



FLIGHT
SAFETY
FOUNDATION



Helicopter Emergency Medical Services (HEMS) Industry Risk Profile



About the HEMS Industry Risk Profile

An industry risk profile (IRP) presents a strategic risk picture of the key risk issues that face a nominated sector within an industry at a given point in time. An IRP contains the definition of the context of the industry and the context of the risk profile, identification of risk issues, their associated impacts, the risk rating and presents proposed high level treatment strategies the associated residual risk and the risk ranking. An IRP provides the platform for industry to develop a detailed risk reduction plan, outlining the agreed risk reduction measures, timelines for implementation and accountabilities.

About the Flight Safety Foundation

www.flightsafety.org



Flight Safety Foundation is an independent, nonprofit, international organization engaged in research, auditing, education, advocacy and publishing to improve aviation safety.

The Foundation's mission is to pursue the continuous improvement of global aviation safety and the prevention of accidents.

The Foundation's objectives are to:

- Pursue the active involvement and participation of the diverse elements of global professional aviation;
- Anticipate, identify and analyze global aviation safety issues and set priorities;
- Communicate effectively about aviation safety; and,
- Be a catalyst for action and the adoption of best aviation safety practices.

About Aerosafe Risk Management

www.aerosafe.com.au



The Aerosafe Group is a global aviation safety and risk management company, which provides risk management services, support and tailored solutions to aviation companies around the world. With offices in North America, Australia, India, China and New Zealand, Aerosafe is recognized as an international leader in this important field. The Aerosafe Group has been invited to set standards with aviation regulators, industry groups and companies alike and operates at the operational, enterprise, sector and industry levels in the application of modern risk management practices.

About the Foundation of Air Medical Research & Education

www.fareonline.org



The Foundation for Air Medical Research & Education (FARE) was established in 2001 to support charitable, scientific and educational programs and other initiatives, including outreach to the public, for the air medical and critical care medical transport community. Everything we do is for the patients we serve. The Foundation for Air-Medical Research & Education (FARE) is a non profit 501 (c) (3) charity serving the international air-medical community through:

- supporting essential air-medical and critical-care transport research and education initiatives;
- sponsoring educational opportunities and scholarships for air medical professionals;
- advancing patient and aviation safety;
- funding grants that result in important clinical, safety and operational research;
- publishing award-winning public policy literature that helps air-medical practitioners keep abreast of cutting-edge research and technologies;
- providing financial support to families in crisis after an air medical accident;
- informing the public about air medical and critical-care transport;
- convening worldwide forums for industry leaders to discuss the global initiatives, challenges and opportunities for air-medical and critical care transport systems.

Helicopter Emergency Medical Services (HEMS) Industry Risk Profile



APRIL 2009

Published by:

Flight Safety Foundation

Developed by:

Aerosafe Risk Management

Developed for:

HEMS Industry, United States of America

Printed & Distributed by:

Foundation of Air Medical Research & Education

© Copyright Aerosafe Risk Management Inc, April 2009

This document has been developed by Aerosafe Risk Management Inc (Aerosafe) in response to a specific body of work that was commissioned and funded by industry. The background intellectual property expressed through the methodologies, models, copyright, patent and trade secrets used to produce the Industry Risk Profile remains the property of Aerosafe.

Aerosafe grants the Flight Safety Foundation an exclusive, world-wide, royalty-free licence to publish, release and distribute the IRP to industry. This licence includes the ability for Flight Safety Foundation to sub-license printing and distribution of hard copy prints of the IRP. The intellectual property expressed in this copyright information is governed by the contract between Aerosafe and Bell Helicopter Textron and the subsequent licensing agreement with the Flight Safety Foundation.

While the author and publisher have taken reasonable precaution and have made reasonable efforts to ensure accuracy of material contained in this report, Aerosafe does not guarantee that this publication is without flaw of any kind. The authors and publisher makes no warranties, express or implied, with respect to any of the material contained herein and therefore disclaims all liability and responsibility for errors, loss, damage or other consequences which may arise from relying on information in this publication.

Table of Contents

INTRODUCTION:	Managing Risk in the HEMS Industry
Foreword	7
How to use the HEMS Industry Risk Profile (IRP)	8
Next steps: Completing the risk management process.	9
<hr/>	
PART 1:	Context of the Industry Risk Profile
Background	12
Purpose	13
Objectives	14
Assumptions	15
Limitations	16
Risk Criteria	16
Depth of Analysis	17
Methodology: Risk Management Process.	19
Methodology: Industry Risk Profile Model.	20
<hr/>	
PART 2:	Summation of Results
Summation of results risk profile.	24
Risk reduction plan	29
<hr/>	
PART 3:	Industry Risk Profile Tabulated Data
<hr/>	
PART 4:	Supporting Appendices
A. HEMS IRP stakeholder and distribution list	59
B. Supporting documentation	60
C. Abbreviations.	61
D. Project contact details and project acknowledgements	62

INTRODUCTION

Foreword

The Helicopter Emergency Medical Services (HEMS) industry is to be congratulated for taking a leadership role in developing an industry approach to the management of risk in the vital area of air medical transportation.

Aviation has a long and proud history of addressing and managing risk, but the very nature of HEMS calls for new and innovative ways of ensuring that risk, in all its forms, is subjected to a rigorous process for the management of risk at all levels of the industry.

Risk is all about understanding the effect of uncertainty on organizational or in the case of the HEMS industry, the industry's objectives. This Industry Risk Profile is the starting point on the journey of addressing the objectives of HEMS participants, large and small, and the risks that they must manage in order to maximize their opportunities whilst minimizing threats.

The risk management process utilized in the HEMS Industry Risk Profile has many years of practical application throughout the world by all manner of industries including the full gamut of military and civilian aviation organizations. The adoption of the process set out in ISO FDIS 31000, which is derived from the long standing and well tested process of AS/NZS 4360:2004 is to be applauded.

Having received this Industry Risk Profile the challenge for the HEMS industry is to take the next step of developing their own unique risk framework to integrate the process into the management systems at all levels of the industry. This will allow those governing and leading the industry to fully understand the risks that must be effectively and efficiently managed if all the objectives of the industry are to be achieved.

This document is an excellent starting point and I congratulate those who commissioned this independent assessment, the authors, those who participated in its development and revision and the Flight Safety Foundation for their unwavering commitment to safety and the willingness to take on the role of custodian of the HEMS Industry Risk Profile.



Kevin W Knight AM
CPRM, Hon FRMIA, FIRM (UK), LMRMIA
Chairman
International Standards Organization (ISO) Working Group on Risk Management

How to use the HEMS Industry Risk Profile

The HEMS IRP was developed for use at the national level by industry leaders, standard setters, industry associations, industry bodies and groups that have the ability to develop, resource and implement voluntary industry wide change initiatives to reduce the risk profile of the HEMS industry. The risk information presented in the HEMS IRP presents and assesses the identified risks and highlights appropriate performance based risk treatments or risk reduction measures.

Many of the treatments transcend the sphere of influence of any one individual organization such as an individual Air Medical Program or Operator and must therefore be managed across traditional divides. While the actions proposed are largely voluntary, it is accepted that some issues raised in the IRP may only be resolved by regulatory or mandated action by the customers that engage or utilize HEMS.

The HEMS IRP does not identify the risks of any particular individual or group of Air Medical companies rather it presents the systematic risks inherent in the entire industry landscape that ultimately have the potential to induce risk at many levels of the industry.

Developing Risk Reduction Plan

This profile is based upon the assumption that there are four key ways of bringing change to the industry;

- Legislative change by Congress
- Regulatory change by the aviation, medical or state regulators
- Mandated change driven by the Customers
- Voluntary change by the industry

The HEMS IRP predominately focuses on the voluntary change that can be made by industry, yet the IRP recognizes the intersection of the other three areas and can be used as an evidence based tool to inform change in these areas as well.

The true value of an industry level risk profile is not gained until an action plan is derived and committed. The Industry groups listed at Annex A, upon receiving the HEMS IRP, also receive an open invitation to participate in an industry wide effort to develop and implement the Risk Reduction Plan.

The HEMS Industry Risk Reduction Action Plan will outline the detailed actions, tasks and activities designed to reduce risk. Each individual strategy will vary in its effectiveness, however when combined, the cumulative effect will be an overall reduction in the industry profile. The responsibility for the management and implementation of each treatment is assigned to an entity, association or organization. This accountability or responsibility for implementation is also indicated on the HEMS Industry Risk Reduction Action Plan.

The HEMS IRP will change over time

Risk management is an iterative process. It is acknowledged that the HEMS IRP is dynamic and will change over time to reflect risk changes in the industry. This IRP provides a snapshot of the risk profile of the HEMS industry at the time of development (January – April 2009) based upon an analysis of the information available and accessed. As further data or information becomes available the risk profile can be updated. In addition to this, as risk reduction measures are completed the risk profile will reduce and the residual risk rating will be realized. It is anticipated that the HEMS IRP will be revisited every six months specifically with the intent of monitoring progress of risk reduction measures committed to by industry.

Next Steps: Completing the risk management process

The profile of the HEMS industry is dynamic. In order to provide confidence that the risks identified in this IRP are being effectively addressed and managed a plan for assurance monitoring has been outlined. The key focus is the identification, allocation and implementation of a detailed risk reduction plan and the associated accountabilities to ensure action or to provide assurance that action is already in progress. Timelines and activities are subject to industry participation.

ACTIVITY	DETAILS	TIMELINE
Launch of HEMS IRP to industry	Launch coordinated by Flight Safety Foundation as industry custodian of the IRP. Technical briefing provided to the media. Registered downloadable electronic files available at www.flightsafety.org	April 20, 2009
Release and distribution of HEMS IRP by FARE	FARE has approved a grant to fund the printing and distribution of copies of the HEMS IRP to the industry distribution list outlined in Annex A. Additional copies available through FARE. www.fareonline.org	April 30, 2009
Development of industry response including submission of current or proposed industry risk reduction measures	An inclusive invitation is made for the full spectrum of industry stakeholders to work through the HEMS IRP and develop an individual submission of those industry level risk treatment strategies that are either already being undertaken or are willing to be undertaken, resourced and implemented by the submitting organization. A step by step guide to aide the preparation of submissions can be downloaded from the Flight Safety Foundation website.	May 1, 2009 – July 15, 2009.
Risk reduction planning conference	One authorized representative from each stakeholder group will be invited to the inaugural risk reduction planning conference where risk reduction strategies will be agreed to and prepared as the HEMS Industry Risk Reduction Action Plan for presentation to industry.	August 13-14, 2009
Finalization of the HEMS Industry Risk Reduction Action Plan	A small group of representatives from the industry to review the proposed HEMS Industry Risk Reduction Action Plan. An assurance regime for monitoring and reporting progress will be established.	August 25, 2009
Release of HEMS Industry Risk Reduction Plan	Industry Risk Reduction Plan formally released to industry.	August 31, 2009
SIX MONTHLY CYCLE	Check point reporting	Those industry stakeholders who have taken responsibility for an individual risk treatment strategy will provide a status report on their progress against the HEMS Risk Reduction Action Plan. This information will be compiled and a report card prepared for public release.
	Update risk reduction plan	Upon receiving the progress report from the above activity, the HEMS Industry Risk Reduction Action Plan will be updated and prepared for presentation to the risk monitoring and assurance group.
	Report to industry on progress	A formal progress report will be released to industry.
Update HEMS IRP Continuous follow up until profile is reduced to an acceptable level	As the context of the industry changes, appropriate triggers for a full update or overhaul of the HEMS IRP will be determined. These triggers may include significant progress in completion of the risk reduction measures, emergence of significant new risks, context of the industry shifts significantly or the accident profile of the industry is not visibility decreased. The Industry to continue on the six monthly cycles for the formal management of risk until an acceptable risk profile is achieved.	As determined Ongoing

PART 1

Context of the Industry Risk Profile

Background

Air medical transportation has become a key component of healthcare in many countries throughout the world. Air medical transport services are particularly important in large countries where traveling times to hospital care may be excessive by surface vehicles or where remote communities might otherwise be deprived of the required level of healthcare service. In addition to acting as an air ambulance service, aircraft are particularly important in times of national emergency or to provide support to rescue and other emergency services.

While air medical services may at first glance appear expensive compared to traditional ground ambulances, an examination of the cost structures and benefits on an annual system wide basis demonstrates its cost effectiveness. In many cases, air medical services may be the only option and the difference between life and death for the patient. In other circumstances timely, appropriate initial care may provide ongoing reduced cost over the lifetime of the patient. Integrated air medical resources are therefore an essential component of contemporary Emergency Medical Services (EMS) systems.

Helicopter Emergency Medical Services (HEMS) and EMS services are provided in the United States through a multitude of relationships involving Part 135 air carriers, public entities, hospitals and EMS providers, by both profit and not-for-profit organizations. It is estimated by the Association of Air Medical Services (AAMS) that helicopters transport 400,000 patients annually in the United States.

As the medical benefits of rapid transport by air medical providers have become more recognized, there has been ongoing growth and expansion since the 1970's with HEMS operations beginning in 1972. Recent data shows that since 1995 the number of helicopters used in the EMS industry increased by approximately 130% to 2008. Prior to 1995, there was a similar doubling of the number of helicopters being utilized within the HEMS Industry over a ten year period.

