

VOLUME 4 AIRCRAFT EQUIPMENT AND OPERATIONAL AUTHORIZATIONS**CHAPTER 5 AIR AMBULANCE OPERATIONS****Section 5 Safety Assurance System: Operational Risk Analysis Programs for Helicopter Air Ambulance Operations****4-981 BACKGROUND.**

A. Introduction. Helicopter air ambulance (HAA) operations are commercial aviation activities that are performed by a certificated air carrier, and are required to be conducted with the highest level of safety. To meet this requirement, risks must be identified, assessed, and managed to ensure that they are mitigated, deferred, or accepted according to the operator's ability to do so and within the regulations and standards appropriate to the operation. Evaluation of an HAA operator's Federal Aviation Administration (FAA)-approved risk analysis program should include their documentation, training and operational use of the regulatory-required program. This section is related to Safety Assurance System (SAS) Element 3.3.1 (OP), Operational Control. The basic concepts of risk management include:

1) The pilot in command (PIC) retains the final authority to decline a flight assignment. His or her decision to accept a flight assignment is subject to review if identified risks exceed an operator-defined risk threshold.

a) The PIC's decision to decline, cancel, divert, or terminate a flight overrides any decision of other parties to accept or continue a flight.

b) The PIC's decision to accept a flight assignment may be overridden by other personnel through the use of established and documented operational control procedures and policies of the certificate holder, including the use of risk analysis and management tools and techniques.

2) If the PIC has declined a flight assignment, no other parties (management, operations, etc.) should continue to conduct risk analysis pertaining to that flight, as their input could not be used to override the pilot's decision to decline the assignment.

3) A preflight risk analysis is a tool used by the operations control staff and flightcrews to expand the parameters of decisionmaking for the PIC and flightcrew and to assist in preflight planning and operational control of the aircraft. The operator must have procedures defining how to mitigate excessive risk to an acceptable level or, alternatively, to decline the flight.

4) If the PIC's initial risk analysis indicates a significant level of risk, the next step is to follow the operator's documented risk analysis plan and implement a risk mitigation process. This must be completed, and the risk must be reassessed, taking into consideration proposed mitigation measures. If the risk mitigation process successfully reduces the high-risk elements and the residual risk falls below the acceptance limit, the final risk may be considered acceptable and the flight may be authorized.

5) As potential hazards are identified in the risk analysis process, the Operations Control Specialist (OCS) may assist the flightcrew in preflight risk mitigation strategies and controls. Such joint decisionmaking should never result in the questioning or overruling of the PIC's decision not to make a flight and instead should focus on mitigating the risk through changes made in the flight parameters to reduce the risk to the maximum extent practical, in an attempt to fall below the operator's documented acceptable level.

B. Preflight Risk Analysis: Regulatory Requirement. An inspector must evaluate the operators' implementation of the overall risk analysis program. Title 14 of the Code of Federal Regulations (14 CFR) part 135, § 135.617 mandates each certificate holder conducting HAA operations must perform a risk analysis prior to initiation of the first leg of each HAA flight operation. This analysis should consider not only the primary intended flight operation but also all contingencies that can reasonably be foreseen. If diversion to a different destination is received in flight and the newly offered assignment falls within risk contingencies already evaluated, the PIC does not have to land and perform a new risk analysis prior to accepting the assignment offering a change in destinations.

C. Preflight Risk Analysis Worksheet. Section 135.617, Preflight Risk Analysis, requires that an FAA-approved preflight risk analysis program be established by each HAA operator. This program must be documented.

1) In accordance with the provisions of § 135.617(d), certificate holders conducting HAA operations must use and retain preflight risk analysis worksheets. Preflight risk analysis worksheets (paper or electronic means) are completed and signed by the PIC in accordance with the certificate holder's documented program. Electronic signature or other means acceptable to the principal operations inspector (POI) may be applied in lieu of a physical signature.

2) The OCS (if applicable), in compliance with § 135.619(a)(4)(iv), will review the completed risk analysis submitted by the PIC. The OCS verifies the content of the worksheet is accurate, and, if the total risk is acceptable, the OCS shall acknowledge in writing that the risk analysis is complete and accurate, and that, in the OCS's professional judgment, the flight may be conducted safely. This OCS acknowledgement, to include the date and time the risk analysis has been reviewed, may be separate from the risk analysis worksheet. All preflight risk analysis worksheets must be retained for at least 90 days from the date of the flight. The risk analysis program is outlined in the current edition of Advisory Circular (AC) 135-14, Helicopter Air Ambulance Operations, paragraph 3-4 and Appendix A, which also includes examples of suggested preflight risk analysis worksheets. Any format is acceptable.

