mission sectors
- Records to NAA of extensions and NAA oversight measures.

6.1.2 Economic Impacts of FTL Changes for FDP Duration and Extensions

Those economic impacts which are judged likely to be most significant following proposed regulatory changes are tabulated below (Table 6.1).

Table 6.1: **Economic Impacts Associated with Potential Changes to FDP Duration Provisions**

Potential change	**Reference situation in Europe**	**Identification of generic economic impacts**	**Factors which will affect size of impacts**
Harmonisation of basic max. FDP duration	Based on the survey of 8 States in Europe (D1) FDPs vary from 8 to 14 hours depending on State, number of pilots, FDP start time and number of sectors.	Changes to basic max. FDP duration (including impact of WOCL encroachment or number of sectors) could lead to the need for augmented crew and hence changes in pilot costs or if dramatically reduced could make certain missions impossible.	Size of impact will depend on how close to FDP limits operators currently fly. If close to the limits and limits change then could be significant need for more/ less crew.
Harmonisation in flexibility to extend FDPs to meet medical emergencies	Based on the survey of 8 States in Europe (D1) extensions vary from 0 up to 4 hours depending on State and type of emergency.	The main reason for extending is if an aeroplane is in the middle of a mission and is in a better position to continue and bring a patient back to hospital for example rather than have a new crew get ready and proceed from the airport/ base. Therefore any changes in this flexibility would not necessarily have any significant impact on crew numbers or economic impacts (except for extended rest requirements described below).	Social impacts more significant.

Potential change	Reference situation in Europe	Identification of generic economic impacts	Factors which will affect size of impacts
Harmonisation of required extended rest after an extended FDP	Based on the D1 survey the required rest after an extended FDP can vary from = FDP up to 48 hours depending on State.	Changes to the amount of rest following an extended FDP will affect crew availability. If a new requirement for extended rest following an extended FDP is introduced then extra crew may need to be made available to cover such an event.	The percentage of FDPs that get extended beyond proposed regulatory change. How much spare crew capacity operators have to cover such events currently.

An indication of the process for determining the economic impacts of proposed changes is illustrated by the following example relating to additional extended rests following extended FDPs:

- Assume that a regulatory change leads to an additional 24 hours rest being allotted whenever an extended FDP beyond X hours is flown.
- Assume that each crew member experiences an extended FDP exceeding X hours for Y times a year.
- The change will lead to an average of Y extra rests days (24Y extra rest hours) per year per crew member.
- Data from 2 states indicates that an AEMS crew member will average about 1300 duty hours per year.
- If the extra rests reduce duty time directly, this would cause a 24Y/1300 × 100% reduction in crew productivity. In practice extra operational data would be needed about the impact of extra rests on duty time.
- When data is available this could be combined with information from Section 2.2 where it is estimated that crew costs are about 20% of total operating costs (although with a significant range from 15% to over 30%).

6.1.3 Social Impacts of FTL Changes for FDP Duration and Extensions

Those social impacts which are judged likely to be most significant following proposed regulatory changes are tabulated below (Table 6.2).

Table 6.2: Social Impacts Associated with Changes to FDP Duration Provisions

Potential change	Reference situation in Europe	Identification of generic social impacts	Factors which will affect size of impacts
Harmonisation of basic max. FDP duration	Based on the survey of 8 States in Europe (D1) FDPs vary from 8 to 14 hours depending on State, number of pilots, FDP start time and number of sectors.	If dramatically reduced could make certain AEMS missions impossible.	See row below.

Potential change	**Reference situation in Europe**	**Identification of generic social impacts**	**Factors which will affect size of impacts**
Harmonisation in flexibility to extend FDPs to meet medical emergencies	Based on the survey of 8 States in Europe (D1) extensions vary from 0 up to 4 hours depending on State and type of emergency.	If changes lead to reduction in this flexibility then it could take longer to reach and transport patients in events which occur close to FDP limits. No other social impacts considered significant.	The percentage of FDPs that get extended beyond proposed regulatory change. The percentage of these extended FDPs that do actually “save lives” – would expect this percentage to be high as event needs to be urgent to justify an FDP extension.
Harmonisation of required extended rest after an extended FDP	Based on the D1 survey the required rest after an extended FDP can vary from = FDP up to 48 hours depending on State.	If extra rest days cannot be covered due to economic constraints then service levels would be affected. Economic impacts could lead to jobs created or lost.	The size of the change in required extended rest compared to current provisions. The frequency of extended FDPs. The amount of crew cover an operator has to accommodate extended rests.

An indication of the process for determining the social impacts of proposed changes is illustrated by the following example relating to restricting duration of extended FDPs:

- Assume that a regulatory change leads to a reduction in extensions from X hours maximum extended FDP to Y hours maximum FDP.
- Assume that an operator currently experiences extended FDPs between X and Y hours duration Z times per year.
- Assume that for 10% of these events the extension allowed a patient’s life to be saved.
- The social impact of this regulatory change for this operator would be approximately 10/100 × Z extra patient fatalities per year.

As with the equivalent HEMS calculation these assumptions would need to be replaced by actual data from operators and health services to enable actual social impacts to be estimated.

6.2 FDP Extension With Augmented Crew

6.2.1 Safety Impacts of Changes for Extended FDP due to Augmented Crew

The key issues associated with this hazard are:

i. Length of FDP and fatigue level
ii. Length of extended rest after an extended FDP
iii. Availability and quality of in-flight rest facilities
iv. Other potential mitigations.

6.2.1.1 Length of FDP and Fatigue Level

Literature Review

Some issues with extended duration FDP's can be avoided by augmenting the crew during long flights with an additional crew member(s). Augmented crews allow pilots to take in-flight rest and obtain sleep in order to maintain alertness and reduce fatigue.

Numerous studies have shown that both objective physiological measures and subjective ratings of alertness demonstrate improvement following an in-flight rest taken during periods of sustained wakefulness and that sleep can also reduce or delay expected performance decrements (Simon, 2007). Timing and duration of rest/ sleep can be designed for optimal impact on alleviating fatigue.

CAS modeling

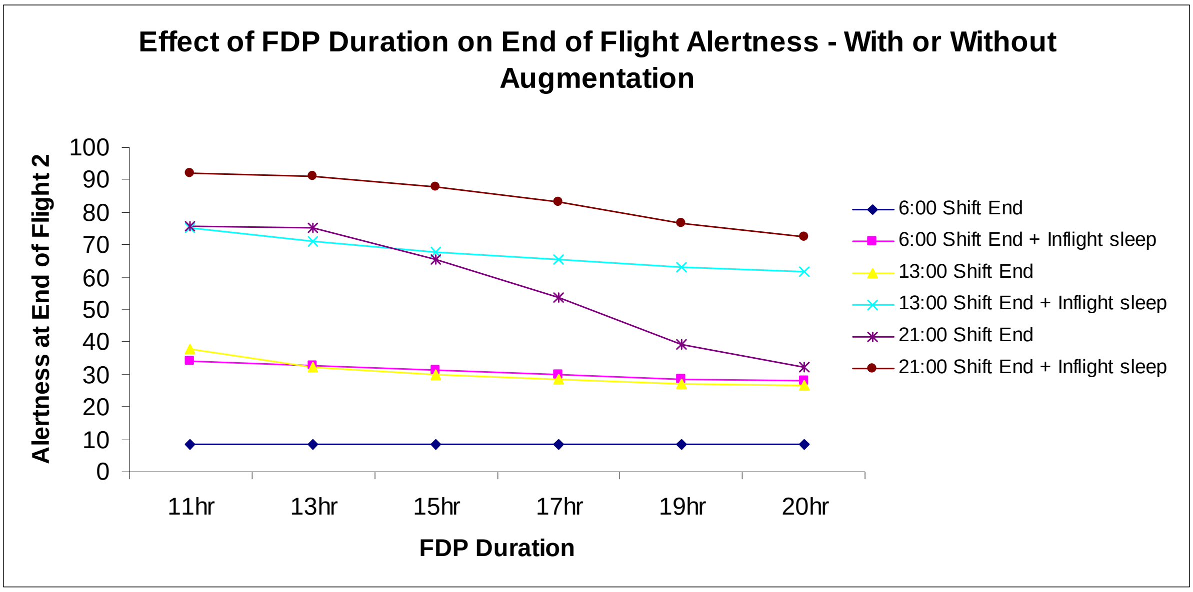
As some States and AEMS operators make use of augmented crew FDPs that are significantly longer than those allowed in Subpart Q, modeling of longer FDPs is considered useful to future rule making discussions.