Current Safety Concerns

The National Transportation Safety Board (NTSB) notes that there were 55 EMS related accidents (fatal and non-fatal) that occurred between January 2002 and January 2005 and that many of them could have been prevented with simple corrective actions including: oversight, flight risk evaluations, improved dispatch procedures and the incorporation of available technologies. In the last twelve months the NTSB investigated an additional nine fatal EMS accidents which killed 35 people. The Board has also added helicopter EMS safety to its "Most Wanted List" of transport safety improvements.

The recent increase in the fatal accidents has created general concern by the Air Operators, the Air Medical Programs and the broader public community. The HEMS industry is actively working on many fronts in an attempt to identify those issues that have led to these avoidable and, hence, unacceptable accidents. Parallel to these industry driven initiatives, the government also committed to proactively examining the causes of the high accident profile. This culminated in the February 2009 NTSB Public Forum regarding Operational Safety in the Helicopter EMS Industry and an agreement by the industry that a "call to action is required".

Over recent years, many industries have recognized that effective management of risk allows regulators, organizations and operators to target resources strategically to meet both governance obligations, commercial objectives and improve levels of safety.

Risk management takes place at multiple levels. This Industry Risk Profile (IRP) provides at a strategic level, a description of risk for the HEMS industry as a whole. The risk management process allows

¹

Ira Blumen, An Analysis of HEMS Accidents and Accident Rates, 2009 NTSB Hearings into the EMS Industry, 2009

operators within the industry to develop individual risk frameworks and risk management plans. It can also assist Regulators to develop regulatory solutions which achieve the statutory safety outcomes while allowing individual operators the flexibility to effectively meet their corporate goals.

An Industry Risk Profile can also be a “call to action” for all parties involved in the industry. It sets out in a clear and concise document both the problems and, more importantly, the solutions that are available to reduce the inherent risk profile.

Commission to Develop the HEMS Industry Risk Profile

As part of the industry’s commitment to the efforts of the International Helicopter Safety Team (IHST) and the achievement of the published goal of an 80% reduction in global helicopter accidents in the next 10 years, the industry commissioned and funded the development of the HEMS IRP.

The IRP methodology utilized is usually applied by industry regulators or those industry sectors that have been delegated self administration by the regulator. This innovative step for the HEMS industry to adopt and utilize this methodology demonstrated a level of maturity that is not common in industries under the public and regulatory spotlight.

The industry recognized the need for a holistic and broader view of the systemic strategic risks that are inherent in the current national HEMS model. It was realized that a ‘different’ approach was needed and there was great value in an industry wide risk assessment that would provide a platform for the coordination of nation wide initiatives to aggressively reduce the risk profile and the associated negative trend in safety.

Purpose

The purpose of the HEMS IRP is to identify the latent and systemic issues inherent in the current national HEMS structure and model that have the potential to induce operational or safety risk in order to proactively address issues that have not yet been subject to attention.

Based on the use of the Reason accident causation model, and the accepted hierarchy of layers, barriers and defenses that exist in any organizational or industry level system, the HEMS IRP focuses on the systemic issues that exist at the strategic level of the HEMS Industry.

Objectives

1. Identify the systemic risks inherent in the current HEMS structure that may induce operational, safety or organizational risks taking the industry wide assessment beyond traditional analysis of historical data into a proactive, risk based approach.
2. Utilize a data driven, evidence based approach that leverages off the array of current and past investigations, reviews, studies, papers, analysis and knowledge publicly available on the topic of HEMS safety. These efforts have been harnessed and utilized as risk identification inputs into the HEMS IRP.
3. Provide the strategic view of industry risks in one document that can be commonly understood by all stakeholders (aviation, medical, EMS, industry, regulatory, customer and government) and used as a focal point for defining the accountability for change.
4. Utilize an accepted methodology (risk management) that is used broadly in both corporate America and the international aviation community allowing a common language to be adopted that is familiar to the industry and regulator alike.
5. Allow industry a tool to effectively rank and prioritize efforts for risk reduction, and where the risks are unable to be controlled by the industry itself, the IRP provides a platform for the transfer or referral of risk to the appropriate accountable body
6. Allow the alignment of accountability, responsibility and resourcing for the management and reduction of risk at multiple levels of the industry.
7. Provide industry with opportunity to develop alternate solutions that will achieve the reduction in risk that is expected or even demanded by the government and the community
8. To propose risk treatment strategies that are performance or outcome based solutions rather than the traditional prescriptive recommendations that often come out of studies, reviews or investigations
9. A platform for the coordinated management of risks across the Industry - Prioritize the identified risks in order of seriousness and to provide a general sense of urgency for the treatment of risks to meet the industry's duty of care obligations
10. Assist the HEMS Industry in meeting recommendations from the National Transportation Safety Board (NTSB)
11. Provide an up-to-date formal document that can be used by the HEMS industry to track and monitor implementation of risk treatment and ultimately provide effective oversight and governance of the Industry
12. Provide Industry Associations with a vehicle to manage governance, compliance and liability issues by demonstrating a proactive and risk based approach to change
13. Provide a framework within which individual operators can develop their own organizational risk profiles and risk management plans to effectively position or respond to industry level risks

Assumptions

This Industry Risk Profile was developed within the context of the following assumptions:

1. Citizens of the United States of America have the right to expect a reasonable standard of emergency medical transportation regardless of their location within the country.
2. The current accident and fatality rate in HEMS transport is unacceptable to Industry as a whole, individual operators, regulators and the public.
3. The information provided to Aerosafe Risk Management by the HEMS Industry for the purposes of developing this industry risk profile is complete, true and correct
4. Matters of concern raised in the consultation process, which could not be substantiated or verified by other risk identification sources, were considered as perceived risk for the purposes of the profile.
5. The Industry Risk Profile will be provided to stakeholders and interested parties for use in strategic planning, business planning, reporting and other processes to ensure appropriate monitoring and oversight.
6. Statements made during the NTSB hearing (February 2009) were regarded as stakeholder interviews and those interviewed included in the stakeholder list.
7. Formal position papers, documents and resources lodged on the public docket for the NTSB hearing were used in the HEMS IRP literature review and included in the documentation list.
8. Formal position papers by AMOA, AAMS and HAI were taken as a representative view of the members it represents and this data input source was used in the HEMS IRP development process – follow on discussions and surveys with individuals from these organizations augmented this initial data input source.
9. The definition of the HEMS Industry is taken to mean the full spectrum of stakeholders involved in HEMS activities at all levels and is not simply the part 135 operators.
10. That all invited industry stakeholders will actively participate in the development of the HEMS Risk Reduction Work Plan and that this plan will acknowledge the many current initiatives already underway and in progress.
11. The Aerosafe Risk Management risk profiling model and methodologies revealed to the HEMS Industry will not be used, modified or reproduced without formal consent.
12. Addresses HEMS operations in the United States of America.

Limitations

This Industry Risk Profile is subject to the following limitations:

1. The Industry Risk Profile is confined to rotary wing operations. However, many of the risks identified will be common to, and useful in, the development of a broader risk profile for EMS operations. This profile excludes fixed wing air medical operations.
2. The IRP specifically addresses both commercial for-profit and not-for-profit operations which operate under Part 135 of the Federal Aviation Regulations.
3. This IRP does not cover the full spectrum of risk and other issues associated with public use HEMS operators (County and Police) which conduct business as private category operations under Part 91 of the Federal Aviation Regulations.
4. Not every stakeholder in the industry was subject to an individual interview in preparing the HEMS IRP.
5. During the consultation phase (review and interaction with the industry on the draft risk profile made available from February 12, 2009 to April 10, 2009) a large degree of fragmentation and differing understanding of the risk management process was noted.
6. The current environment and the sensitive debate around proposed legislative change affected the ability of some stakeholder groups to effectively participate in this process.
7. The risk treatment strategies listed in the HEMS IRP have not been agreed or allocated to the industry at the time of release.
8. The HEMS Risk Reduction work plan is under development and was not sufficiently developed by industry to release concurrently with the release of the HEMS IRP.
9. The current context and structure of the HEMS industry does not lend itself to a collaboration, ready agreement or a collective responses to risk.
10. The existing regulatory regimes across aviation, healthcare and EMS are not visibly integrated.
11. The HEMS IRP does not claim to have utilized every data source available to the industry. However a rigorous and comprehensive process has been used and as a result, an 85% confidence rating in the integrity of the data and associated profile is acknowledged.
12. The industry have actively and visibly communicated the desire for voluntary change, yet the ability for the industry to implement such change has not been evaluated or assessed.

Risk Criteria

The following criteria were developed to allow the evaluation and quantification of risks. Since risk has two components, likelihood and consequence, consideration was given to issues including:

- The positions of Association of Air Medical Services, Helicopter Association International and the Air Medical Operators Association, as stated in their paper to the NTSB Hearing, February 2009, that they "maintain a position of zero tolerance for accidents in the air medical industry." It is implied by this criteria that all reasonable measures will be taken to ensure that accidents do not happen and that risks are appropriately managed.
- A positive perception of the Industry by the public, families of the deceased, the media, politicians, legislatures, the Regulators and investigators is vital to the continued viability of the industry.
- A person/patient transported by a HEMS operator has the right to the same protections as any other member of the public traveling by air transport.
- Where the person/patient transported by a HEMS operator does not have a choice of carrier, a

higher protection or duty of care than that of the travelling public exists.

- While the safety of the patient is the most important factor to be considered, the safety of the medical personnel and other crew on board is also critically important.
- Where emerging technologies will mitigate risk at reasonable costs, they should be considered as optional adjuncts for operational safety.

Depth of Analysis

The following is a synopsis of the depth of analysis used to develop the HEMS Industry Risk Profile:

- **Context of the profile:** This Industry Risk Profile has been developed in the context of providing a detailed, data-driven analysis of the issues that affect the key objectives of the HEMS Industry. By defining and focusing on the HEMS Industry as a single entity, this profile can provide insight into the various elements of the Industry and how the elements interact to achieve Industry objectives. The risk profile will be developed to cover the next ten year period commencing in January 2009.
- **Literature review of publicly available documentation:** A comprehensive review of a large and varied range of publicly available documents published over the past two decades was conducted. This review contributed to the development of an understanding of the HEMS Industry from a historical perspective. The documentation review also provided the basis on which key industry risk issues were identified. A total of 267 Documents were reviewed during the document review process.
- **Stakeholder Analysis:** A comprehensive stakeholder analysis was conducted in order to identify the stakeholders within the Industry that could provide the insight into the operations, status and issues impacting the HEMS Industry. The analysis identified stakeholders from public, private and government organizations, enabling the project team to conduct interviews with key industry decision makers. A total of 161 stakeholders were identified during the initial stakeholder analysis process and an additional 21 stakeholders were identified in the review of the draft HEMS IRP.
- **Stakeholder Interviews:** Once the industry stakeholders had been identified, several decision makers and opinion leaders within the industry were personally interviewed in order to collect a wide variety of information, both from the medical arena and the aviation industry. During these interviews a significant number of industry risk issues were identified.
- **Note:** In line with the risk management process, the identified stakeholders were examined and it was determined whether formal communication, consultation or interaction was needed at the identification, review or solution development phase of work. As a matter of clarification, the stakeholder analysis determined the best match of risk identification method to each stakeholder group. As a result, formal interviews or surveys were not conducted on every stakeholder. Alternate risk identification methods were exercised on those remaining stakeholders.
- **Collection of Risk Issues:** A total of 1280 risk issues were identified from the initial risk identification sources. During the review of the draft HEMS IRP, and additional 200+ issues were identified and cross mapped to the risks listed in the HEMS IRP. The tabulated data was updated with these additional inputs. The main additions or amendments were in the risk impacts, a minor adjustment in the risk calculation and some additional proposed risk treatment strategies. Culminating in the presentation of 26 industry level risks worthy of attention, the HEMS IRP was finalized within the specific context outlined above.
- **Risk Identification:** This risk profiling methodology allows for a greater level of depth in the identification, selection and analysis of the risk information used in the risk identification step. In general available risk data consists primarily of qualitative information. As an attempt to minimize subjectivity, fourteen separate risk identification methods were used and the data collected from these sources layered and cross mapped for themes and grouping against the IRP model.

Rationale for Analysis Methodology

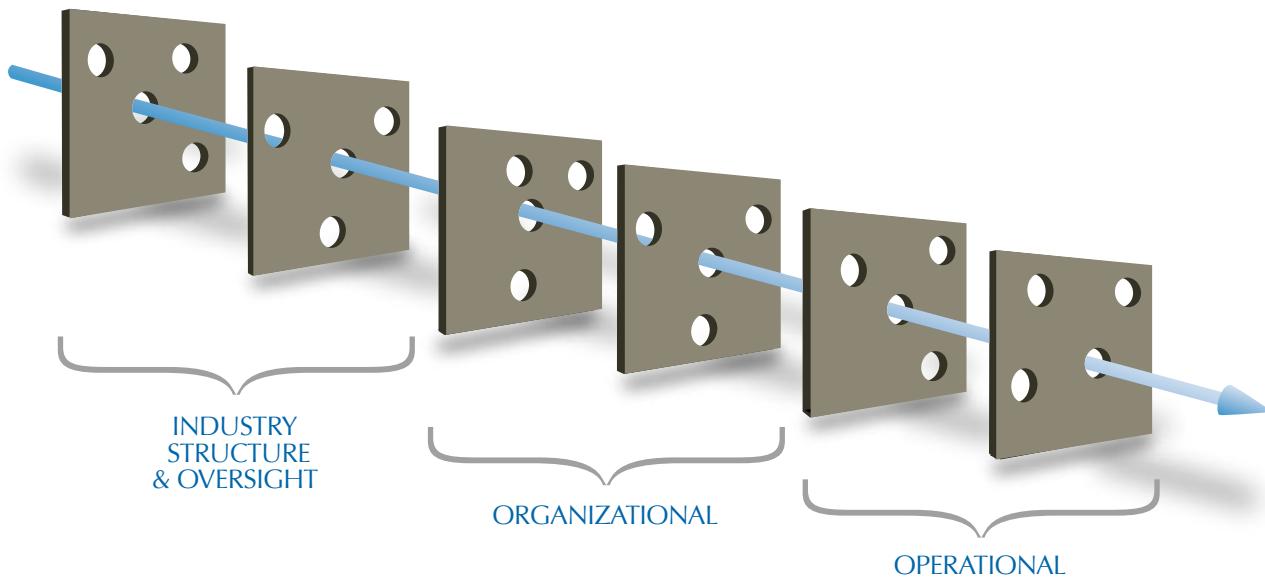
The HEMS Industry is committed to providing timely, quality patient transportation throughout the United States. This objective carries significant challenges considering the large landmass involved, the diverse terrain, weather conditions encountered and the complexity of the business and regulatory models. Solutions which are appropriate and effective in highly urbanized areas may not work in rural and isolated environments. Given such variability in mission profiles, options which ensure overall system safety, while allowing local flexibility, require evaluation.