D. Risk Factors Analyzed. The preflight risk analysis quantifies at least the following risk factors:

- 1) **Aircraft Performance, Flight Route and Landing Area Considerations.**
- 2) **Current and Forecast Weather.**
- 3) **Human Factors.** This includes sources of stress such as health, fatigue, circadian effects, flight difficulty, operational complexity, and potentially distracting life events. All these are among the many potential contributors to human failure. Human factors considerations

should include information such as pilot experience level (both in general and reflecting the specific area of operations or type of HAA) and operation-specific hazards that also reflect environmental factors.

4) Declined HAA Flight Requests. The operator must establish a procedure for determining whether another HAA operator has declined the flight request under consideration and, if so, for what reason. This information must be factored into the required risk analysis process (if applicable, refer to AC 135-14, paragraph 3-4). The required procedure for determining whether another HAA operator has refused or rejected a flight request as required by § 135.617(a)(4) must be documented. This procedure could be as simple as having the individual receiving the request (whether or not an employee of the operator) ask the requestor whether or not he or she has already received a refusal for this same request and, if so, for what stated reason (e.g., weather or equipment out of service).

5) Risk Determined Independent of Patient Condition. Best practices in the industry indicate the medical condition of a patient should not be considered in the risk analysis process and that the PIC should not be briefed on this factor in advance of decisionmaking.

E. Mitigation. Identified risks may be mitigated by changing how a proposed HAA flight is conducted. The operator must develop and document strategies and procedures for controlling risks imposed by identified hazards. For examples of mitigation, refer to AC 135-14, Appendix A.

F. Calculation of Residual Risk. After risk is analyzed, quantified, and mitigated, the degree of residual risk is assessed. Residual risk is the safety risk that exists after all controls have been implemented or exhausted and verified.

G. Elevation of Higher Risk Analysis to Appropriate Management. An HAA operator is required to define risk-based flight authorization limits based upon a quantitative risk analysis for each specific flight. Risk analysis results that exceed the certificate holder's predetermined limit are referred to an appropriate manager with operations control authority for review and approval or denial of the request.

H. Reconsideration of Flight Authorization. Material changes in any of the major risk factors considered in the decisionmaking process must trigger reconsideration of flight authorization. This especially applies to deterioration in weather or other environmental conditions.

4-982 INSPECTOR RESPONSIBILITIES. Inspectors should evaluate the operator's preflight risk analysis policies, procedures, forms, and instructions to verify compliance with § 135.617. Each operator will consider its own operational and environmental needs in developing its risk analysis tool(s) and plans and will design its risk analysis program accordingly.

A. Evaluation of Risk Analysis Program. The inspector must ensure the regulatory requirements are observed by the operator in their risk analysis program. This evaluation should focus on:

1) All regulatory risk factors for a particular (potential) flight (refer to § 135.617(a)) are considered and incorporated in the risk analysis worksheet. An example of this is shown in AC 135-14, Appendix A.

2) Additional operator-designated risk factors (considering flight environment, aircraft limitations, pilot qualification, recency of experience, familiarity with the area, preparedness, etc.) may be added (in accordance with § 135.617(a)(5)(b)) if they are an integral part of a documented methodology that has been used for training by the operator.

3) Documented and operator-accepted or operator-approved mitigation strategies (for which training has been provided) may be applied and risk recalculated. If overall residual risk remains above an operator-designated and documented approval level or threshold, joint decisionmaking, to include OCS (as applicable) concurrence and/or higher level management concurrence, must be obtained prior to initiating the flight.

B. Guidance and References. Inspectors assigned to HAA operators should review this guidance, applicable ACs, and the applicable regulations before evaluating a certificate holder's risk analysis programs. The principal inspector (PI) should evaluate the operator's documented processes and controls, along with the documentation and implementation of training in the application of these procedures, to verify that regulatory required and safe risk analysis practices are being applied in HAA flight operations.

RESERVED. Paragraphs 4-983 through 4-990.