FDPs in the range 11 to 20 hours have been considered with 3 person augmented crews. The scenario specific assumptions are:

- Two sectors of 5 hours each, first flight starting 30 minutes after start of FDP and second flight ending at end of FDP, half hour post flight duties
- Full rest before FDP
- 90 minute sleeps as part of inflight rests were placed in the middle of each flight
- No time-zone complications for this scenario

As in section 6.1.1.1 three different finish times for the FDP have been selected, 0600 (worst case in terms of alertness), 13:00, and 21.00. Figure 6.2 shows alertness at the end of the last flight for these 3 different finish times for augmented and non-augmented crew.

Figure 6.2: **Impact of FDP duration on alertness at end of Augmented Crew FDP**



The graph indicates that:

- For the end time where alertness is highest (2100) crew augmentation is effective in maintaining alertness at the end of the second flight (compared to Figure 6.1 with non-augmented crew).
- In the case of 06:00 end time the alertness is low even with augmentation and at this finish time the alertness shows only weak dependence with FDP duration.
- Alertness is at intermediate levels with an afternoon (13:00) end time and augmentation shows clear benefits.

6.2.1.2 Length of Extended Rest After an Extended FDP

See Section 6.1.1.2 above for relevant scientific literature.

In the UK, an additional 'day off' (minimum 34 hours which includes 2 local nights) must be taken on completion of the full rest entitlement after an extended crew augmented FDP for AEMS.

In France, the minimum rest at home base following extended crew augmented FDP is 48 hours with 2 local nights.

6.2.1.3 Other Potential Mitigations

Other potential mitigations could be incorporated into the RIA options. These may include:

- Specifying minimum rest durations at destination and at home
- Additional compensation time over and above the standard rest time

- Sleep opportunities at the airport after long missions
- Promote and pay for use of public transport after long missions which mitigates the risk of car accidents for AEMS flight crew
- Technical criteria for in-flight rest facilities
- Minimum duration of rest period onboard required
- Limiting the frequency of such extended augmented FDPs
- Limiting the number of sectors.

6.2.2 Economic Impacts of FTL Changes for Augmented Duty Duration and Extensions

Those economic impacts which are judged likely to be most significant following proposed regulatory changes are tabulated below (Table 6.3).

Table 6.3: **Economic Impacts Associated with Potential Changes to Augmented FDP Provisions**

Potential change	**Reference situation in Europe**	**Identification of generic economic impacts**	**Factors which will affect size of impacts**
Harmonising FDP hours for augmented crew and/ or requirements for onboard rest facilities	FDPs up to 34 hours for ULR (ex-scope) and up to 18 hours for non-ULR.	If a change requires 4 crew instead of 3 to fly an FDP of a certain number of hours this will clearly lead to increased crew costs. Alternatively operators may choose to upgrade onboard rest facilities (if practical) to achieve desired FDPs with available crew with consequent capital costs.	Size of impact will depend on how close to FDP limits operators currently fly. If close to the limits and limits change then could be significant need for more/ less crew.
Harmonising extended rest after an augmented FDP	The required rest after an extended FDP can vary from = FDP up to 48 hours depending on State (greater for ULR).	Changes to the amount of rest following an extended FDP may affect crew availability. If a new requirement for extended rest following an augmented FDP is introduced then extra crew may need to be made available to cover such an event.	The percentage of FDPs that get extended beyond proposed regulatory change. How much spare crew capacity operators have to cover such events currently.

An indication of the process for determining the economic impacts of proposed changes is illustrated by the following example relating to additional extended rests following extended augmented FDPs:

- Assume that a regulatory change leads to an additional 12 hours rest being allotted whenever an extended augmented FDP beyond X hours is flown.
- Assume that each crew member experiences an augmented FDP beyond X hours Y times per year.
- The change will lead to an average of 12Y hours extra rest per year per crew member.
- This can be used to assess the impact on crew costs and overall operating costs as per the other illustrative examples above.

6.2.3 Social Impacts of FTL Changes for Augmented Duty Duration and Extensions

Those social impacts which are judged likely to be most significant following proposed regulatory changes are tabulated below (Table 6.4).

Table 6.4: Social Impacts Associated with Potential Changes to Augmented FDP Provisions

Potential change	Reference situation in Europe	Identification of generic social impacts	Factors which will affect size of impacts
Harmonising FDP hours for augmented crew and/ or requirements for onboard rest facilities	FDPs up to 34 hours for ULR (ex-scope) and up to 18 hours for non-ULR.	Could make it difficult/ impossible to reach certain patients. For example, an operator may need to fly into a conflict zone where it is dangerous to stay over for a night and/or this would put patient at further risk. In such cases the ability to fly an extended FDP using crew augmentation may be the only solution.	The percentage of augmented FDPs that extend beyond proposed regulatory change. The percentage of these augmented FDPs that do actually “save lives” – would expect this percentage to be high as event needs to be urgent to justify mission.
Harmonising extended rest after an augmented FDP	The required rest after an extended FDP can vary from = FDP up to 48 hours depending on State (greater for ULR).	For any changes it seems reasonable to assume that service levels will be maintained with minimal impact on patient safety and health. If extra rest days cannot be covered due to economic constraints then service levels would be affected.	N/R unless there are significant economic impacts.

6.3 Time of Day Effects and Night Duty

6.3.1 Safety Impacts of FTL Changes Relating to WOCL Encroachment

There is consensus within the scientific literature and from operational experience that the length of the FDP should be reduced if sleep is restricted, e.g. if a crew member cannot sleep during the WOCL and then finds it difficult to sleep at other times of the day. The CAS modeling in Section 6.1.1.1 shows low alertness for FDPs ending at the end of the WOCL. The review of AEMS FTL provisions in D1 showed that the States either followed Subpart Q or had a similar approach to reducing FDP for WOCL encroachment which is a mitigation for transient effects.

Other potential mitigations aimed at cumulative fatigue include:

- Providing additional rest – e.g. if two or more FDPs encroach the WOCL during a week, the weekly rest could be extended from 36 hours to 48 hours. This could include other periods of extended rest not necessarily weekly.
- Limiting the frequency of such WOCL encroached FDPs – generally given the relatively low frequency of AEMS missions such frequency limits may not be so effective.

Mitigations aimed at both transient and cumulative fatigue are:

- Planning to optimize sleep opportunity (a Subpart Q provision) – this is hard to guarantee for an on-demand service such as EMS.
- Personnel trained to recognize fatigue and respond appropriately (see HEMS section on night duties, section 5.2.1).

6.3.2 Economic Impacts of FTL Changes Relating to WOCL Encroachment

The major potential impacts are judged to be any future rule changes affecting:

- Additional rest to compensate for WOCL encroachment – the economic impact will be the equivalent of that described in Table 6.1 for Extended Rest after Extended FDP and the illustrative calculation of impacts of extra rest time after Table 6.1.
- Changes in the manner that FDP is adjusted if WOCL is encroached – the economic impact will be equivalent to changing the maximum FDP duration shown in Table 6.1.

6.3.3 Social Impacts of FTL Changes Relating to WOCL Encroachment

The major potential social impacts are judged to be any future rule changes affecting:

- Additional rest to compensate for WOCL encroachment
- Changes in the manner that FDP is adjusted if WOCL is encroached

These will be equivalent to those described in Table 6.2.

6.4 Home Standby

The use of short call home standby is used by many European AEMS operators (see Appendix 4). Long call home standby (at least 10 hours before start of an assigned duty) is not considered below as safety impacts are not considered so significant and is not so relevant to EMS on-demand operations.

6.4.1 Safety Impacts of FTL Changes Relating to Home Standby

The key issues associated with this hazard are:

i. Maximum duration of standby
ii. Taking account or not of standby time in FDP hours and duty hours and subsequent rest calculations
iii. Other potential mitigations.

6.4.1.1 Maximum Duration of Standby

In terms of the scientific literature the Principles and guidelines for duty and rest scheduling in Commercial Aviation 'NASA Study' (Dinges, 1996) does not consider 'on call reserve status' as duty, but recommends that 'a protected 8 hour sleep opportunity' should be protected from interruption by assignment to a flight duty period.

Crew Factors in Flight Operations XI: A Survey of Fatigue Factors in Regional Airlines Operations (Co, E., 1999) notes that: '*The nature of flying on reserve means that crewmembers must respond when called for duty, thus creating unpredictability in their schedules. This unpredictability can lead to sleep loss, for example, when a call for duty occurs when a sleep period was planned. As evidence that sleep loss occurred, crewmembers reported getting 5.6 h of sleep before duty on average—2.3 h less than their normal average sleep*.'