In recent years, developments such as the Reason Model have been used in the analysis of accidents and incidents in the aviation industry. Reason identified that accidents occur when there are multiple failures in the various levels of defenses - "when the holes line up". This model can also be used to design safety systems by identifying "defenses in depth". Analysis of "defenses in depth" allows safety experts to identify potential points of failure and minimize the possibility of total system failure. Risk analysis (identification and assessment) is the tool that identifies potential points of failure in the Reason Model.

Defenses in Depth and the Relationship with Risk Reduction

A systems approach also allows a structured consideration of possible defenses which can be layered to provide safe outcomes. A systems approach also has the further advantage of identifying the defenses which are necessary for overall system integrity. In locations where specific tools for risk mitigation prove ineffective or inappropriate, alternatives can be derived to manage the risk. A hierarchy of defenses (legislative, regulatory, mandated customer driven change and voluntary change by industry), which link directly to the risk treatment or risk reduction strategies, will be developed and presented in order of outcome effectiveness.

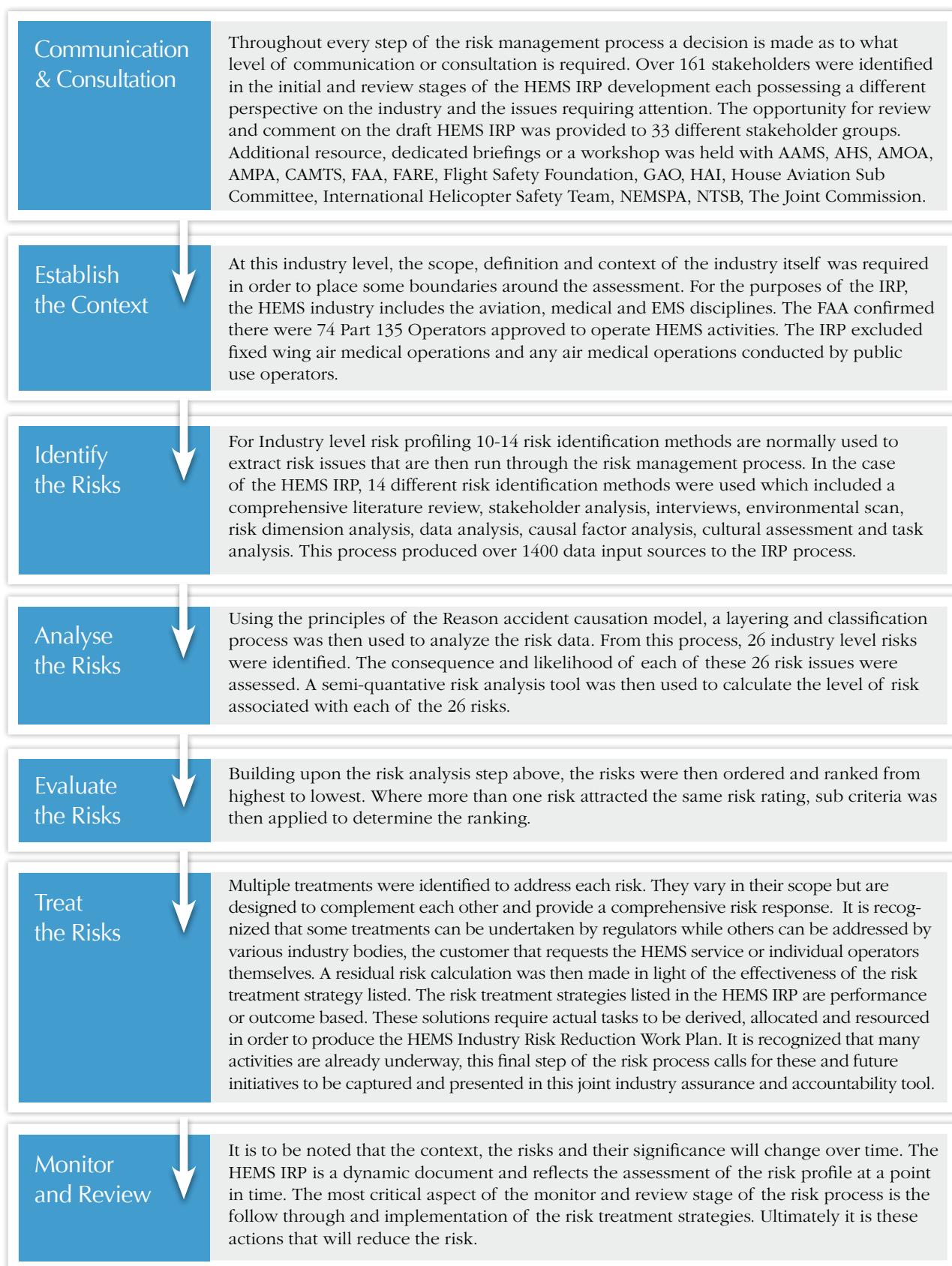
ADAPTED FROM REASON ACCIDENT CAUSATIONAL MODEL



Methodology: Risk Management Process

Risk Management Process

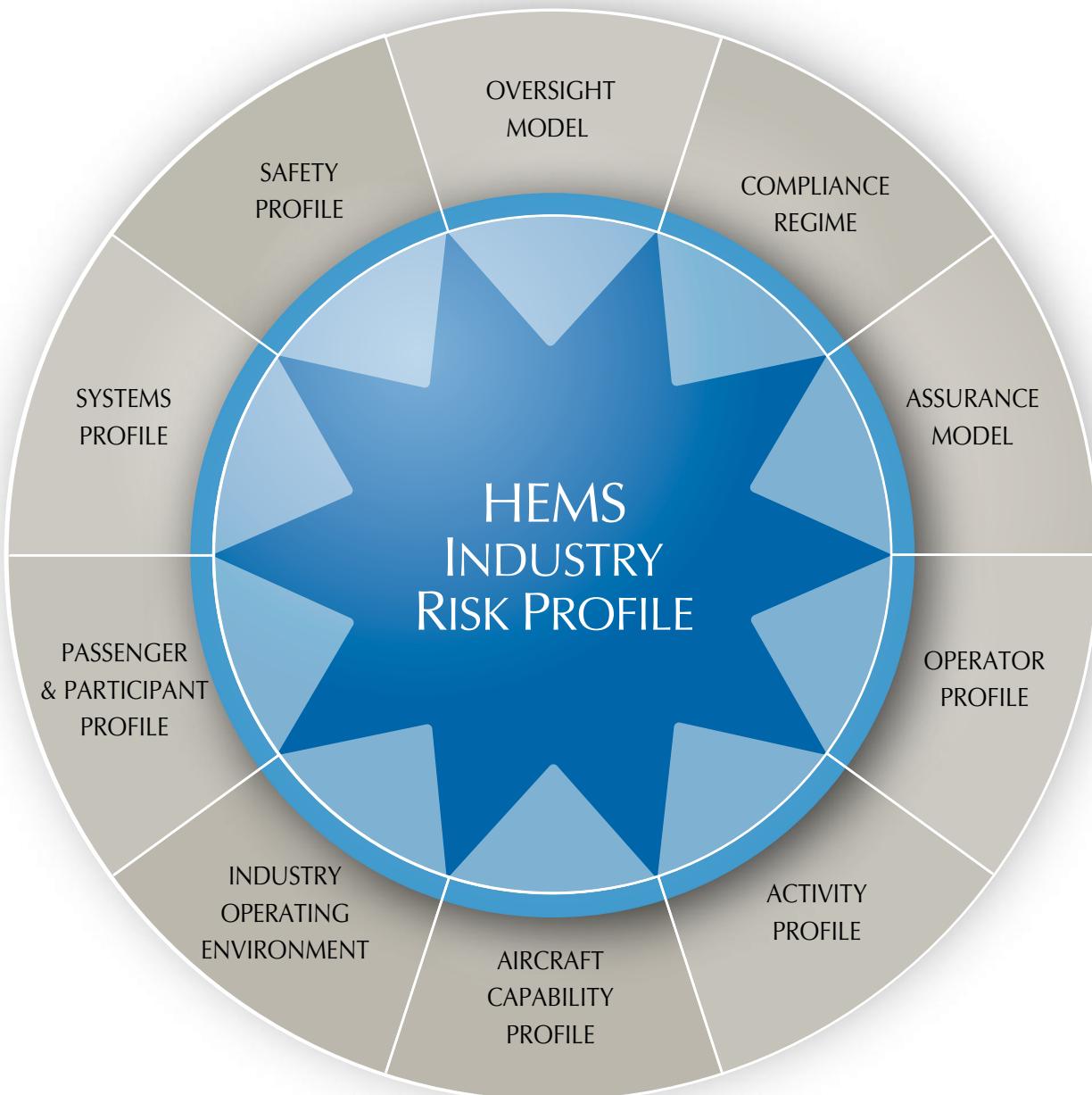
The International Standards Organization (ISO) draft standard on risk management (FDIS ISO31000) outlines the methodology and risk management process used to develop the Industry Risk Profile. The following pictorial model is consistent with FDIS ISO31000 and provides the structure to classify, present and prioritize risk information. The risk profile was developed using the following process:



Methodology: Industry Risk Profile Model

The industry risk profile model is used to classify and catalogue the risks identified in the HEMS IRP. This structure is used across the aviation industry and groups the issues into categories that generally guide the level of action required. The first three elements of the IRP model (oversight, compliance and assurance) combine to form the governance of the industry.

From here, other important elements are then depicted. It is to be noted, that each of these areas can be further examined and assessed to a greater level of depth. For example the efforts of the International Helicopter Safety Team's JSAT, JSIT and subsequent HEMS Safety Committee or the efforts of the NTSB individual accident investigation process would be the next layer of depth provided in the safety profile element of the HEMS IRP model.



OVERSIGHT MODEL:

The governance regime that exists within the industry in all facets at the highest level. In the case of the HEMS industry this includes governance for the aviation, medical and emergency management services aspects. This element of the IRP model is closely aligned with the compliance and assurance elements.

COMPLIANCE REGIME:

Considers the statutory and regulatory and framework in which the industry operates. The compliance element, along with the assurance element is a sub component of the overall oversight model. At the industry risk profiling level, these two pieces are addressed individually.

ASSURANCE MODEL:

What level of assurance is provided and to what level of depth? These aspects are explored in the assurance element of the Industry Risk Profile. The objective of assurance is to provide ‘confidence’.

OPERATOR PROFILE:

The operator profile looks at the composition, structure and models of the operator group within the industry. A greater level of depth can be provided to this element if required by conducting an individual risk profile of each operator within the industry sector. Individual operator risk profiles are normally undertaken by the regulator as part of the regulators routine surveillance and intervention regime.

ACTIVITY PROFILE:

This element of the Industry Risk Profile examines the range of operational activities undertaken by the industry. In relation to the HEMS industry risk profile the activity profile includes inter facility transfers, scene flights, speciality team transports, training, maintenance, communication functions to name a few.

AIRCRAFT CAPABILITY PROFILE:

This element looks at the aircraft capability, technology and equipment.

INDUSTRY OPERATING ENVIRONMENT:

The industry operating environment includes the overall setting and landscape of the environment in which the industry operates in its entirety.

PASSENGER & PARTICIPANT PROFILE:

Considers the demographics of the passengers or participants who are involved in the activity. This element excludes aircrew or employees of the aviation operator which is covered in the operator profile.

SYSTEMS PROFILE:

The definition and maturity of the various management systems available and utilized within the industry are covered in the scope of this element of the Industry Risk Profile. This includes but is not limited to management systems, business systems, information systems and safety management systems.

SAFETY PROFILE:

This element of the Industry Risk Profile takes into account the incident and accident statistics and the overall safety profile of the industry sector. Much of the information and data covered in this element is historical in nature.

PART 2

Summation of Results

The results of the HEMS IRP can be examined in the following ways:

Risks presented by Risk Ranking (Pages 24-28)

The tabulated data indicated below in table 1 presents the risks from highest to lowest. For those risks that have the same number (see numbering system in the far right hand column) this indicates the risk has been quantified at the same level. Where this is the case, sub criteria have been used to rank the risks within this classification. The summation of results in this presentation format only depicts the risk assessment, being the identification and quantification of risk and does not list any solutions to reduce the risk. This information is provided as a snapshot of the issues from highest to lowest and is to be read in association with Part 3.