The survey in D1 revealed maximum short call home standby durations of 12 hours and 24 hours (sometimes renewable for 2 or more days). The degree to which crew can obtain 8 hours sleep during a 24 hours standby is unclear.

If an operator is using different standby types it can be possible to use the crew on 24 hours standby as a "last resort" and hence minimize the chance that their sleeps will be disturbed (see below under "Other potential mitigations"). Hence the scale of safety significance and the impact of changing maximum standby duration is uncertain.

Thus this is an issue where operational experience will have a large input in future RMT discussions rather than the scientific literature or modeling. A key question is – does operational experience (and any outputs from FRMSs) show that AEMS pilots are able to get 7-8 hours sleep when on 24 hour standbys?

6.4.1.2 Taking Account of Standby Time in FDP Hours, Duty Hours and Subsequent Rest Calculations

There is very little scientific research covering this topic. However, Torsvall and Akerstedt (1988) showed that sleep quality is affected in ships' engineers based on whether they are on-call or not. Changes in sleep quality were noted before any alarms went off, suggesting that sleep was disrupted in anticipation of being called out for duty.

The survey in D1 revealed wide variation in this issue. Clearly reducing the allowable FDP length to allow for some/ all of the standby time before a callout will, on average, reduce the chance of crew fatigue. However, it will also reduce the ability of the AEMS operator to provide a service to a patient and/ or have economic impacts (see below). Accounting for home standby hours in duty hours (either in full or in part) would not clearly have significant flight safety benefits for AEMS crew. In general AEMS crews fly less annual hours than other types of pilots and cumulative fatigue is less of an issue than peak fatigue after long missions. New provisions that lead to extra rest requirements might affect pilot competence and hence flight safety if crew hours drop too low.

Thus this is an issue where operational experience will again have a large input in future RMT discussions rather than the scientific literature or modeling. Key questions include – does operational experience (and any outputs from FRMSs) show that AEMS pilots are able to manage time at home so they do not arrive fatigued for FDPs, what fatigue training and awareness do they receive concerning home standby and do they obtain sufficient overall rest to manage cumulative fatigue? Fatigue training and awareness could cover use and quality of afternoon naps, effect of meal and drinks, effects of home based tasks on fatigue, etc.

6.4.1.3 Other Potential Mitigations

Other potential mitigations include:

- FRMS and crew's individual management of rest during standby – a FRMS can help raise crew's awareness of the importance of napping, avoiding heavy home working tasks, etc.
- Management of standby so operator avoids placing crew on repeated 24 hr duration standbys, and preferential use of persons on standby who should be better rested.

6.4.2 Economic Impacts of FTL Changes Relating to Home Standby

Those economic impacts which are judged likely to be most significant following proposed regulatory changes are tabulated below.

Table 6.5: Economic Impacts Associated with Potential Changes to Home Standby Provisions

Potential change	Reference situation in Europe	Identification of generic economic impacts	Factors which will affect size of impacts
Harmonised limit on standby duration	Varied national provisions up to a maximum of 24 hours (see Appendix 2, D1).	If limit on standby duration is reduced (e.g. 24 hours to 12 hours) this is likely to increase pilot costs although this may vary depending on what extent standby counts towards cumulative duty and how the standby shifts are organised. .	The extent will depend on what standby patterns operators are currently using and how much reliance is being placed on longer home standbys.
Harmonisation of the contribution of standby to FDP, duty hours and subsequent rest calculations	Varied national provisions for contribution of home standby to FDP and cumulative duty hours can vary from 100% to 0%, depending on State and associated factors (see Appendix 2, D1).	If home standby which does not lead to a duty is followed by a rest period (e.g. in accordance with ORO.FTL.235) and no rest has been accorded before, there will be a reduction in average crew availability and a need for higher crew costs to maintain EMS service level.	Frequency of standbys. Duration of extra rest periods following standby based on proposed change.

An indication of the process for determining the economic impacts of proposed changes is illustrated by the following example relating to additional rests following home standby that does not lead to duty:

- Assume that a regulatory change leads to a new requirement for X hours rest following a Y hour home standby.
- Assume an average of Z days home standby per crew member, with average of Y hours per standby.
- New requirement would introduce Z × X hours of extra rest per year.

In addition operational data would be needed on how often a mission occurs immediately after a standby period and hence whether the extra rest would increase required crew numbers.

6.4.3 Social Impacts of FTL Changes Relating to Home Standby

Those social impacts which are judged likely to be most significant following proposed regulatory changes are tabulated below.

Table 6.6: **Social Impacts Associated with Potential Changes to Home Standby Provisions**

Potential change	**Reference situation in Europe**	**Identification of generic social impacts**	**Factors which will affect size of impacts**
Harmonised limit on standby duration	Varied national provisions up to a maximum of 24 hours (see Appendix 2, D1).	24 hour standby can have a negative social effect for crew relative to 12 hour standby as it does not allow relaxation time, e.g. going out in the evening. On the other hand having to conduct 12 hour standbys twice as often as 24 hour standbys can also have social impacts for crew. For any changes it seems reasonable to assume that EMS service levels will be maintained with minimal impact on patient safety and health unless economic impacts mean that cover has to be reduced.	The size of impact will depend on what standby patterns operators are currently using and how much reliance is being placed on longer home standbys.
Harmonisation of the contribution of standby to FDP, duty hours and subsequent rest calculations	Varied national provisions for contribution of home standby to FDP and cumulative duty hours can vary from 100% to 0%, depending on State and associated factors (see Appendix 2, D1).	If a rule change leads to home standby contributing to subsequent FDP if called out, this may reduce the ability of the operator to fly sufficient hours to respond to emergency in a timely manner. Additional crew may enable patient service provision to stay the same (e.g. through providing augmented crew), but may be uneconomic to maintain. Reaching cumulative duty hour limits earlier or later could also impact service provision.	Frequency of standbys and distribution of callouts during the standby periods. Contribution of standby to subsequent FDP based on proposed change. Percentage of missions which cannot be flown as allowable FDP is no longer sufficient – relates to distribution of distances of emergencies from home base.

An indication of the social impacts of proposed changes is illustrated by the following calculation relating to home standby contributing to subsequent FDPs:

- Assume a regulatory change requires standby to contribute to FDP if called out after X hours and FDP is shortened by the amount of standby time exceeding X hours.
- Assume an average of 80 days home standby per crew member (see Appendix 4), and assume called out on 50% of standbys.
- Assume conditional probability of being called out after X hours of standby is 50%.

- Assume chance of mission no longer being possible because of effective FDP shortening is Y%.
- From the above assumptions $80 \times 0.5 \times 0.5 \times Y/100$ additional times per year an individual crew member will not be able to respond to a mission.

This simple illustrative example can be replaced with more realistic data in the future.

6.5 Pilot in Command Discretion

The safety, economic and social impacts for FTL rule changes in AEMS PIC discretion will be similar to those under HEMS PIC discretion in Section 5.5.

7.0 Conclusions

EMS operations have certain higher risk characteristics relative to other aircraft operations such as time pressures to reach and transport patients and flights made at short notice with potentially challenging topographical features and weather conditions. In addition there are aspects of flight time limitations and rest provisions that could lead to fatigue and increased risk, e.g. requirements to extend a duty period to respond to an emergency.

It is difficult to draw firm conclusions about the actual record of controlling fatigue risk in EMS operations in Europe due to potential under-reporting of fatigue as a causal factor of accidents/ incidents. The scientific literature and the modelling described in this report indicate that operating to the extremes of the national FTL ranges[4] currently allowable in Europe could have a significant impact on fatigue and alertness. Hence harmonisation of FTL provisions is likely to have safety impacts; in particular if the higher risk bounds of the ranges are reduced there will be positive safety impacts.

With respect to economic and social impacts a large number of potential FTL changes have been considered including harmonisation of:

- Maximum shift/ FDP durations
- Flexibility for shift/ FDP extensions due to EMS events
- Block hours over different time periods
- Extended rest requirements following extended shifts/ FDPs
- Availability of relief crews for HEMS night shifts
- Number of consecutive HEMS shifts (day/night)
- Periodic increases in rest
- How standby contributes to FDP and cumulative duty hours
- Reduced rest provisions
- Augmented crew arrangements.