Risks presented against risk matrix (Page 29)

Risk is a measure of consequence and likelihood, the presentation of results against the risk matrix provide a visual representation of the risks scatter plot. The two matrix provide a visual representation of the 'before' and 'after' risk treatment. The second being referred to as residual risk, or the risk that is remaining after full implementation of risk reduction measures are achieved.

Risks presented against the IRP Model Categories (Pages 32-58)

Part 3 of the HEMS IRP provides the risk information catalogued against the elements of the Industry Risk Profiling model. This functional grouping allows the reader to examine risks in the related category. The information is presented in this fashion, as it is often the case that high level stakeholders are looking for information against these classification elements (such as governance, aircraft capability, safety etc).

TABLE 1 Risks Presented by Risk Ranking

NUMBER	RISKS	RISK LEVEL
1	Risks associated with the lack of or limited definition of the national EMS structure or governance framework for HEMS. The current regime was not purposefully designed and has evolved over the past twenty years to the current regime in the absence of a framework. (Risk Reference 1 HEMS IRP)	VERY HIGH (1)
2	The risk that the current medical reimbursement model (primary payer model) is no longer adequate to provide the appropriate level of financial coverage for either the current operating costs of the service or the impending upgrade of capability required through the addition of technology. (Risk Reference 15 HEMS IRP)	VERY HIGH (1)
3	The risks associated with the complexity, non alignment and lack of clarity around the roles and scope of federal, state and county agencies involved in oversight of the HEMS industry. (Risk Reference 3 HEMS IRP)	VERY HIGH (1)

TABLE 1**Risks Presented by Risk Ranking**

NUMBER	RISKS	RISK LEVEL
4	<p>Cumulative risk associated with the variability among States over licensing requirements and standards for HEMS programs, as well as inconsistent interpretation of the States' authority to determine a need for, and location of, new or existing HEMS programs and bases, has produced widespread variability in quality and safety in HEMS transport.</p> <p>(Risk Reference 8 HEMS IRP)</p>	VERY HIGH (2)
5	<p>There are significant risk entrenched within the current tasking continuum used for allocating HEMS air medical assets. This inconsistency and lack of standardization in the tasking continuum spans the following process flow that includes:</p> <ul style="list-style-type: none"> - The evaluation of the patient need for care - The necessity of utilization of an aircraft for the passenger transport - The requesting agency - The tasking process including the allocation of the task to a specific resource - The acceptance of a task by a HEMS operator - Through to operational control once the task has been accepted and undertaken <p>(Risk Reference 16 HEMS IRP)</p>	VERY HIGH (2)
6	<p>The industry has many different business models that often have competing objectives and interests. The diversity in this industry structure has the potential to induce industry and organizational level competition and growth in turn increasing the operational and safety risk exposure of the industry.</p> <p>(Risk Reference 10 HEMS IRP)</p>	VERY HIGH (2)
7	<p>Safety management systems are only starting to be introduced in the HEMS industry are not yet sufficiently mature to manage the level and depth of change required in the safety philosophies, processes and practices required.</p> <p>(Risk Reference 21 HEMS IRP)</p>	VERY HIGH (2)
8	<p>The industry does not have one accredited agency that provides collective definition, oversight or monitoring for the combined aviation, health-care and emergency management functions that shape the HEMS (or broader air medical) industry.</p> <p>(Risk Reference 2 HEMS IRP)</p>	VERY HIGH (3)
9	<p>The broad spectrum of stakeholders to the HEMS industry are not aware of the entire industry risk profile leading to an inability for the industry to effectively identify, analyze and reduce the risks in a orchestrated and cohesive way.</p> <p>(Risk Reference 4 HEMS IRP)</p>	HIGH (4)

TABLE 1**Risks Presented by Risk Ranking**

NUMBER	RISKS	RISK LEVEL
10	The lack of National Airspace System and other infrastructure constraints in the airspace where HEMS operate dictate the conditions for the operational profile for flight removing the option to HEMS Operators to fly IFR. (Risk Reference 17 HEMS IRP)	HIGH (4)
11	The complexity of the oversight, compliance and regulatory regimes does not provide the structure required for the industry to have an inclusive assurance regime or program of audits, accreditation and checking leading to an inability to provide confidence that the industry is being appropriately managed. (Risk Reference 7 HEMS IRP)	HIGH (4)
12	Owing to the nature of the task profiles conducted in HEMS and the close working relationship the aircrew have with medical personnel involved in the tasks, there is increased blurring of lines of role and responsibility in respect to the medical personnel contribution to safe operation of the aircraft. This risk of ambiguity is increased with medical personnel involvement in NVG operations, passenger briefing, task briefing, loading and unloading of aircraft, operational risk management assessments and crew briefing and debriefing processes. (Risk Reference 20 HEMS IRP)	HIGH (4)
13	The risks associated with the lack of development of a tangible safety culture that truly understands risk and the management of risk. (Risk Reference 26 HEMS IRP)	HIGH (5)
14	There is inherent complexity in the compliance regime used to govern the HEMS industry which is confusing and dictated by a myriad of non-related stakeholders leading to an increased chance that HEMS operators are non-compliant. This risk is induced by a number of factors that includes: <ul style="list-style-type: none"> - There are three distinct disciplines that all set the compliance regime that affects the HEMS industry (aviation, healthcare and emergency services) - The overlap or interface between these compliance regimes has not been clearly mapped out or is not easily accessible - There is no agreed inter-discipline hierarchy for regulation, policy or standards of either the national ascending hierarchy (Risk Reference 6 HEMS IRP)	HIGH (6)

TABLE 1**Risks Presented by Risk Ranking**

NUMBER	RISKS	RISK LEVEL
15	Risk that the current definition and scope of the industry is not well defined leading to limitations in the ability or appropriate agencies and stakeholders to effectively govern their aspect of the industry. The key risk induced by this issue is the limitations on the ability for a complete and industry wide data driven national solution to manage the landscape to be identified, coordinated and effectively implemented. (Risk Reference 9 HEMS IRP)	HIGH (6)
16	The current safety analysis and monitoring of the HEMS industry is not data driven leading to an inability for the Regulator or the Industry itself to have an accurate picture of real safety picture. (Risk Reference 24 HEMS IRP)	HIGH (6)
17	The operating environment and the associated infrastructure and standard industry practices for the two routine task profiles (inter-facility & scene flights) is not sufficiently designed at the HEMS System level, leading to the increased variance and application of flight profiles, safety standards and safety risk exposure to patient, aircraft, aircraft and the public. (Risk Reference 12 HEMS IRP)	HIGH (7)
18	Lack of integration and alignment of accountability, responsibility and resourcing for the standardization of helipad operations in the inter-facility environment by hospitals, impacting upon operation, maintenance and continuous hazard management of helipads in the inter-facility environment by hospitals, primary HEMS operator and other helipad users. (Risk Reference 18 HEMS IRP)	HIGH (7)
19	The current training regime for a high percentage of the HEMS industry does not employ the use of simulators and advanced training methods broadly used in other parts of the aviation industry predominately due to cost. (Risk Reference 25 HEMS IRP)	HIGH (7)
20	The current regulatory philosophy combined with the financial risks induced by the funding model of the industry engender a mind set or culture in the HEMS industry to only meet minimum prescribed standards rather than managing risks in the operation through the implementation of better practices. (Risk Reference 5 HEMS IRP)	HIGH (8)

TABLE 1**Risks Presented by Risk Ranking**

NUMBER	RISKS	RISK LEVEL
21	<p>There is no activity or task profile definition set for the HEMS industry sector making it difficult to oversee the risks associated with the various task profiles at an industry, national or State level. In addition to this, changes to the trends in industry activities are not easily identified or monitored and the platform for data driven monitoring does not exist to the level of maturity required to capitalize.</p> <p>(Risk Reference 11 HEMS IRP)</p>	HIGH (8)
22	<p>The risk that the HEMS industry does not consistently identify, adopt, utilize and maximize aircraft technology available in the aviation industry to enhance safety parameters leading to a decrease in the risk of an accident or incident.</p> <p>(Risk Reference 13 HEMS IRP)</p>	HIGH (8)
23	<p>The risk associated with the inability to effectively resource and manage the operational, technical and cultural change related to the introduction of new technology into service.</p> <p>(Risk Reference 14 HEMS IRP)</p>	HIGH (8)
24	<p>The profile of the passenger or participant (patient and medical crew) profile in the HEMS industry differs significantly from that of other sectors of the aviation community by virtue of the fact that the patient does not have a choice in the operator allocated to undertake their transport.</p> <p>(Risk Reference 19 HEMS IRP)</p>	HIGH (8)
25	<p>Aviation and medical safety management systems are not integrated at a compliance or policy level leading to incoherent, conflicting or competing priorities or practices which may stifle the effective introduction of the SMS within the HEMS Industry.</p> <p>(Risk Reference 22 HEMS IRP)</p>	HIGH (8)
26	<p>Lack of effective and sound implementation of operational control arrangements within the HEMS industry leading to the increased increases the risk of poor operational decisions and misalignment of accountability and responsibility for flight operations.</p> <p>(Risk Reference 23 HEMS IRP)</p>	HIGH (9)

TABLE 2 Risks Presented against Risk Matrix

TABLE 2.A: BEFORE RISK TREATMENT

		LIKELIHOOD			
		CERTAIN	LIKELY	POSSIBLE	UNLIKELY
CONSEQUENCE	EXTREME	VERY HIGH 	VERY HIGH (2) 	HIGH (5) 	HIGH (9) 
	CRITICAL	VERY HIGH (3) 	MEDIUM (4) 	HIGH (8) 	MEDIUM (12) 
	MAJOR	HIGH (5) 	MEDIUM (7) 	MEDIUM (11) 	MEDIUM (14) 
	MINOR	HIGH (10) 	MEDIUM (13) 	LOW (15) 	LOW (16) 

TABLE 2.B: AFTER RISK TREATMENT. RESIDUAL RISK

		LIKELIHOOD			
		CERTAIN	LIKELY	POSSIBLE	UNLIKELY
CONSEQUENCE	EXTREME	VERY HIGH (1) 	VERY HIGH (2) 	HIGH (5) 	HIGH (9) 
	CRITICAL	VERY HIGH (3) 	HIGH (4) 	HIGH (8) 	MEDIUM (12) 
	MAJOR	HIGH (6) 	HIGH (7) 	MEDIUM (11) 	MEDIUM (14) 
	MINOR	HIGH (10) 	MEDIUM (13) 	LOW (15) 	LOW (16) 

PART 3

Industry Risk Profile Tabulated Data

How to Read Tabulated Data

Part 3 of the HEMS IRP is a technical document which has been written to provide the in-depth identification, analysis and proposed management strategies to treat the risk. When reading the tabulated data, the contents are to be read from left to right. These risks are not ordered in priority from highest to lowest, but rather are grouped and classified against the IRP Model elements outlined on page 20. The table sub heading at the top of each page in the blue bar reflects the relevant IRP model element for each risk.

Each page of the tabulated data contains explicit, in depth information. The far left column labelled “Description of the Risk” provides an overview of the risk statement. It is to be noted that these risks statements are worded as risks (the chance something could happen - not the certainty that it is happening) to this end the risk statement is to be read in concert with the likelihood column for that item for a complete picture of the risk.

The column to the right of the Risk Description is the impact that that risk may have on the HEMS Industry. These dot points are potential consequences written long hand and are to be read in concert with the ‘Consequence’ column in the risk assessment component of the table. This consequence rating is the semi-quantitative assessment of the word picture outlined in the “Impact” column. In essence these two columns indicate one and the same thing using different language and methods.

Risk level is calculated by multiplying consequence and the likelihood on a two dimensional matrix. The risk level is indicated by both a word e.g. “High” and a number e.g.”(5)”. This number correlates to the placement on the matrix as indicated on page 29 given each risk level spans a number of boxes.

The most critical aspect to the whole tabulated data and the IRP itself is the identification, resourcing and implementation of risk reduction measures known as “Risk Treatment Strategies”. For the purposes of this IRP, the risk treatment strategies listed in this tabulated data are “Performance or Outcome based” and are not specific tasks allocated to any one group in industry. These reduction measures need to be further developed into actual tasks that can be implemented, tracked and measured. This information will be held in the HEMS Industry Risk Reduction Action Plan.

The residual risk rating uses this same process as the risk assessment step while taking into account the forecast of the risk level calculation (of both consequence and likelihood) once the proposed set of treatments has been implemented. The residual risk can only be claimed by the industry once the treatments have been allocated, resourced and completed. A progress report against the implementation should be undertaken regularly to track a downward motion of the risk profile.

The far right hand column labelled “Priority” provided an indication of where that itemized risk falls in the risk ranking from 1-26.