This report provides information and preliminary analysis to be considered for the RIA development for RMT .0346 on FTL for EMS with a view to assist in an overall balanced assessment of safety, economic and social impacts.

[4] See report D1 tables and Appendix 2 for these ranges.

8.0 References

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9.0 Acronyms/ Abbreviations

Term	Description
AAIB	Aircraft Accident Investigation Board
ADAC	Allgemeiner Deutscher Automobil-Club e.V.
ADREP	(ICAO's) Accident Data Reporting system
AEMS	Aeroplane Emergency Medical Services
API	American Petroleum Institute
CAA	Civil Aviation Authority
CAP	Civil Aviation Publication
CAS	Circadian Alertness Simulator
CAT	Commercial Air Transport
CM	Crew Member
CRD	Comment Response Document
CS	Certification Specification
DNV	Det Norske Veritas
DRF	Deutsche Rettungsflugwacht e.V./German Air Rescue
EASA	European Aviation Safety Agency
EEG	Electro-encephalography
EHAC	European HEMS and Air Ambulance Committee
EMS	Emergency Medical Services
ETSC	European Transport Safety Council
EU OPS	European Union (Safety Regulations) Commercial Air Transportation Operations
FAA	Federal Aviation Administration
FDP	Flight Duty Period
FDT	Flight Duty Time
FMCSA	Federal Motor Carrier Safety Administration
FRM(S)	Fatigue Risk Management System
FTL	Flight Time Limitations
HEMS	Helicopter Emergency Medical Services
h or hrs	hours
ICAO	International Civil Aviation Organisation
IFR	Instrument Flight Rules
IR	Implementing Rules
JAR OPS	Joint Aviation Requirements on Commercial Air Transportation Operations
LPR	Lotnicze Pogotowie Ratunkowe
MSLT	Multiple Sleep Latency Test
MWT	Maintenance of Wakefulness Test
NAA	National Aviation Authority
N/A	Not Applicable
NASA	National Air and Space Administration

Term	Description
NM	Nautical Miles
NPA	Notice of Proposed Amendment
N/R	Not Relevant
NTSB	National Transportation Safety Board
NVG	Night Vision Goggles
NVIS	Night Vision Imaging System
PIC	Pilot In Command
REGA	Swiss Air Ambulance
REM	Rapid Eye Movement
RIA	Regulatory Impact Assessment
RMG	Rule Making Group
SRG	Safety Regulation Group
TNO	Nederlandse Organisatie voor Toegepast Natuurwetenschappelijk Onderzoek (Netherlands Organisation for Applied Scientific Research)
ULR	Ultra Long Range
VFR	Visual Flight Rules
VMC	Visual Meteorological Conditions
WOCL	Window Of Circadian Low

Appendix 1 – EMS Safety Data

EMS Accidents with Fatigue as a Causal Factor

Two European EMS accident reports were identified by DNV/ Circadian which contain significant text on fatigue and its possible role in the respective events. These reports were identified through search of public domain websites of accident investigation boards and information sent by the NAAs surveyed. In addition DNV/ Circadian identified three references to NTSB investigations on EMS accidents in the USA which are described below.

EASA's Safety Analysis Section also conducted a search of the EASA copy of the ICAO ADREP data base. This uncovered one further European accident and 2 non-European EMS occurrences where fatigue appears to have been a factor.

Europe Event 1 – Scotland 2005
http://www.aaib.gov.uk/cms_resources.cfm?file=/Summary%20%20AAR%202-2006%20Pilatus%20Britten-Norman%20BN2B-26%20Islander,%20G-BOMG.pdf

On 15 March 2005, a Britten-Norman Islander aircraft crashed into the sea while descending toward Campbeltown Airport in western Scotland. The aircraft was operating an air ambulance flight[5] on behalf of the Scottish Ambulance Service. The pilot and paramedic both died in the crash. Given the relevance of this accident to the current study quotes are taken from the UK AAIB report below.

AAIB Report No: 2/2006 Report on the accident to Pilatus Britten-Norman BN2B-26 Islander, G-BOMG, West-north-west of Campbeltown Airport, Scotland, on 15 March 2005

Abstract/ Summary

"*The Glasgow based Islander aircraft was engaged on an air ambulance task for the Scottish Ambulance Service when the accident occurred. The pilot allocated to the flight had not flown for 32 days; he was therefore required to complete a short flight at Glasgow to regain currency before landing to collect a paramedic for the flight to Campbeltown Airport on the Kintyre Peninsula.*

Poor weather at Campbeltown Airport necessitated an instrument approach. There was neither radar nor Air Traffic Control Service at the airport, so the pilot was receiving a Flight Information Service from a Flight Information Service Officer in accordance with authorised procedures. After arriving overhead Campbeltown Airport, the aircraft flew outbound on the approach procedure for Runway 11 and began a descent. The pilot next transmitted that he had completed the 'base turn', indicating that he was inbound to the airport and commencing an approach.

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[5] Air ambulance flights are defined in CAP 371 as "*When the sole reason for the flight is to carry an ill or injured person to a recognized medical facility, or the carriage of a human organ necessary for a transplant operation*."

Nothing more was seen or heard of the aircraft and further attempts at radio contact were unsuccessful. The emergency services were alerted and an extensive search operation was mounted in an area based on the pilot's last transmission. The aircraft wreckage was subsequently located on the sea bed 7.7 nm west-north-west of the airport; there were no survivors.

The investigation identified the following causal factors:

1. The pilot allowed the aircraft to descend below the minimum altitude for the aircraft's position on the approach procedure, and this descent probably continued unchecked until the aircraft flew into the sea.

2. A combination of fatigue, workload and lack of recent flying practice probably contributed to the pilot's reduced performance.

3. The pilot may have been subject to an undetermined influence such as disorientation, distraction or a subtle incapacitation, which affected his ability to safely control the aircraft's flightpath."

AAIB Section on Pilot rest

"The pilot was rostered for a night standby duty on 14 March 2005, to be conducted from home and commencing at 2300 hrs. He had finished a two week leave period on 12 March, and had been rostered for a day off on the 13 March. During his leave he had gone on holiday to Italy with his family, returning to the UK on 9 March and travelling home on 12 March. He spent the remainder of the weekend at home with his family. On the evening of 13 March he had retired at about 2245 hrs and had an uninterrupted night's sleep. On the day of the 14 March the pilot awoke at about 0645 hrs and spent the day attending to domestic tasks. He was called at 2136 hrs by the operations officer and notified of the intended flight. He dressed and drove to work, arriving at about 2220 hrs. There was no indication that the pilot attempted or achieved any sleep during the day or early evening."

The aircraft took off about 23.30 after a short currency flight. The crash happened 15 March 2005 at 0018 hrs.

AAIB Section on Pilot fatigue

"The pilot was well rested prior to the day of the accident flight, and had achieved a normal sleep pattern for the 72 hours prior to the accident. He reportedly achieved about seven hours 45 minutes of sleep during the night and was not known to have suffered from any sleep disorders that may have reduced the quality of his sleep. The average human adult physiologically requires about eight hours of sleep for optimal performance and alertness, so the pilot was probably close to maximum 'sleep credit' at the start of the day.

Although he had been rostered a night standby duty, the pilot was called only infrequently on such duties and did not normally aim to achieve any sleep during the day. Such seems to be the case on the day of the accident. The difficulty of achieving sleep during the day *preceding an initial night duty is well recognised, and for many individuals the best that can be achieved is a period of rest.*

How long an individual remains awake is a physiological factor that can affect performance and alertness. Generally, performance and alertness can be maintained up to 12 hours of wakefulness, after which some reduction in performance occurs. Sixteen to 17 hours of continuous wakefulness can be associated with significantly reduced performance and alertness. At the time of the accident the pilot had been awake for 17 hours 15 minutes and is therefore likely to have been suffering from fatigue to some extent."