Serial No. 1	OVERSIGHT MODEL	DESCRIPTION OF RISK	IMPACT OF THE RISK ON THE HEMS INDUSTRY	RISK ASSESSMENT	RISK TREATMENT STRATEGY	RESIDUAL RANKING	PRIORITY:	
			<p>Risks associated with the lack of or limited definition of the national EMS structure or governance framework for HEMS. The current regime was not purposefully designed and has evolved over the past twenty years to the current regime in the absence of a framework.</p> <ul style="list-style-type: none"> - The development of state based EMS systems which are not connected or consistent - Divergence in standards at a State level which can have national implications - Increased chance of conflicting legislative and regulatory practices nation wide - Confusion in the industry around accepted practices - The continuum of individual patient care and the level of healthcare is interrupted or not streamlined - Increasing variance in business models creating potential conflict locally and nationally - No publicly visible accountability structure for the industry - Increased occurrence of competing interests - Challenges in gaining agreement on standards, accreditation, practices and procedures in use across the industry - Variance in criteria for professionals working in this field - Difficulties for HEMS programs to navigate through the compliance regime - Lack of design of the EMS system could stifle growth or expansion - Duplication of resources - Disparity in matching appropriate resources to the healthcare needs - Lack of confidence by the stakeholders that effective healthcare can be effectively delivered - Greater reliance on the HEMS operators to make decisions regarding policy and position on patient transport – rather than being able to rely on endorsed and accepted national protocols - Increase probability of induced under or over utilization of resources - Lack of leadership and direction on the future of EMS and in particular HEMS - Potential for increased control by States 	<p>RISK LEVEL VERY HIGH (1)</p> <p>LIKELIHOOD: CERTAIN</p> <p>CONSEQUENCE: EXTREME</p>	<p>PRIORITY: 1</p> <p>RESIDUAL RISK: MEDIUM (12)</p>			

Serial No. 2	DESCRIPTION OF RISK	IMPACT OF THE RISK ON THE HEMS INDUSTRY	RISK ASSESSMENT	RISK TREATMENT STRATEGY	RESIDUAL RANKING
		<p>The industry does not have one accredited agency that provides collective definition, oversight or monitoring for the combined aviation, healthcare and emergency management functions that shape the HEMS (or broader Air Medical) industry</p> <ul style="list-style-type: none"> - Lack of visible direction and authority for this industry sector – no one body in charge - Challenges in providing an adequate level of assurance that is complete and encompassing in nature - Complex and multiple reporting and compliance requirements over -burdening individual operators - Potential for fragmentation in the industry by HEMS operators siding or preferring one accreditation program over another - Lack of combined oversight for medical, EMS and aviation functions is not provided to the customer or the community at large - Continued and enhanced debate about whether the aviation or medical industry is the primary authority or controller responsible for ultimate standard setting and assurance - Conflicts of or competing interests - Growth of multiple agencies and accreditation bodies that have a some stake in setting industry standards - Potential for the duplication of efforts by separate organizations or entities to address the same, or similar industry risk issues - Best practice operations and procedures are not propagated through the industry. - Confusion over what entity has jurisdiction over issues oversight and resolution - Non alignment of accountability, responsibility and resourcing for the management of industry level risks - Increased cost to HEMS Operators and therefore the increased overhead to the industry's operating cost 	<p>PRIORITY: 4</p> <p>RESIDUAL RISK: LOW (15)</p> <p>RISK LEVEL: VERY HIGH (2)</p> <p>LIKELIHOOD: CERTAIN</p> <p>CONSEQUENCE: CRITICAL</p>	<ul style="list-style-type: none"> - Seek acknowledgement of HEMS as its own industry owing to the unique features and reliance on the interoperability and intersection of aviation, healthcare and emergency services - Establish an interagency task force charged with identifying, defining and assessing the issues associated with the intersecting points of the three disciplines in the HEMS industry from a governance and oversight perspective - Industry to establish a voluntary custodian group to oversee and monitor the risk profile of the industry - Identify the legislator, regulator, customer and industry for the aviation, medical and emergency services aspects of HEMS (eg locate the regulator for healthcare aspects of HEMS) - Develop options to resolve lack of clarity regarding federal vs state oversight of the medical component of HEMS operations. - Establish a joint task force or entity (albeit it temporary) to oversee alignment of regulation as required 	

Serial No. 3	DESCRIPTION OF RISK	IMPACT OF THE RISK ON THE HEMS INDUSTRY	RISK ASSESSMENT	RISK TREATMENT STRATEGY	RESIDUAL RANKING
		<p>The risks associated with the complexity, non alignment and lack of clarity around the roles and scope of federal, state and county agencies involved in oversight of the HEMS industry</p> <ul style="list-style-type: none"> - Inconsistency with the criteria and protocols that dictate the use of HEMS assets - Challenges for the industry in mapping out the requirements that they should either be complying with or striving to achieve - Lack of clarity around that body or agency is truly accountable - No single regulatory body has responsibility for overseeing the EMS system as a whole - Conflicting regulatory priorities may place operators in a position where they make decisions that are not optimal for either the aviation or medical areas of the sector - Regulators can make independent decisions which may compromise safety in the other area - The scope and definition of the industry remains unclear leading to inability to implement an effective national governance regime - Economic challenges and potential changes to Federal, State and private insurance reimbursement regimes 	<p>PRIORITY: 3</p> <p>RESIDUAL RISK: MEDIUM (11)</p>	<ul style="list-style-type: none"> - Undertake a detailed analysis of all bodies within the USA that have some level of accountability or responsibility for the regulatory aspects of the HEMS system in order to develop a centralized stakeholder database and reference point for change - Clarify and publish the definition of roles of the various stakeholders - Design national level performance based requirements for national use noting the need for consistent implementation at the State level - As part of the key industry and regulatory body task force in 1 above, establish working group to develop an integrated oversight model for HEMS that takes into account the legal jurisdiction and accountabilities of the various stakeholders. - Develop options to resolve the lack of clarity around those areas that cross the bounds of both federal and state oversight regimes. - Define the legislator, regulator, customer and industry for the aviation, medical and emergency services aspects of HEMS - Once the medical regulator is located, develop and set minimum standards for air ambulance medical care <p>- Implement treatments from number 1 and 2</p>	

Serial No. 4	DESCRIPTION OF RISK	IMPACT OF THE RISK ON THE HEMS INDUSTRY	RISK ASSESSMENT	RISK TREATMENT STRATEGY	RESIDUAL RANKING
<p>The broad spectrum of stakeholders to the HEMS industry are not aware of the entire industry risk profile leading to an inability for the industry to effectively identify, analyse and reduce the risks in a orchestrated and cohesive way</p> <ul style="list-style-type: none"> - The full extent of the risk profile of the HEMS industry has not been identified, analysis or measured and is therefore not completely known and can therefore not be entirely managed. - Inability for the HEMS industry to regain confidence by the community that the risks are being effectively managed - Risks are not appropriately identified, assessed or managed - Prolonged question around the integrity of the HEMS industry and associated operators from the patient and hospital communities - The industry may not effectively manage the strategic, safety, operation, technical, transitional and competition risks currently present in the industry - The right bodies, organizations or agencies may not be aware of the role they play in providing a key solution that would reduce the risk profile - Incident or accident rate could continue at an unacceptable level - Loss of confidence by the insurance industry leading to the price of insurance being driven up or in some cases not underwritten - The efforts to provide a solution to the array of industry issues may not be coordinated - Increased change in duplication of effort in some areas and lack of coverage in others - Increased level of 'silo' behavior across the industry due to lack of cross functional knowledge, awareness of ownership - Negative impact on the industry's national reputation - Loss of public confidence in the industry's ability to adequately provide oversight and manage the resources and public money provided to fund medical transport - Increased spot light by regulators and legislators - Increase chance that legislative solutions will be pursued - Division in the industry – leading to ultimate impact upon the delivery of patient care 	PRIORITY: 9	RESIDUAL RISK: LOW (15)	RISK LEVEL HIGH (4)	LIKELIHOOD: LIKELY	CONSEQUENCE: CRITICAL

Serial No. 5	COMPLIANCE REGIME DESCRIPTION OF RISK	IMPACT OF THE RISK ON THE HEMS INDUSTRY	RISK ASSESSMENT	RISK TREATMENT STRATEGY	RESIDUAL RANKING
		<p>The current regulatory philosophy combined with the financial risks induced by the funding model of the industry engender a mind set or culture in the HEMS industry to only meet minimum prescribed standards rather than managing risks in the operation through the implementation of better practices.</p> <ul style="list-style-type: none"> - Prescriptive regulatory regimes provide detailed descriptions of how compliance must be achieved rather than providing opportunities for meeting the regulation through appropriate actions that are specific and achievable to individual operators - They limit the ability of operators to implement efficient systems to meet the safety intent of the regulations - Operators may conduct VFR flights due to limitations in the regulations - Operators may not implement required changes due to delays in updating regulations - Operators may incur compliance costs for actions which have limited safety value - Increases the practice within industry of waiting for prescriptive regulations to be released rather than taking a proactive better practice stance 	<p>PRIORITY: 20</p> <p>RESIDUAL RISK: MEDIUM (12)</p>	<p>RISK LEVEL HIGH (8)</p> <p>LIKELIHOOD: POSSIBLE</p> <p>CONSEQUENCE: CRITICAL</p>	<ul style="list-style-type: none"> - Industry to develop and adopt an action agenda to implement voluntary change to address the key risk areas the industry is in a position to control and influence - Industry to develop or recognize better practice standards (community practices) that exceed the minimum regulatory compliance - Encourage a performance based philosophy to be adopted for the spectrum of new developed regulations pertaining to the HEMS Industry - Implement an education campaign across the industry on the purpose, benefit and usage of performance based regulation - Implement an executive leadership program for the customers (hospital executives, EMS personnel and Part 135 executive) on the nature, role and responsibilities associated with performance based regulation - Formally showcase better practice models with a focus of shifting the base mind set and culture

Serial No. 6	DESCRIPTION OF RISK	IMPACT OF THE RISK ON THE HEMS INDUSTRY	RISK ASSESSMENT	RISK TREATMENT STRATEGY	RESIDUAL RANKING
			PRIORITY:	14	RESIDUAL RISK:
			RISK LEVEL	HIGH (6)	LIKELIHOOD:
			CONSEQUENCE:	MAJOR	CERTAIN
<p>There is inherent complexity in the compliance regime used to govern the HEMS industry which is confusing and dictated by a myriad of non-related stakeholders leading to an increased chance that HEMS operators are non-compliant. This risk is induced by a number of factors that includes:</p> <ul style="list-style-type: none"> - There are three distinct disciplines that all set the compliance regime that affects the HEMS industry (aviation, healthcare and emergency services) - The overlap or interface between these compliance regimes has not been clearly mapped out or is not easily accessible - There is no agreed inter-discipline hierarchy for regulation, policy or standards of either the national ascending hierarchy or cross functional disciplines 	<ul style="list-style-type: none"> - Standards or requirements could become conflicting in nature - Increased risk exposure from a legal and safety perspective - Increased chance standards and criteria are not being met - Industry falls back onto voluntary standards and accreditation bodies as they do not have the capacity or are not aware of the depth and complexity of the issues at hand - The industry does not adopt or implement accepted standards - Increases the possibility of differing interpretations or opinions - The link between the regulatory regime and the operational standards could increase confusion among industry participants - The historical basis for decisions is not adequately documented - Requirements or standards can be easily changed with a re-write of a manual or document - Compliance requirements may not be met - Induce conflict or disagreement between industry stakeholders - Inconsistency across the industry <ul style="list-style-type: none"> - Operating standards and protocols may be disjointed in nature and duplication may be excessive - Increase burden on the operator to establish 	<ul style="list-style-type: none"> - Establish a cross discipline oversight taskforce to identify the intersections of the HEMS industry at the highest level - Develop a standard compliance road map which informs the HEMS industry of the complexities of the multidiscipline compliance regime to provide a means of local level navigation around federal and state requirements - Regulators in the three functional areas meet to agree on collaborative arrangements to streamline compliance definition, monitoring and intervention - Develop options to resolve the question of lack of clarity and intersect points of federal vs state oversight of certain component of HEMS operations. - Key industry stakeholder and organizations cooperate to identify and address structural and operational safety issues 			

Serial No. 7	ASSURANCE MODEL DESCRIPTION OF RISK IMPACT OF THE RISK ON THE HEMS INDUSTRY	RISK ASSESSMENT	RISK TREATMENT STRATEGY	RESIDUAL RANKING
	<p>The complexity of the oversight, compliance and regulatory regimes does not provide the structure required for the industry to have an inclusive assurance regime or program of audits, accreditation and checking leading to an inability to provide confidence that the industry is being appropriately managed</p> <ul style="list-style-type: none"> - The auditing and checking that does take place does not cover the full context of the HEMS operation - The need for multiple audits, accreditation and checking programs - Inability for integration and economies of scale to reduce the compliance burden for operators - No one body holds the complete picture of compliance and assurance to give the level of confidence required - Those agencies or accreditation bodies that offer accreditation may not have protection under a statutory authority to formally authorise or sanction participant other than the withholding of accreditation. - Operators have to comply or achieve multiple accreditation or audits as there is no one all embracing assurance regime that meets all needs - There is a lack of clarity around exactly who expects what - Lack of consistency around whether the level of service required is being delivery and achieved - Potential for audits from different bodies to issue conflicting findings and requirements - Potential for different standards being required in each State. 	<p>PRIORITY: 11</p> <p>RESIDUAL RISK: MEDIUM (11)</p> <p>RISK LEVEL HIGH (4)</p> <p>LIKELIHOOD: LIKELY</p> <p>CONSEQUENCE: CRITICAL</p>	<ul style="list-style-type: none"> - Regulators in the three functional areas (aviation, healthcare and EMS) to meet and define the relationships between the governance and oversight arrangements in order to remove lack of clarity around who provides what assurance - At a voluntary level develop an industry level assurance regime as part of the industry self governance arrangements mapping what needs to be checked, to what level of assurance and by what entity - As part for the industry level assurance regime, develop an integration map of all available industry accreditation and certification programs to aide in educating the industry on the similarities and differences - Where possible identify any potential gaps or overlaps which could be mutually accredited via an approved parallel path. - Consideration of a self administration model for certain aspects of the HEMS industry with the appropriate mandate for utilization. 	

Serial No. 8	DESCRIPTION OF RISK	IMPACT OF THE RISK ON THE HEMS INDUSTRY	RISK ASSESSMENT	RISK TREATMENT STRATEGY	RESIDUAL RANKING
		<p>Cumulative risk associated with the variability among States over licensing requirements and standards for HEMS programs, as well as inconsistent interpretation of the States' authority to determine a need for, and location of, new or existing HEMS programs and bases, has produced widespread variability in quality and safety in HEMS transport</p> <ul style="list-style-type: none"> - National level consistency is not achieved - States develop their own requirements in lieu of not having guidance inducing a divergence of operations - HEMS programs operating in more than one state have to track and met different requirements for licensure in each of the states - Increased creation of variability and distraction from focus on patient safety and quality transport - Increased complexity in the compliance regime that needs to be managed at the operator level - Numerous and different interpretations by State legal counsellors and created widespread ambiguity and confusion - Unequal distribution of HEMS services in some areas while other areas may be undeserved or not served at all - Expectations for an equal level of health care across the country is not achieved or delivered by the current emergency medical transport system - ACS level 1 trauma care within two hours of injury is not achieved, thus failing to meet a fundamental expectation of many Americans and trauma care providers - Some areas have potential to be saturated with aircraft or HEMS assets and other areas not serviced at all - Infighting over completion for flights - An increasing number of small operators running on pagers and not adhering to FARS, damaging industry reputation 	<p>PRIORITY: 5</p> <p>RESIDUAL RISK: LOW (15)</p>	<p>RISK LEVEL VERY HIGH (2)</p> <p>LIKELIHOOD: LIKELY</p> <p>CONSEQUENCE: EXTREME</p>	

Serial No. 9	OPERATOR PROFILE DESCRIPTION OF RISK	IMPACT OF THE RISK ON THE HEMS INDUSTRY	RISK ASSESSMENT	RISK TREATMENT STRATEGY	RESIDUAL RANKING	PRIORITY: 15 RESIDUAL RISK: MEDIUM (11)
		<p>Risk that the current definition and scope of the industry is not well defined leading to limitations in the ability or appropriate agencies and stakeholders to effectively govern their aspect of the industry. The key risk induced by this issue is the limitations on the ability for a complete and industry wide data driven national solution to manage the landscape to be identified, coordinated and effectively implemented</p> <ul style="list-style-type: none"> - The true scope of the industry and its activities is not known - The information presented may not be reflective of the entire industry, but rather those who are most active or visible - The profile of the aircraft fleet of the industry sector can not be monitored - The profile of the aircrew (pilots) of the industry sector can not be monitored - The true profile of the activities undertaken by the industry is not known - An accurate calculation of the precise risk exposure is unable to be determined - The oversight model is driven from an experiential base rather than a data based model - The community will not get a clear picture of the HEMS industry as the assurance model is not fully defined and the systems and processes for collecting data are inadequate - A comparison, identification of change, or the monitoring of trends can not easily be achieved - The scope of risk of the industry sector and in particular the safety exposure is unknown - Overreliance on past incident data as a pseudo complete risk profile - The voluntary efforts of industry to reduce the risk profile may be misguided and not focused in the highest area of need 	<p>RISK LEVEL HIGH (6)</p> <p>LIKELIHOOD: CERTAIN</p> <p>CONSEQUENCE: MAJOR</p>	<ul style="list-style-type: none"> - Commission a body of work to accurately define the industry, developing a stakeholder matrix for use by any national or industry wide enhancement to the HEMS industry (eg Air Medical Transport Agenda for the future) - Develop the criteria for data and information that needs to be collected for the purpose of enhanced self oversight - Set up central data collection points, for key industry profiling information, at appropriate places within the industry to develop an accurate and up to date profile of the industry as a whole - Establish an industry documentation registry to enable a single source point for industry literature, studies, research and resource - Through the HEMS Industry Risk Profile updates, track and monitor the shift in industry profile (national system level application of FOQA like program) and use this data to adequately drive the calculated future evolutions to the EMS Framework and model 		

Serial No. 10	DESCRIPTION OF RISK	IMPACT OF THE RISK ON THE HEMS INDUSTRY	RISK ASSESSMENT	RISK TREATMENT STRATEGY	RESIDUAL RANKING
		<p>The industry has many different business models that often have competing objectives and interests. The diversity in this industry structure has the potential to induce industry and organizational level competition and growth in turn increasing the operational and safety risk exposure of the industry</p> <ul style="list-style-type: none"> - The industry has no set standards or guidelines for the governance of individual organizations - Increased sensitivity to taking low cost solutions - Span of control is wide reaching and hard to survey, monitor or control - Increased chance that the industry will be rationalized and consolidated - Conflicting commercial objectives induced companies to target commercial lucrative locations or regions increasing the competition - The hospital or patient demand for air medical service does not drive growth - The chance for inappropriate utilization of assets is increased - Further fragmentation in the industry may occur - Financially viable locations will be over serviced while those with lower volumes may be under serviced - Increased pressures for programs and customers to compensate and run non-viable programs at a loss - Increased occurrence of competing programs encroaching on established EMS program operations - Inadvertent flow down pressure for crews to accept any or all tasks to assist with the survivability of their program and the subsequent security of their employment - An increase that further hybrid business models will arise coupled with the commercial drivers and pressures for viability will shape the industry environment - Potential for exacerbating other misunderstandings within the industry around agendas and political drivers - Increase the difficulty of standardizing process, procedures and cultures throughout the industry - The current operational and safety risk exposure associated with competition between HEMS programs in close or overlapping geographic proximity to each other that encourages transport teams to accept tasking in order to maximize flight volumes that are necessary to preserve the financial viability of programs. 	<p>PRIORITY: 7</p> <p>RESIDUAL RISK: MEDIUM (12)</p>		

Serial No. 11	ACTIVITY PROFILE DESCRIPTION OF RISK	IMPACT OF THE RISK ON THE HEMS INDUSTRY	RISK ASSESSMENT	RISK TREATMENT STRATEGY	RESIDUAL RANKING
		<ul style="list-style-type: none"> - The risk profile or changes to the risk profile may not be identified owing to the lack of structural definition of the industry - The baseline in the industry of current usage is not available - There is no common platform for language or measurement for the industry to compare or contrast at the Federal or State level - The scope, role and task profiles for EMS operators are not defined - Resources and efforts may be directed into the lower risk or lower exposure activities or tasks and not maximizing the impact or opportunity - Changes or developments in industry activities may occur before the regulatory regime can adequately accommodate the compliance implications 	PRIORITY: 21 RESIDUAL RISK: LOW (15)	<ul style="list-style-type: none"> - Develop and maintain a set of standard task profiles for the standard nationally approved HEMS activities associated with various standard tasks - Utilize these task profiles to develop a set of operational risk profiles and link to industry driven FOQA systems to identify, capture, analyze and report deviations from the norm - Adopt operational risk management module as part of the SMS - Key stakeholders to develop nationally accepted EMS transport terms and definitions - Change current HEMS definition to remove the possibility of a 'emergency' driven culture (change name of industry to Air Medical Transport rather than HEMS) - Embed the activity profile definition set into any industry wide data collection in order to accurately monitor the change in the industry overall activity profile - Provide individual operators or air medical program with the criteria for activity profiles in order to allow individual companies to monitor the change in their own profile over time 	

Serial No. 12	DESCRIPTION OF RISK	IMPACT OF THE RISK ON THE HEMS INDUSTRY	RISK ASSESSMENT	RISK TREATMENT STRATEGY	RESIDUAL RANKING	
			PRIORITY:	17	RESIDUAL RISK:	LOW (15)
			RISK LEVEL	HIGH (7)	LIKELIHOOD:	LIKELY
			CONSEQUENCE:	MAJOR		
<p>Inter-facility Task Profile</p> <p>Formal tasks profiles are not evident for risk management of inter-facility transfer flights. Issues in minimizing risk for are :</p> <ul style="list-style-type: none"> - Inter-facility flights are often undertaken VFR/NVFR at low level when IFR might be possible given necessary infrastructure - There is a greater potential for CFTI or loss of control due to inadvertent IMC encountered - Potential for traffic conflicts near busy hospital helipads, especially if itinerant users appear - No structured approach to inter-facility flights <p>Scene Flights Task Profile</p> <ul style="list-style-type: none"> - Scene flights variable profiles, can be high risk, many require VFR operations. - Flights are generally VFR, even in marginal weather conditions - The critical skill of transiting from VFR to instrument flight required by recovery from loss of visual reference is not commonly achieved across the industry - Flights are at low level with less margin for error - Flights at night can encounter very dark conditions which increase the risk for VFR operations - Flights may encounter inadvertent IMC - Pilots may not be able to fly by visual reference - Pilots may not have current training to regain VMC from emergency/failure conditions at low altitude - All legs of an EMS flight are not required to be conducted to the same standard leading to leading to lesser margin of safety 						

Serial No. 13	AIRCRAFT CAPABILITY PROFILE IMPACT OF THE RISK ON THE HEMS INDUSTRY	RISK ASSESSMENT	RISK TREATMENT STRATEGY	RESIDUAL RANKING
				PRIORITY:
				22
				RESIDUAL RISK: LOW (16)
DESCRIPTION OF RISK		RISK LEVEL	HIGH (8)	
		LIKELIHOOD:	POSSIBLE	
		CONSEQUENCE:	CRITICAL	
	<p>The risk that the HEMS industry does not consistently identify, adopt, utilize and maximize aircraft technology available in the aviation industry to enhance safety parameters leading to a decrease in the risk of an accident or incident</p> <ul style="list-style-type: none"> - Technologies are emerging that can assist in the mitigation of risk from low level VFR operations - Adoption of new technologies requires a formal change management plan including training, procedures amendment etc. - Aircraft and crew capability may not match the task profile of the operator, the state or the HEMS industry as a whole - Both proactive and reactive technological enhancements may not be - Assessment processes must identify technology options which provide the most impact for funds available - Technologies must be assessed for their impact on pilot performance for example, increase/reduction of pilot workload, human factors issues such as fixation with task within the cockpit etc, - Increased fatigue and workload issues - Increased reliance and need to undertake and implement formal training and commit the required resources 	<ul style="list-style-type: none"> - Establish an industry/regulator working group to specify and assess current, emergent and future technology - For key pieces of industry applicable wide technology, a risk and opportunity assessment to be conducted by the technology working group and made available to industry to aide in decision making - Assess the suitability and need for the potential creation of a new federal aviation regulation specific to HEMS and fixed wing aero-medical transport. - Mandate the use of certain performance standards (outcome based) that can be achieved through technology - Develop resource plan for industry for funding injection to aide significant technology upgrade - Agreement from manufacturers that certain performance standards will mandate a standard fit of some technology based on the additional safety limits achieved - Purchase, implement and manage technology introduction such as NVGs, HTAWS, FDR etc 		

Serial No. 14	DESCRIPTION OF RISK	IMPACT OF THE RISK ON THE HEMS INDUSTRY	RISK ASSESSMENT	RISK TREATMENT STRATEGY	RESIDUAL RANKING
		<ul style="list-style-type: none"> - There will be a significant shift in the operational context for HEMS providers - The industry can not keep pace the rapid advance of technology - The industry can not independently validate the efficacy of emerging technologies - The current workforce capability may not possess the skills and competencies required to work in this new environment - Subsequent new risks may be introduced that were not identified, assessed or potentially managed - The rapid implementation of new technology can induce unforeseen risks into the operating environment - Operators may underestimate the resources, time and commitment to introduce new technology - There may be a skills shortage in the industry of suitable qualified instructors to aide the training and implementation of new technology - The implementation of new technology without industry level coordination can lead to non standard industry configurations - The potential that funds are inefficiently allocated offers may compromised or not maximized - A belief may develop that new technology is a “silver bullet” and other forms of safety defences may be neglected leading to a false perception of safety boundaries - Other required changes to the operating environment, standards and training may not be as rapidly implemented generating a lag effect 	<p>PRIORITY: 23</p> <p>RESIDUAL RISK: MEDIUM (14)</p> <p>RISK LEVEL HIGH (8)</p> <p>LIKELIHOOD: POSSIBLE</p> <p>CONSEQUENCE: CRITICAL</p>	<ul style="list-style-type: none"> - The financial model of the HEMS industry needs to be accurately assessed to confirm viability of increased standards - Develop and release to industry a “change management” package and toolkit to assist HEMS organization to manage the risk of introduction of new technology - Develop a suite of HEMS industry specific risk based - change management tool kits for 1) introduction of new aircraft 2) opening of a new base 3) introduction of night vision goggles 4) introduction of enhanced aircraft safety equipment 5) introduction of safety management systems 6) mergers and acquisitions - FAA to consult with stakeholder to plan the structured adoption of existing and emerging technology. Consider supporting guidance to the industry in their maturity of uptake. Examine cultural factors such as reward and incentives. 	