Europe Event 2 – Spain 2004

http://www.fomento.gob.es/NR/rdonlyres/7B20C57F-249F-4265-978D-A412E1FA5707/11987/2004_016_A_ENG.pdf

Comisión de Investigación de Accidentes e Incidentes de Aviación Civil, INFORME TÉCNICO A-016/2004 "Accidente ocurrido el 30 de marzo de 2004 al helicóptero Eurocopter SA-365-N1, matrícula EC-GJE, en el término mun. de San Bartolomé de Tirajana (Las Palmas)"

This accident led to five fatalities 3 crew and 2 passengers. Whether fatigue was a contributor is unclear from the report. However, the report includes this text:

"*It seems that the day of the accident the pilot had rested at least during 8 h. The day before, he did not carry out any flight. The last «flight» was done on 24 March in a flight simulator in France. After that course, he had 3 days off (considering that 25 March was devoted to travelling) until he started working again on 29 March. It is therefore considered that short-term fatigue was not a factor in this accident. It is always difficult to carry out a detailed analysis of the so called long-term fatigue, normally associated to 12-hour shifts in 24-hour services along 20 continuous days, with short expected response times when called for an assignment. This process may affect the performance of pilots that spend long periods of inactivity in the same base waiting for a flight to be carried out on demand, followed by short periods of intense activity after an emergency call. This situation may be aggravated if not optimum resting facilities are provided during such long periods.*

Even if such condition existed, it would be very difficult to establish its direct influence in the accident. However, in any case, it is considered convenient to issue a safety recommendation to the DGAC to review the organization and procedures of the emergency medical services of the operator in the Canary Islands regarding activity periods and resting conditions to be sure that the possibility of long term fatigue for the involved pilots is minimized.

REC 04/05. *It is recommended to the DGAC of Spain that they review the organization and procedures of the emergency medical service of the operator in the Canary Islands, in particular regarding activity periods scheduling, change of shifts between pilots, and* *provision of suitable resting places for the flight crews for both day and night shifts, with the intend of minimizing the possibility of long term fatigue*."

USA Event 1, 2004

Reference: National Transportation Safety Board. 2006. *Special Investigation Report on Emergency Medical Services Operations.* Special Investigation Report NTSB/SIR-06/01. Washington, DC.

Abstract: This report discusses safety issues identified during the Safety Board's special investigation of 55 emergency medical services (EMS) aircraft accidents that occurred in the United States between January 2002 and January 2005. Safety issues discussed in this report focus on less stringent requirements for EMS operations conducted without patients on board, a lack of aviation flight risk evaluation programs for EMS operations, a lack of consistent, comprehensive flight dispatch procedures for EMS operations, and no requirements to use technologies such as terrain awareness and warning systems to enhance EMS flight safety.

Dodge City, Kansas

On February 17, 2004, about 0256 central standard time, a Beech BE-B90 twin engine airplane, N777KU, operated by Ballard Aviation, Inc., was destroyed when it impacted terrain about 5 nautical miles (nm) northwest of Dodge City Regional Airport (DDC), Dodge City, Kansas. The pilot, flight nurse, and flight paramedic were killed. The 14 CFR Part 91 positioning flight departed Wichita Mid-Continental Airport (ITC), Wichita, Kansas, about 0210 and was en route to DDC. Night VMC prevailed. The flight was on an IFR flight plan, but the pilot cancelled the IFR flight plan about 37 miles east of DDC and proceeded under VFR.

The Safety Board's investigation revealed that the pilot had been awake for as long as 21 hours at the time of the accident. Additionally, the accident occurred 14.5 hours after his duty day began. Recorded radar data indicate that the airplane initiated a gradual, straight-line descent toward the airport but flew past the airport before descending into the ground. No communications from the airplane were made during this descent, which suggests that the pilot was fatigued.

The Safety Board determined that the probable cause of this accident was the pilot's failure to maintain clearance with terrain due to pilot fatigue (lack of sleep).

USA Event 2, 2010

NTSB Identification: CEN10MA367

Nonscheduled 14 CFR Part 135: Air Taxi & Commuter operating as air ambulance

Accident occurred Sunday, July 04, 2010 in Alpine, TX

Aircraft: CESSNA 421B

Injuries: 5 Fatal.

The airplane impacted terrain shortly after takeoff. The extended landing gear and flaps degraded the climb performance of the airplane. The pilot held an airline transport pilot certificate and had recent night flight experience. According to family members, the pilot normally slept from 2230 or 2300 to 0700; the accident occurred at 0015. Although the investigation was unable to determine how long the pilot had been awake before the accident or his sleep schedule in the three days prior to the accident, it is possible that the pilot was fatigued, as the accident occurred at a time when the pilot was normally asleep. The company did not have, and was not required to have guidance or a policy addressing fatigue management.

The National Transportation Safety Board determines the probable cause(s) of this accident as follows: The degraded performance of the airplane due to the pilot not properly setting the flaps and retracting the landing gear after takeoff. Contributing to the accident was the pilot’s fatigue.

USA Event 3, 2010

March 2010 crash of Hospital Wing helicopter, Brownsville Tennessee, 3 fatalities

Pilot was nearing the end of a 12-hour shift when the crash occurred. The NTSB findings said that fatigue may have been a contributing factor to his error in judgment. The helicopter flew into the "gust front" of an approaching thunderstorm, an area "prone to extreme low-level wind shear," the NTSB said.

"Based on these conditions, the helicopter likely encountered severe turbulence from which there was no possibility of recovery, particularly at low level," the NTSB stated.

"The pilot made a risky decision to attempt to outrun the storm in night conditions which would enable him to return the helicopter to its home base and end his shift there, rather than choosing the safer alternative of parking the helicopter in a secure area and exploring alternate transportation arrangements or waiting for the storm to pass and returning to base after sunrise when conditions improved," the report said.

"This decision-making error played an important causal role in this accident," the report said.

The Brownsville crash occurred just before dawn, a period the NTSB said "can be associated with degraded alertness." But the report said the NTSB was "unable to determine whether or to what degree fatigue contributed to the pilot's faulty decision to attempt to outrun the storm."

Appendix 2 – CAS Modeling

Introduction

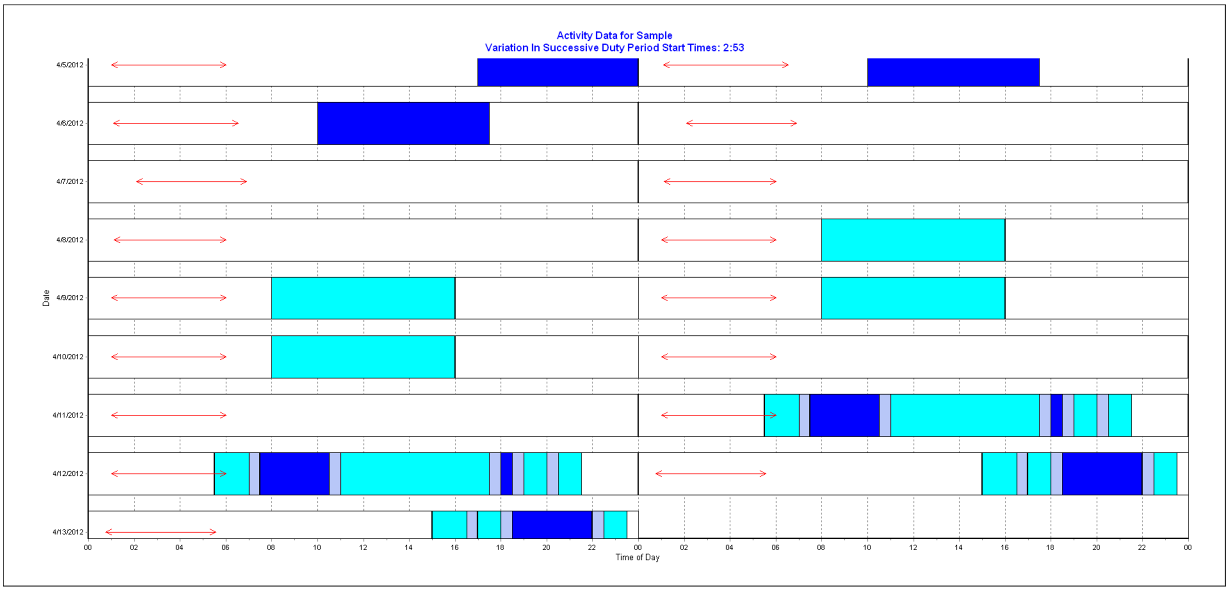
Circadian Technologies, Inc. has developed a Circadian Alertness Simulation (CAS) model that allows the assessment of fatigue risk based on sleep-wake patterns. Since the model includes an algorithm that predicts the most likely sleep pattern given a specific work pattern, it allows the evaluation of duty patterns for fatigue-related risk.

The impact of duty patterns on the alertness level and the resulting fatigue risks of an individual pilot are relatively uncertain and difficult to calculate analytically, especially if the individual sleep characteristics of the employee are not known. Here, the application of a simulation tool is particularly useful. Simulation models help us to understand when situations of extreme fatigue risk occur and why.