Serial No. 15	DESCRIPTION OF RISK	INDUSTRY OPERATING ENVIRONMENT RISKS				
		IMPACT OF THE RISK ON THE HEMS INDUSTRY		RISK ASSESSMENT	RISK TREATMENT STRATEGY	
		PRIORITY:	2	RESIDUAL RANKING		
		RESIDUAL RISK:	HIGH (4)			
<p>The risk that the current medical reimbursement model (primary payor model) is no longer adequate to provide the appropriate level of financial coverage for either the current operating costs of the service or the impending upgrade of capability required through the addition of technology</p> <ul style="list-style-type: none"> - Retention of the inconsistencies in the payor model from State to State - Technology may not be able to be afforded by the industry - Pricing pressure on operators - Delays in the adoption and uptake of technology - Medicare reimbursement alone (without additional commercial insurance sources of reimbursement) will not allow HEMS transport programs to meet operational expenses and maintain financial viability. - Advanced and safer helicopter equipment, e.g., twin-engines, IFR equipped, HTAWS, NVG and more adequately trained transport teams may not be affordable or amortized - The Medicare payment model reimbursement for only transport “loaded miles” creates an unrealistic model for programs in that the covering the overhead expense for implementing appropriate aircraft equipment and crew training to maximize safety is inadequate - Medicare reimbursement for HEMS transport fosters the proliferation of new programs that operate in rural areas and that incur the lowest operational overhead. - The higher reimbursement from Medicare for transports from rural areas, which pays only for “loaded miles,” inadvertently penalizes transport programs operating in urban and suburban areas - Program overhead may be higher than for those programs operating in rural areas not contemplated in the standing model - Increased pressures on programs to use lower cost overhead models to maximize financial model - Accepted safety training practices such as the use of simulator training may be seen as a luxury rather than an essential tool for safety owing to the cost - Negotiating reimbursement for HEMS transport with Medicare regional offices is frequently confrontational, consumes considerable time, is inefficient and wastes resources 						
<p>RISK LEVEL</p> <p>LIKELIHOOD:</p> <p>CONSEQUENCE:</p>		<p>VERY HIGH (1)</p> <p>CERTAIN</p> <p>EXTREME</p>				
<p>Note: Intervention from higher authority may improve quantification of residual risk.</p>						

Serial No. 16	DESCRIPTION OF RISK	IMPACT OF THE RISK ON THE HEMS INDUSTRY	RISK ASSESSMENT	RISK TREATMENT STRATEGY	RESIDUAL RANKING
		<p>There are significant risks entrenched within the current tasking continuum used for allocating HEMS air medical assets. This inconsistencies and lack of standardization in the tasking continuum spans the following process flow that includes:</p> <ul style="list-style-type: none"> - There is question raised around the appropriate utilization of aircraft - Some areas saturated with aircraft, other areas less serviced - Alternate means of transport are not considered or engaged - Increase in occurrences of over utilization or under utilization of aircraft - Standards or protocols are not consistent - Safety risk is induced at any component of the continuum, and in some cases, a cumulative total - Competition for tasks can place pressure on crews to take marginal assignments - The range of risks associated with the current tasking process from assessment of patient need, to the allocation and dispatch of the asset, through to operational control is not standardized or consistent in the industry - Increased pressure leading to an increase in crew fatigue - Systemic issues and risks induced in the tasking process are not able to be minimized or removed <p>- The evaluation of the patient need for care</p> <p>- The necessity of utilization of an aircraft for the passenger transport</p> <p>- The requesting agency</p> <p>- The tasking process including the allocation of the task to a specific resource</p> <p>- The acceptance of a task by a HEMS operator</p> <p>- Through to operational control one the task has been accepted and undertaken</p>	<p>PRIORITY: 6</p> <p>RESIDUAL RISK: TBC</p>		

Serial No. 17	DESCRIPTION OF RISK	IMPACT OF THE RISK ON THE HEMS INDUSTRY	RISK ASSESSMENT	RISK TREATMENT STRATEGY	RESIDUAL RANKING
		<p>The lack of National Airspace System and other infrastructure constraints in the airspace where HEMS operate dictate the conditions for the operational profile for flight removing the option to HEMS Operators to fly IFR</p> <ul style="list-style-type: none"> - Remove the ability for the industry to maximize the opportunity to harness the safety benefits of technology - Restricted low level infrastructure forces operators to employ VFR when IFR might otherwise be possible - Increased exposure owing to the volume and growth of HEMS traffic in the vicinity of helipads - Lack of weather services prevent IFR operations - National Air Space System is not suitable and does not allow for the risk induced through the airspace operating environment to be reduced to as low as reasonably practicable - Assurance for an equivalent level of safety can not be assured - Any desired standard of IFR operations could not be effectively implemented within the current regime of airspace infrastructure - No communication services for hospital helipads - Flights are undertaken at low level when they could be use IFR procedures - In marginal weather conditions ground collision risks are increased - There are no published coordination procedures for operations around facility helipads which may cause collision risks, especially if itinerant operators appear - Lack of published approach/departure procedures force low level arrivals/departures - Inability to manage the broader industry exposure for interaction of HEMS operators with the broader general aviation community - Increased risk of mid air collision of aircraft in and around airports and predominantly uncontrolled airspace 	<p>PRIORITY: 10</p> <p>RESIDUAL RISK: LOW (16)</p>		

Serial No. 18	DESCRIPTION OF RISK	IMPACT OF THE RISK ON THE HEMS INDUSTRY	RISK ASSESSMENT	RISK TREATMENT STRATEGY	RESIDUAL RANKING	
			PRIORITY:	18	RESIDUAL RISK:	LOW (15)
			RISK LEVEL	HIGH (7)	LIKELIHOOD:	LIKELY
			CONSEQUENCE:	MAJOR		
Lack of integration and alignment of accountability, responsibility and resourcing for the standardization of helipad operations in the inter facility environment by hospitals, impacting upon operation, maintenance and continuous hazard management of helipads in the inter-facility environment by hospitals, primary HEMS operator and other helipad users			<ul style="list-style-type: none"> - Lack of standards for hospital helipads increase the risk of sub standard facilities - Uncoordinated departures/arrivals increase collision risk - Lack of procedures increases risk of CFIT - Lack of weather data as part of the approved weather service make IFR operations difficult - Lack of integrations between facilities on accountability and responsibility - Inability to standardized SOP's for inter facility helipads - Confusion between operators on SOPs and preferred practice for varying helipads - Inability to conduct audits and evaluations to an industry standard - Data on hospital helipads is not readily available through the Aeronautical Information Services (AIS) - There is limited (and informal) sharing of operational data on helipads in adjacent locations - Lack of infrastructure and low level ATC system. 			

Serial No. 19 PASSENGER & PARTICIPANT PROFILE	DESCRIPTION OF RISK IMPACT OF THE RISK ON THE HEMS INDUSTRY	RISK ASSESSMENT	RISK TREATMENT STRATEGY	RESIDUAL RANKING
		PRIORITY: 24 RESIDUAL RISK: MEDIUM (12)		

Serial No. 20	DESCRIPTION OF RISK	IMPACT OF THE RISK ON THE HEMS INDUSTRY	RISK ASSESSMENT	RISK TREATMENT STRATEGY	RESIDUAL RANKING
		<p>Owing to the nature of the task profiles conducted in HEMS and the close working relationship the aircrew have with medical personnel involved in the tasks, there is increased blurring of lines of role and responsibility in respect to the medical personnel contribution to safe operation of the aircraft. This risk of ambiguity is increased with medical personnel involvement in NVG operations, passenger briefing, task briefing, loading and unloading of aircraft, operational risk management assessments and crew briefing and debriefing processes.</p>	<p>PRIORITY: 12</p> <p>RESIDUAL RISK: MEDIUM (11)</p>	<p>RISK LEVEL HIGH (4)</p> <p>LIKELIHOOD: LIKELY</p> <p>CONSEQUENCE: CRITICAL</p>	<ul style="list-style-type: none"> - Regulatory clarification of the status of on board medical personnel needs to be provided - Once provided, the implementation of this position and enforcement of compliance with these requirements needs to be undertaken

Serial No. 21	SYSTEMS PROFILE	DESCRIPTION OF RISK	IMPACT OF THE RISK ON THE HEMS INDUSTRY	RISK ASSESSMENT	RISK TREATMENT STRATEGY	RESIDUAL RANKING
	<p>PRIORITY: 8</p> <p>RESIDUAL RISK: LOW (15)</p> <p>RISK LEVEL VERY HIGH (2)</p> <p>LIKELIHOOD: LIKELY</p> <p>CONSEQUENCE: EXTREME</p>					

Generally, safety management systems are only starting to be introduced in the HEMS industry are not yet sufficiently mature to manage the level and depth of change required in the safety philosophies, processes and practices required

- Push back from within EMS organizations resulting in negative perceptions towards what a SMS is and why it should be implemented
- Lack of confidence from operators towards the regulator as a result of not providing guidance for implementation
- SMS becomes a non priority and the status quo takes affect
- Support for SMS from industry is segmented delaying compliance deadlines if set
- Inability to standardize regulatory evaluation and practice of SMS creating confusion in industry
- Fall behind HEMS international best practice
- The potential that key SMS elements are not implemented in a consistent manner across the HEMS industry.
- Operators are unable to obtain a clear picture of the safety risks that impact on their organization.
- Safety information is not collected
- Strategic and operational decisions may be made without a full knowledge of the safety position of the HEMS operator
- The industry is not yet in a position where safety efforts are data driven
- The safety risk profile for the aviation aspects of the SMS are catered for appropriately
- Incident reporting may not get adequately fed back to the leaders driving change in the HEMS industry
- The real safety culture within the HEMS industry may remain unknown
- There is no requirement for operators to have a Safety Management System in line with aviation industry standards
- Safety information within the operators organization and parachuting industry might not be adequately disseminated
- Continued lack of SMS professionals

- Call the industry to action to commit to the implementation of Safety Management Systems prior to its mandated compliance based timelines
- Seek the industry's commitment to adopt an integrated SMS that covers the medical, aviation and communication aspects of HEMS industry
- Develop practical resources for those commencing implementation
- Develop and make available to industry education and training for those that are leading the implementation and introduction of their SMS
- Provide a mechanism to measure the uptake and effectiveness of SMS implementation – providing a benchmark for industry that matures over time

Serial No. 22	DESCRIPTION OF RISK	IMPACT OF THE RISK ON THE HEMS INDUSTRY	RISK ASSESSMENT	RISK TREATMENT STRATEGY	RESIDUAL RANKING
		<p>Aviation and medical safety management systems are not integrated at a compliance or policy level leading to incoherent, conflicting or competing priorities or practices which may stifle the effective introduction of the SMS within the HEMS Industry</p> <ul style="list-style-type: none"> - The HEMS Operator SMS from a pure regulatory perspective only addresses half the operation (aviation aspect), half the aircraft and half the crew (personnel employed by certificate holder) - Lack of agreement between aviation and medical leaders of a HEMS Operator on the importance, scope and resourcing of the SMS - A key functional part of the HEMS industry may not be catered for within the HEMS - The safety management system adopted does not cover the full spectrum of activities covered by the HEMS Operator - Duplication of efforts, policies and practices in respect to the aviation and medical SMS and other existing systems such as the medical quality management / quality improvement systems - Different underpinning philosophies are adopted for the two key aspects of the HEMS team - Differences of opinion of leaders of the HEMS industry or the HEMS Operators - Lack of allocation of resource or commitment to effectively implement - Increased occurrence of the HEMS industry simply re-branding their current safety program as an SMS - Operational risk profiles (risk assessment) only take into account part of the decision making process - The opportunity to increase the rate of implementation of SMS across the EMS Industry is lost - Attitude within the industry that SMS is not needed or will not be implemented unless it is driven by the regulator of the specific discipline - The general absence of any contractual requirement for safety management systems between Medical Programs and EMS Programs. 	<p>PRIORITY: 25</p> <p>RESIDUAL RISK: MEDIUM (14)</p>		

Serial No. 23 DESCRIPTION OF RISK	IMPACT OF THE RISK ON THE HEMS INDUSTRY	RISK ASSESSMENT	RESIDUAL RANKING
		RISK TREATMENT STRATEGY	PRIORITY:
	<p>The potential risk associated with ineffective implementation of operational control arrangements within the HEMS industry leading to the increased chance of poor operational decisions not being identified and intercepted.</p> <ul style="list-style-type: none"> - Misalignment of accountability and responsibility for flight operations. - Tasking decisions can be made without the pilot having access to all the necessary information - Decision making en route can be made without the pilot having all the necessary information - Pilot may be unaware of key changes to operationally significant information - Poor information flow and suboptimal decision making both pre and during flight. - Management of resources may be less effective - The probability of flying into IMC and in particular hazardous conditions such as fog at night are increased - Increased potential for aborted missions - Poor communication and/or administrative procedures 	<p>PRIORITY: 26</p> <p>RESIDUAL RISK: MEDIUM (12)</p> <p>RISK LEVEL HIGH (9)</p> <p>LIKELIHOOD: UNLIKELY</p> <p>CONSEQUENCE: EXTREME</p> <ul style="list-style-type: none"> - Adoption of advanced operational control arrangements - Commission a formal comparative study between the operational control model of Part 121 and Part 135 operators to assess the benefits and suitability of the approach to the context of HEMS operations - Develop formal strategies to review and improve communication both between operators operating in the same area and internally within companies. - In respect to sending and receiving aspects of the HEMS operational equation, consider the viability of the application and adaptation of 'operational control' to the healthcare and EMS arrangements – and if implemented adopt a performance or outcome based regime to provide flexibility yet consistency in application 	

Serial No. 24	SAFETY PROFILE & PARTICIPANT PROFILE				
	DESCRIPTION OF RISK	IMPACT OF THE RISK ON THE HEMS INDUSTRY	RISK ASSESSMENT	RISK TREATMENT STRATEGY	RESIDUAL RANKING
			PRIORITY:	16	RESIDUAL RISK:
			LIKELIHOOD:	CERTAIN	MEDIUM (14)
		<ul style="list-style-type: none"> - Safety priorities are driven from an experiential base rather than a data based model - There is no centralized data source that the Industry can draw upon to drive industry safety change - The industry is driven by reactive data (accident statistical analysis) rather than proactive risk based surveillance and analysis - Data collection activities are fragmented and may posses gaps - The scope of risk of the industry sector and in particular the safety exposure is unknown - Without an ongoing analysis of standardized industry data the potential exists that early warning of industry safety risks will not be identified in time for the implementation of corrective action across the industry - Data collected cannot be accurately collected <ul style="list-style-type: none"> - do you mean cannot be validated? - A comparison, identification of change, or the monitoring of trends can not easily be achieved - HEMS operators are always “fighting fires” in regards to safety issues - Safety monitoring is not data driven leading to emotive rather than fact based change - Safety and risk documentation stagnates and losses relevance to operations. - Degenerative culture that doesn't fully comprehend consequence of actions - Inability to trend accurately resulting in poor data analysis and incorrect findings with subsequently inappropriate treatment strategies - No evolution of data analysis - The down side of risks are only ever evaluated missing opportunities that may present themselves. - “Good catches” are not recognized, analyzed or rewarded resulting in poor morale amongst EMS personnel - Negative media coverage, industry safety statistics and mismanagement of SMS - Inaccurate statistics and reporting. 			