CAS – Model Concept

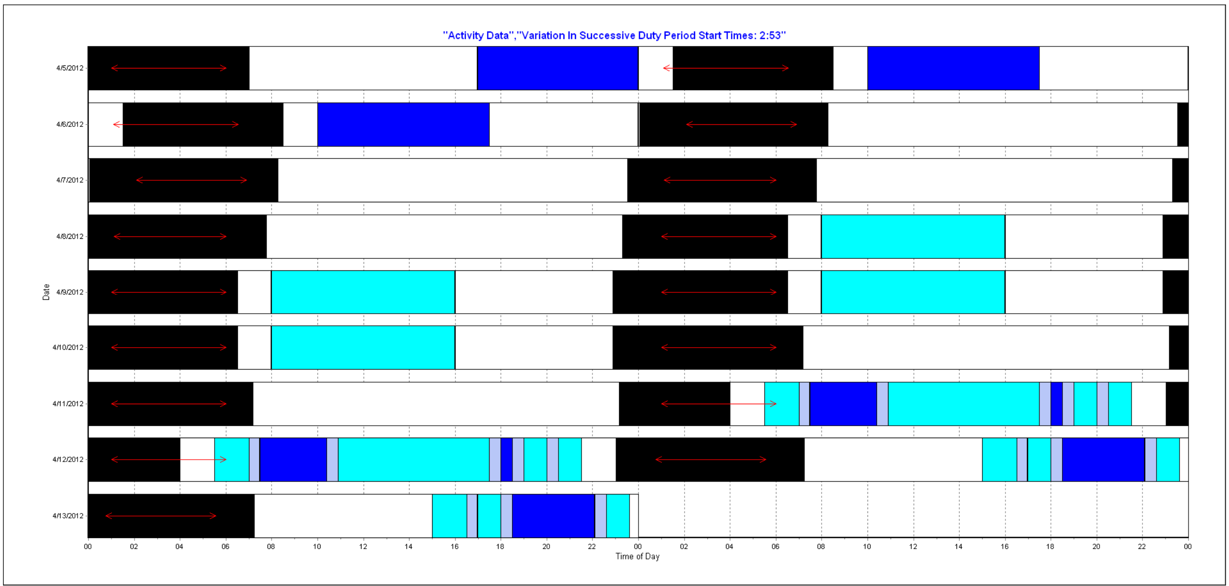
The CAS concept is based on the Three-Process Model of sleep regulation. A homeostatic component, a circadian component, and a sleep inertia component are combined to calculate an alertness curve. Figure 1 through 3 show the steps in the process between activity data (horizontal bars), the alertness calculation and the results output. Alertness at any specified point in time is entirely a function of all preceding data points. It therefore includes the effects of acute and cumulative fatigue.

Figure 1: Duty-Rest data without sleep



Based on the calculation of alertness, CAS5 predicts a sleep/wake pattern by triggering sleep when alertness reaches a certain lower threshold. The algorithm assumes sleep and calculates the subsequent data points assuming sleep until an upper wake-up threshold or an activity block (e.g., work, commuting) is reached. This capability was used for the model validation and it allows the analysis of data where there is no information about the person's actual sleep pattern (e.g. duty logs, time and attendance data, proposed work schedules).

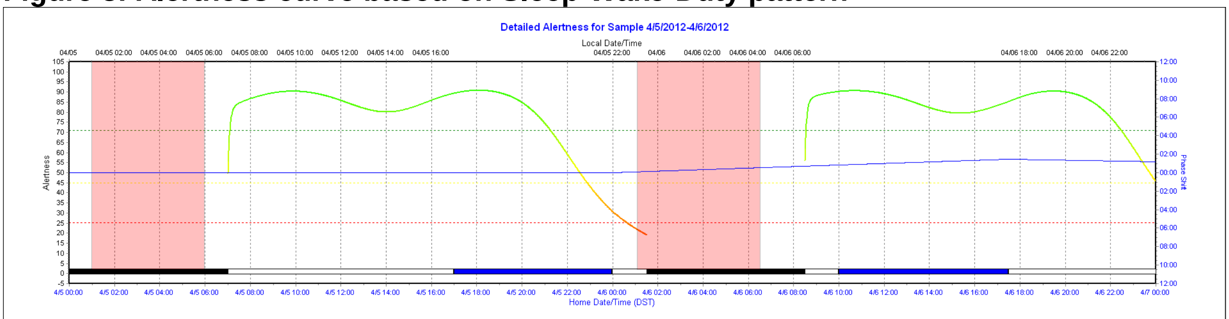
Figure 2: Duty-Rest data with sleep (black blocks)



After CAS5 has added sleep into the duty pattern, the model can now calculate an alertness value based on the three processes mentioned before:

- Alertness decreases during duty and non-sleep and increases during sleep (homeostatic component)
- Alertness fluctuates throughout the day (circadian component)
- Alertness is temporarily lowered after sleep depending on length of sleep and level of alertness on wake-up (sleep inertia component).

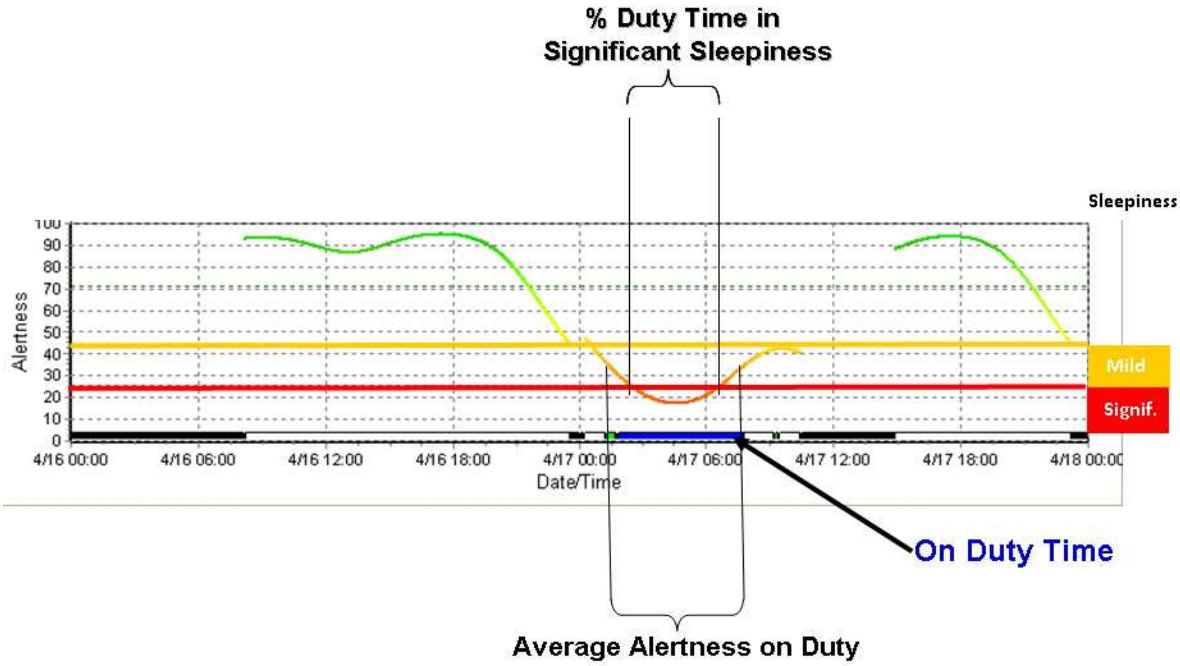
Figure 3: Alertness curve based on Sleep-Wake-Duty pattern



The CAS5 model can adjust various parameters of the model to reflect individual sleep profile properties (morning vs, evening type, long sleeper vs. short sleeper, habitual wake-up time, napping propensity, etc.). These adjustments affect the alertness calculation. However, at a planning stage there cannot be an individual profile since it is not known which specific person will work any of the simulated patterns.

The calculated alertness can then be used to analyze specific moments or periods in time, i.e. alertness at the end of a duty period, alertness during a scheduled flight/sector.

Figure 4: Sleepiness During a Specified Duty Pattern



Appendix 3 – EMS Operational Data

Operational data concerning the scale of EMS activities has been obtained from the following States:

- UK
- Poland
- Czech Republic
- Norway
- France

Some States did not have ready access to such data and provided Operator details to contact. In addition, publicly available websites were used to supplement the data search.