Serial No. 25	DESCRIPTION OF RISK	IMPACT OF THE RISK ON THE HEMS INDUSTRY	RISK ASSESSMENT	RISK TREATMENT STRATEGY	RESIDUAL RANKING	PRIORITY:	19
		<ul style="list-style-type: none"> - Crew are unprepared for unusual or rare situations - Crew are unprepared for emergency situation such as engine failure - Crew cohesiveness not as strong and structure as it might be - Traditional training methods do not provide appropriate training for unusual or emergency situations - Limited knowledge of strengths and weaknesses of new technology - Decision making and risk management less structured that it could be - An established culture that has built a resistance to change as a result of inadequate safety and risk management education through the EMS educational process - Lack of confidence within the HEMS community because of the varying educational requirements and limited standardized across the country - Inability to audit and evaluate against an industry criteria. - Inability to benchmark against international training standards - The desired level of pilot skill based and training standards are not adequately achieved 	<p>RISK LEVEL HIGH (7)</p> <p>LIKELIHOOD: LIKELY</p> <p>CONSEQUENCE: MAJOR</p>			RESIDUAL RISK:	MEDIUM (11)

Serial No. 26	DESCRIPTION OF RISK	IMPACT OF THE RISK ON THE HEMS INDUSTRY	RISK ASSESSMENT	RISK TREATMENT STRATEGY	RESIDUAL RANKING
			PRIORITY: 13	RESIDUAL RISK: MEDIUM (12)	
			RISK LEVEL HIGH (5)	LIKELIHOOD: POSSIBLE	
			CONSEQUENCE: EXTREME		

The risks associated with the lack of development of a tangible safety culture that truly understands risk and the management of risk

- The desired level of pilot skill based and training standards are not adequately achieved
- The industry culture can reward risk taking behavior
- The industry is just beginning to implement safety management systems
- Senior management may not be aware of the importance of a reporting culture
- The status quo is maintained as a result of inadequate regulation and guidance from industry
- The HEMS industry becomes non sustainable
- The industry develops a poor reputation in the aviation sector resulting in inability to attract a sustainable workforce
- “old school of thinking” is maintained leading to increased challenges to truly achieve the desired culture
- Implementation of change takes longer than required
- Resilient staff over-motivated to transport and care for critically injured/ill patients
- Lack of human factor tools/initiatives

- Develop an 10 point industry plan for cultural change including the industry's list of most unacceptable behaviours, practices and attitudes and seek commitment from Air Operators, customer and industry groups alike to join the campaign to enhance the culture
- Implement an agreed industry wide education campaign for the industry in respect to the complexities of the safety equation in the HEMS industry
- Implement a dedicated executive seminar series for senior leaders within the industry at the governance and program management levels
- Implement a dedicated customer and user training series to encourage the customer base to play a more active role in oversight and governance
- Develop a serious socialised marketing and communications campaign to promote and instil the key messages and behaviours within industry
- Design and implement a culture that rewards sound risk decision making
 - Adopt just culture and non-punitive reporting systems across industry
 - Redesign and update of current crew resource management (CRM) and Air Medical Resource Management (AMRM) training to better reflect 5th or 6th generation CRM (including error and threat management etc) as part of an wide human factors standards and program.

PART 4

Supporting Appendices

Appendix A

HEMS IRP STAKEHOLDER AND DISTRIBUTION LIST

Aerospace Medical Association (AsMA)

Aerosafe Risk Management

Air Medical Operators Association: United in Safety (AMOA)

Air Medical Operators holding a Part 135 Certificate (copy per organization)

Air Medical Programs (copy per organization)

Air Medical Physicians Association (AMPA)

Air and Surface Transport Nurses Association (ASTNA)

American Academy of Pediatrics (AAP)

American Ambulance Association (AAA)

American Association of Critical Care Nurses (AACN)

American Association for Respiratory Care (AARC)

American College of Emergency Physicians (ACEP)

American College of Surgeons (ACS)

American Hospital Association (AHA)

American Helicopter Society (AHS)

American Society for Healthcare Engineers (ASHE)

American Society for Healthcare Risk Management (ASHRM)

Association of Air Medical Services (AAMS)

Aviation Safety Network Executive Group (ASN)

Aviation Safety Network Alumni (ASN Alumni)

Bell Helicopters Textron

Commission Accreditation of Medical Transport Systems (CAMTS)

Department of Health and Human Services

Emergency Nurses Association (ENA)

Federal Aviation Administration (FAA)

Flight Safety Foundation

Foundation for Air-Medical Research and Education (FARE)

Government Accountability Office (GAO)

Helicopter Association International (HAI)

Helicopter Emergency Medical Services Committee

House Aviation Sub Committee

International Association of Flight Paramedics (IAFP)

International Helicopter Safety Team (IHST)

International Standards Organization Committee for Risk Management

National Association of Air Medical Communications Specialists (NAACS)

National Air Transport Association (NATA)

National Association of EMS Physicians (NEMSP)

National Association of Emergency Medical Technicians (NAEMT)

National Association of Neonatal Nurses (NANN)

National Association of State EMS Officials (NEMSO)

National EMS Pilots' Association (NEMSPA)

National Transportation Safety Board (NTSB)

Patients First Air Ambulance Alliance (PFAA)

Risk & Insurance Management Society Inc (RIMS)

The Joint Commission

Appendix B

SUPPORTING DOCUMENTATION

Accompanying Documentation:

- Executive Summary: An executive summary is provided to assist the industry in understanding the background, scope and contents of the HEMS IRP. The next steps for risk reduction are also outlined.
- HEMS Industry Risk Reduction Plan: the main driver of assessing risk is to proactively reduce risk through the implementation of risk treatment strategies of solutions to the risk issues. Following the release of the HEMS IRP a facilitated process will take place calling for submission by stakeholders who wish to take carriage of industry wide risk reduction measures. This work will be compiled into the HEMS Industry Risk Reduction Plan.

Information Packages

- Technical Media Briefing Package: Given the comprehensive nature of the information presented in the HEMS IRP, a technical briefing was delivered to the media on Monday April 20, 2009 at the National Press Club in Washington DC.
- FAQs: Frequently asked questions are provided as a supporting resource.

Guide & Template

- Industry Submission – Risk Treatment Strategies: Guidance material has been made available to industry to assist in the preparation of their submission of risk treatment strategies that will be compiled in the HEMS Industry Risk Reduction Plan.
- Guide for Associations – How to use the HEMS IRP: Provided for use by industry associations and groups to inform their members and boards.
- Guide for Air Medical Operators – How to use the HEMS IRP: Provided for use by Part 135 Operators to assist in understanding how the HEMS IRP can be utilized at an organizational level by Board Members, CEOs and Company Executives.
- Guide for Air Medical Programs – How to use the HEMS IRP: Provided for use by Air Medical Programs to assist in understanding how the HEMS IRP can be utilized at an organizational level by Board Members, Hospital Executives CEOs, Program Directors, Program Executives.
- Guide for State EMS Agencies – How to use the HEMS IRP: Provided to State EMS Agencies in order to provide information on how the HEMS IRP could be utilized at the State level.

Appendix C

ABBREVIATIONS

AAMS	Association of Air Medical Services
ADS(B)	Automatic Dependent Surveillance - Broadcast
AHS	American Helicopter Society
AMOA	Air Medical Operators Association: United in Safety
AMRM	Air Medical Resource Management
ATC	Air Traffic Control
CRM	Crew Resource Management
EMS	Emergency Medical Services
FAA	Federal Aviation Administration
FARE	Foundation for Air-Medical Research and Education
FOQA	Flight Operation Quality Assurance
FSF	Flight Safety Foundation
GAO	Government Accountability Office
HAI	Helicopter Association International
HEMS	Helicopter Emergency Medical Services
HTWAS	Helicopter Terrain Warning Avoidance System
IFR	Instrument Flight Rules
IHST	International Helicopter Safety Team
IMC	Instrument Meteorological Conditions
IRP	Industry Risk Profile
IRSMS	Integrated Risk & Safety Management Systems
ISO	International Standards Organization
JSAT	Joint Safety Analysis Team (part of IHST)
JSIT	Joint Safety Implementation Team (part of IHST)
NTSB	National Transportation Safety Board
NVG	Night Vision Goggles
SMS	Safety Management Systems
VFR	Visual Flight Rules

Appendix D

PROJECT CONTACT DETAILS AND PROJECT ACKNOWLEDGEMENTS

Project Contact	Kimberley Turner Chief Executive Officer Aerosafe Risk Management 1325 G Street NW Washington DC Ph: 202 449 7693 Fax: 202 449 7701 kturner@aerosafe.com.au
Staff Acknowledgments	In addition to the contact named above, Bradley Glassington, HEMS IRP Project Manager; Robin Graham, Senior Risk Advisor (Aviation); John W. Overton, Jr., M.D., Senior Risk Advisor (Medical) and Katherine Robinson, Senior Planner & Communications Manager have all made key contributions to this report. Graphic Design provided by GraphikExposure.
Technical Review	Special thanks to Kevin W Knight, Chairman ISO Standards Committee Risk Management for undertaking a technical review of the HEMS IRP.
Custodian of the HEMS IRP	Flight Safety Foundation is to be commended for their enthusiasm in taking on the role as custodian of this body of work. It is with great appreciation and deepest thanks to Joan Sullivan Garrett, Vice Chairman Flight Safety Foundation; William R. Voss President and CEO Flight Safety Foundation; Emily McGee, Director of Communications for the support and interest in this initiative.
Review & comment on the Draft HEMS IRP	The opportunity for review and comment on the draft HEMS IRP was provided to 33 different stakeholder groups. Additional resource, dedicated briefings or a workshop was held with AAMS, AHS, AMOA, AMPA, CAMTS, FAA, FARE, Flight Safety Foundation, GAO, HAI, House Aviation Sub Committee, International Helicopter Safety Team, NEMSPA, NTSB and The Joint Commission. The project team would like to thank these organizations for the time taken to review, discuss and provide feedback on either the concept of utilizing risk management at the industry level or the provision of comment on the draft HEMS IRP over the period February 12, 2009 – April 15, 2009.
Obtaining Copies of the HEMS IRP	Flight Safety Foundations web site www.flightsafety.org Copies are available at no cost.
Order by mail or phone	The Foundation of Air Medical Research and Education has taken on responsibility for printing and distribution of the HEMS IRP to industry. Contact details for ordering copies are on the back cover of this document. Special acknowledgment and thanks to FARE Board, their Chair Dr Kevin Hutton and staff for their ongoing commitment to safety research & education.

The HEMS Industry Risk Profile helps fulfill FARE's mission of raising awareness, and advancing research in the emergency-medical-transport field. FARE is distributing this document, in its hardcopy form, to air-medical service professionals and others interested in the field to be used as a tool in advancing safety for the entire HEMS community.

To order your copy of the HEMS IRP go to
www.fareonline.org

FOR MEDIA INQUIRIES, CONTACT:



EMILY MCGEE, Director, Communications
Flight Safety Foundation, 601 Madison Ave, Alexandria VA 22314
Phone: 703 739 6700 Email: mcgee@flightsafety.org

FOR INQUIRIES ON THE HEMS IRP, CONTACT:



BRADLEY GLASSINGTON, HEMS IRP Project Manager
Aerosafe Risk Management, 1325 G Street NW, Washington DC
Phone: 202 449 7693 Email: bglassington@aerosafe.com.au

TO REQUEST YOUR COPY OF THE HEMS IRP CONTACT:



AMBER BULLINGTON, Program Manager
Foundation Air Medical Research and Education
526 King Street, Suite 415, Alexandria, VA 22314
Phone: 703 836-8732 Email: abullington@aams.org