UK – source direct information from NAA

Data Required	**HEMS**	**Aeroplane EMS (AEMS)**
Number of missions per year in State (either typical year or last year)	17 500	550 with largest operator (at least another 1000 with other operators)
Number of flightcrew flying EMS in State	60 (line pilots)	13 – with largest operator
Number of aircraft flying EMS in State	30	6 - with largest operator
Number of operators flying EMS in State	6	32 (too many to give answers to the number of flight crew and aircraft)
Names of (main) operators		
Operator 1	Bond Air Services (C)	AirMed (C) Only specific AirMed figures given
Operator 2	Police Air Services (C)	CEGA (C)
Operator 3	Sloanes (C)	Loganair (C)
etc	Premiar (C)	Manhattan Jet Management (C)
If too many operators to list, a few of the larger ones is sufficient.		The UK has 32 operators who hold approval under their FTL scheme to conduct AEMS flights

- Solely EMS services (S), or
- Combined with Air Taxi or another type of operation (C)

Poland – source direct information from NAA

Data Required	**HEMS**	**Aeroplane EMS (AEMS)**
Number of missions per year in State (either typical year or last year)	8833 flights	653 flights
Number of flightcrew flying EMS in State	-	-
Number of aircraft flying EMS in State	23	2
Number of operators flying EMS in State	1	1
Names of (main) operators		
Operator 1	SP ZOZ Lotnicze Pogotowie Ratunkowe	SP ZOZ Lotnicze Pogotowie Ratunkowe

Czech Republic – source direct information from NAA

Data Required	**HEMS**	**Aeroplane EMS (AEMS)**
Number of missions per year in State (either typical year or last year)	Private information	Private information
Number of flightcrew flying EMS in State	Private information	Private information
Number of aircraft flying EMS in State	Approx. 16	Approx. 12
Number of operators flying EMS in State	3 (2 main ones below)	5
Names of (main) operators		
ALFA-HELICOPTER, s.r.o.	(C)	--
DSA, a.s.	(C)	(C)
SILESIA Air, s.r.o.	--	(C)
AEROTAXI, s.r.o.	--	(C)
AIR BOHEMIA, a.s.	--	(C)
AIR PRAGUE, s.r.o.	--	(C)
If too many operators to list, a few of the larger ones is sufficient.		

Norway – source direct information from NAA

N.B. HEMS data below just relates to missions and aircraft from Norsk Luftambulanse and the military, not Lufttransport which provides other services as well as EMS. Lufttransport transported just over 10,000 patients in 2007 (see http://www.lufttransport.no/) which is about half the amount carried by Norsk Luftambulanse.

Data Required	**HEMS**	**Aeroplane EMS (AEMS)**
Number of missions per year in State (either typical year or last year)	8579 (2009) + 2084 Military missions	8988 (2009)
Number of flightcrew flying EMS in State		
Number of aircraft flying EMS in State	11 +12 military	8
Number of operators flying EMS in State	2 +military	1
Names of (main) operators		
Operator 1	Lufttransport AS (C) http://www.lufttransport.no/	Lufttransport AS (C)
Operator 2	Norsk Luftambulanse AS (S) http://www.norskluftambulanse.no/forsiden/om-nla/kort-fortal/nla-as/	

France - source direct information from NAA

N.B. 1 Part of the service (be it medical transportation, under CAT rules, or HEMS, under part CAT+ part SPA rules) is provided by civil servants (“Protection civile”, “Gendarmerie”...)

The flights performed by these state services are not to comply with CAT nor Part SPA rules.

The vast majority of these flights is performed by the 39 helicopters owned by the “Protection civile”. In 2011, the “Protection civile” realized 11 800 emergency medical missions.

Yet, these missions are not limited to medical services (e.g. “search and rescue”, “police”, “fire protection”).

N.B. 2 Part of the service is provided by “private” helicopters, performed under OPS rules. The table below only refers to these helicopters, which, furthermore, are all hospital based.

Only HEMS data are readily available. Data for aeroplanes are far more difficult to gather as they may be conducted flights other than EMS.

Data Required	**HEMS**
Number of missions per year in State (either typical year or last year)	No statistics available. Yet, one of the most important operators indicates 4 500 missions with 10 helicopters (which is a little bit more than 1 mission/helicopter/day). On can conservatively infer from the number of “private” helicopters operated in France that there are more than 15 000 missions per year
Number of flightcrew flying EMS in State	No statistics available. Yet, given the number of hospital bases to which helicopters are dedicated and assuming 3 to 5 pilots for each base, that leads to at least 150 Full Time Equivalent
Number of aircraft flying EMS in State	Around 40
Number of operators flying EMS in State	Mainly 5
Names of (main) operators	
Operator 1	Groupe SAF (SAF Hélicoptères +Helicap) Around 10 hospital bases
Operator 2	Mont Blanc Helicoptères Around 10 hospital bases
Operator 3	INAER Around 10 hospital bases
Operator 4	Helicoptères de France 7 hospital bases
Operator NHV	Helicoptères de France 2 hospital bases
If too many operators to list, a few of the larger ones is sufficient.	

Notes

Most helicopters used for HEMS or ambulance fly between 400h and 600h. The helicopter that flew most last year flew 800h (Marseille hospital)

All operators mentioned above have different activities : CAT (touristic flights or Air Taxi), Specialised Operations. Some are also Type Rating Training Organisations. Yet, it does not mean that pilot switch from an activity to another activity. Once a pilot has begun its cycle, he is not supposed to change activity.

REGA in Switzerland – source www.rega.ch/en/about-us/in-brief.aspx and Annual Report

Key figures 2011

Total number of missions	**14,240**
- Missions by helicopter	10,797
- Missions by ambulance jet	1,052
- Other missions*	2,391
Number of patrons (in millions)	2.380
Number of employees**	319
Number of helicopter bases	13

* Other missions: transports by ambulance, organ transports by taxi, missions on behalf of the Swiss Alpine Club (SAC), Speleo-Secours, Redog etc.
** Full and part time employees as at December 2010 (Job Count)

Number of helicopters – 17

Number of ambulance jets - 3

N.B. Two other EMS providers in Switzerland are Air-Zermatt (www.air-zermatt.ch) and Air-Glaciers (www.air-glaciers.ch)

ANWB of Netherlands – source www.anwb-maa.nl

4200 HEMS flights a year

Largest provider of air ambulance EMS in Netherlands

6 helicopters (4 in active use, 2 in reserve)

27 pilots included in 36 staff members

Germany

Operator A

Data Required	HEMS	Aeroplane EMS (AEMS)
Number of missions per year (2011)	38,366 rescue missions, involving helicopter missions at 31 HEMS bases in Germany, Austria and Denmark	469
Number of pilots flying EMS	144 (160 in total including AEMS pilots)	16
Number of aircraft flying EMS	Over 50 helicopters	3
Number of patients attended/ transported per year		460

Operator B

Data Required	Aeroplane EMS (AEMS)
Number of missions per year (either typical year or last year)	551
Number of pilots flying EMS	27
Number of aircraft flying EMS	4
Number of patients attended/ transported per year	1426

Operator C

Data Required	HEMS
Number of missions per year (either typical year or last year)	46305
Number of pilots flying EMS	140
Number of aircraft flying EMS	48
Number of patients attended/ transported per year	42229 patients 17057 transported by helicopter

Appendix 4 – Example Shift Patterns, AEMS and HEMS

AEMS

Two distinct patterns of AEMS operations are seen in Europe.

1. Based on short call home standby – this is described in the presentation made to the EASA Stakeholder Meeting ("Flight Time Limitation (A)EMS, RMT.0346, RMT.0429 & RMT.0430" by Urs Nagel, Chairman AEMS Working Group, Head of Jet Operation and Chief Pilot, Swiss Air Ambulance). Further information has been obtained from NAAs and operators.
2. Based on short call airport/ base standby – described in information obtained from NAAs and operators (Norway, Poland, UK - Scotland).

Based on short call home standby

Home standby patterns:

- Operator 1 uses 11, 14.5 or 24 hour durations. 7 days of standbys/ duties and then 3-4 days' rest.
- Operator 2 uses 24 hour standbys with 5 days on, 2 days' rest.
- Operator 3 uses 24 hour standbys, 3 blocks of 6 consecutive days of standby separated by 3 blocks of 4 days' rest.
- In the UK most operators use 4, 6 or 8 hours standby typically starting at 0600 and rolling through the day (so 0600-1400, 1400-2200, 2200-0600 for example).
- In Spain – typical standby from 0800 to 2000.

Amount of home standby per year:

- Operator 1 for 2011 was 1375 standby hours per flight crew.
- UK home standby is 63 days averaged over the operators although contactable days are frequently used for air ambulance coverage and this would double this figure.
- Spain – around 180 home standby days per year.

Callout probability:

- Operator 1: flight crew are called out for 52% of standby days.
- Operator 2: 50-60%
- Operator 3: 45%
- In the UK the value is 25% for the largest air ambulance operator, but for those with mixed air taxi the value would be higher.
- In Spain: 30-60%

Typical call up times for duty are 60, 90 or 120 minutes.

In terms of flights and FDPs:

- Operator 1: FDPs can range from 4 hours covering domestic operations up to and in excess of 20 hours in order to reach New Zealand for example. The number of sectors within an FDP could vary from 1 to 6 typically and from 15 minutes up to 8 hours 15 minutes (maximum endurance of the AEMS aircraft). Operator 1 conducts some 70 Ultra Long Range (ULR) operations per year (N.B. ULR operations are ex-scope for this study).
- Operator 2: FDP durations 13-14 hours. Typically 4-6 sectors per FDP with sectors of 2-3 flight hours. No ULR operations.
- Operator 3: FDPs with typically 7 sectors of 1.5 to 2.0 hours. Some ULR operations.
- In the UK a typical sector would range from 1.5 hours (European only operations) up to 5 hours. Some of the multi-sector long haul FDPs may go up to 18 hours (beyond which it would be ULR).
- Spain – typical sectors of approximately 1.5 hours. No ULR.

Typical annual hours for AEMS pilots:

- Operator 1: 2011 values of 1180 duty hours and 427 flight (block) hours per flight crew.
- Operator 2: 800 duty hours (standby not counted as duty).
- Operator 3: 700 duty hours (standby not counted as duty).
- For UK operators a value of 1400 duty hours was provided.
- Spain – 1000 duty hours including training.

Based on short call airport/ base standby

Norway, Poland and Scotland make use of airport/ base standby for AEMS.

In Norway the shift pattern is more like that used for HEMS (see below):

- Shifts involve 24 hours a day at base, one week on, one week off, one week on, two or three weeks off.
- Active duty time up to 14 hours in any 24 hours.
- Average sector length 10 minutes to 2 hours, average about 35 minutes.

In Scotland, the AEMS day shift is based on airport standby - pilots cover consecutive shifts between 0700 hrs and 2100 hrs, normally at 30 minutes readiness in the crew rest room at the airport. The night shift is from home standby.

Typical annual hours for AEMS pilots involved in these shorter range operations:

- Norway 1800 duty hours.
- Poland 1900 duty hours.

HEMS

In this section examples of HEMS shift patterns from European States and operators are set out. HEMS is based on very short call from HEMS bases.

Switzerland

The FTL System in Switzerland is based on a flat rate recording regulation. Depending on the time of the "Airport Standby" period during a 24 hour-day a flat rate has to be recorded as "Duty Time". Some example schedules are given below:

				Flat Rate Duty Time over the year
a)	Fix Airport Standby Time:		0800 h to 1800 h	9.5 hours
	Max. 15 duty/ standby days per month			
b)	Or changing duty times as follows:			
	January – March:		0800 h to 1730 h	
	April – June:		0800 h to 1830 h	
	July – August:		0800 h to 1930 h	9.5 hours
	September – October:		0800 h to 1830 h	
	November – December:		0800 h to 1630 h	
	Max. 5 duty/ standby days per period and max 15 duty/ standby days per month			
c)	Or changing duty times as follows:			
	Summer:	01.04. – 31.10.	0800 h to 2200 h	
	Winter:	01.11. – 31.3.	0800 h to 2000 h	13 hours
	Max. 2 duty/ standby days per period and max 11 duty/ standby days per month			

If the Airport Standby Time is extended to 14 hours the recording flat duty time over the year has to be increased to 13 hours of flight duty time.

The duty pattern in c) is typically used at bases in the non-mountainous parts of Switzerland. Extensions into the night beyond 2200 are relatively common in such bases. The shorter daily duty times in a) and b) are typical of the HEMS bases serving the mountainous parts of Switzerland.

France

In France, duty hours and on-site standby can be organised in three different cycles:

1. Weekly cycle (calendar week from Monday to Sunday): comprising 5 on site standbys, by day only (no night standby) between periodic rests (periodic rest being : 24h+rest generated by previous on site standby)). *Eg. On site standbys from Monday to Friday of week 1 then 2 days of rest (Saturday and Sunday), then 2 days of rest on week 2 (Monday and Tuesday) and 5 days of on site standbys from Wednesday to Sunday.*

2. 18 weeks cycle : comprising on site standbys, by day only (no night standby), limited to 12 consecutive days between periodic rests.

3. 12 weeks cycle: comprising on site standbys, by day or by night, limited to 7 consecutive on site standbys, between periodic rests. *Between two periodic rest, the on-site standbys shall be only be day or only by night (no mixing).*

Periodic rest

- Cycle 1 : two consecutive days (0h-24h) after 5 consecutive days of planned on site standbys
- Cycle 2 : 6 consecutive days (0h-24h) after 12 consecutive days of on site standby
- Cycle 3 : 7 consecutive days (0h-24h) after 7 consecutive days of on site standby

Duration of duties :

- Daily limit for on site standby :

-12h maximum for flight technical crew members (including flight crew)

- Additional limits:

Cycle 1 : 12h per 24h

Cycle 2 : 12h per 24h

Cycle 3 : 14h per 24h

UK

HEMS shifts are daytime only, normally of 10 hours duty time, but crew may be up to 12 hours at the HEMS base. These are usually worked as a 4 on/ 4 off pattern with a 60 hour limit per 7 consecutive days.

Norway

Operators operate 24 hours a day at base, 1 week on/ 2 week off/ 1 week on/ 3 weeks off. Maximum active duty per 24 hours period is 14 hours during summer and 13 hours during winter.

Czech Republic

There are two types of bases:

- 24hrs operations – arranged around 2 shifts of 12 hours each
- VFR daytime - 1 shift covering period from sunrise to sunset

Poland

Again there are two types of bases:

- 24hrs operations – arranged around 2 shifts of 12 hours each, 0700 to 1900 and 1900 to 0700.
- Daytime from 0700 to 2300 arranged as two shifts on 0700 to 1500 and 1500 to 2300.

Operator 1

The day shift starts at 06.30, handover is at 07.00, the crew work through to 19.00, with handover until 19.15 (12.75 hours at base).

The night shift starts at 18.30, handover at 19.00, work until 07.00, handover until 07.15 (12.75 hours at base).

A shift can stretch to 15.5 hours if there is a flight at the end of shift. However this is only permitted if the pilot has had a break of at least 2 consecutive hours that day.

3 consecutive day or 3 night shifts typically. Minimum of 3 days off, maximum of 6.

Typical roster would be 3 days on, 3-6 off, 3 nights on 3-6 off. Operator does not roster day and night in consecutive shifts.

Operator does not allow more than 1.5 hours travel before a shift.

Operations from dusk until dawn are conducted using Night Vision Goggles (NVG).

Typically 5-6 calls per day.

Annual duty including training = 1710 hrs (121 shifts)
Annual flight hrs = 120 hrs

FTL only allows for a reduced rest period of 8 hrs and 30 min. If rest is reduced to less than 10 hrs the maximum commute time is 15 minutes, if rest is reduced to 9hrs and 30 min or less, sleeping at the base is obligatory.

Operator 2

Typical roster would be 3-4 days on, 2-3 days off.

Minimum of 24 hours rest between a series of days and nights.

Annual duty = 1900 hrs (160 duties per year)
Annual flight hrs = 120 hrs
Minimum rest of 9 hours provided that suitable accommodation is available at the HEMS base.

Operator 3

The bases are either on day-duty or 24-hour-duty.

On 24-hour-bases two 12-hour-shifts are worked. During daytime there is one pilot and one HEMS Crew Member, during night-times there are two pilots. There are eight pilots per base. Usually pilots work 7 days and have 7 days off. During the wintertime (longer night time), the day pilot stays longer and/or one of the night pilots begins earlier and works 14 hours.

Day-duty means starting work at sunrise – 30 minutes (earliest 6:30 AM) until sunset + 15 minutes. On some bases in summertime sunset can be as late as 21:45. So the day begins at 6:30 AM and ends at 10:00 PM, which is 15.5 hours duration. There are three pilots per base. In summertime a pilot works a maximum of 4 days and has at least 2 days and normally 7 days off (except if a colleague has vacation).

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