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16. Abstract

- **INTRODUCTION.** The purpose of the study is to determine the Acceptable Level of Safety (ALOS) for pilot incapacitation in part 121 operations when the assumptions underlying the internationally recognized "1% rule" are revised using current data. The study was begun as a response to FAA Order VS 8000.367D, *AVSSMS with QMS Requirements:* Oversight organizations [such as the Office of Aerospace Medicine] must determine the acceptable level of safety performance for those components of the aerospace system for which they have oversight responsibility. The 1% rule was used as a model because it was the initial framework linking aeromedical risk acceptance to airworthiness risk accepted by engineers, it has been incorporated into European Joint Aviation Authorities' guidance, it is accepted in EASA guidelines, and has been endorsed by ICAO as threshold of choice. **METHODS.** A literature search produced 1% rule information that was deconstructed to give eight statements which, together, provide a logical development for the existing rule. Each of these statements was then examined, in view of literature, to determine whether it was still operable and whether it was consistent with aviation regulations and practices within FAA jurisdiction. Each statement that was no longer operable or FAA consistent was replaced using information developed from current literature. The resulting rule was assessed using FAA Order 8040.4C. **RESULTS.** Order 8040.4C specifies three levels of safety risk: low risk is acceptable without active management, medium risk is acceptable without mitigation but requires tracking and monitoring, and high risk can only be accepted by AVS-1. A critical parameter, number of accidents per incapacitation event during critical period, has been set at three different values in the literature: 0.01, 0.005, and 0.0025. For the most conservative of these, 0.01, the modified rule results in a medium risk level as a 1% and a 2% rule (but not 5%). And for the 0.005 parameter value the modified rule results in a medium risk level as 1%, 2%, and 5% rules. The 0.0025 parameter value results in a low risk as a 1% rule and medium risk as 2% and 5% rules. **DISCUSSION.** At least two of the assumptions used to develop the modified rule bear further scrutiny: the actual number of accidents per incapacitation event during critical period should be reviewed – is it 0.01, 0.005, 0.0025 or something else? The assumption that a fatal accident results only if (a) incapacitation event occurs, (b) critical phase of flight, and (c) ineffective assumption of control by second pilot is central to the risk analysis, and should be reviewed.

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Refreshing the “1% Rule” as the Basis for an AAM Acceptable Level of Safety

Presented to: AAM Safety Council

By: Richard Greenhaw and Anthony Tvaryanas

Date: 6/20/2023

Federal Aviation Administration

Objective

Determine the Acceptable Level of Safety (ALOS) for pilot incapacitation in part 121 operations when the assumptions underlying the internationally recognized “1% rule” are revised using current data

AVS SMS requirements

- Office of Aerospace Medicine part of the “AVS oversight organization”
- FAA Order VS 8000.367D, *AVSSMS with QMS Requirements:* Oversight organizations must determine the **acceptable level of safety** performance for those components of the aerospace system for which they have oversight responsibility

1% rule background

- Premised on AsMA paper (1973) linking aeromedical risk acceptance to airworthiness risk accepted by engineers
- Proposed at the first UK Workshop on Aviation Cardiology (1984)
- Incorporated into European Joint Aviation Authorities' guidance
- Accepted in EASA guidelines
- Endorsed by ICAO as threshold of choice
- Transport Canada
  - 2% annual incapacitation risk for all certificate classes
  - 5% annual incapacitation risk if flying with a certified safety copilot
- Not used by the FAA to date

1% rule development: Rationale / assumptions

Rule statements	Rationale / assumptions
1) Likelihood of incapacitation event in a year ≤1%	Proposed pilot medical certification threshold
2) This is about 10^{-6} incapacitation events/hour	= 0.01 events per 24x365 = 8,760 hours ≈ 10,000 hours ≈ 0.01 events per 10,000 hours = 1 event/1,000,000 hour
3) Flight duration is about 1 hour	Early 1980s European air carrier typical flight time
4) Assume fatal accident only if (a) incapacitation event occurs, (b) critical phase of flight, and (c) ineffective assumption of control by second pilot	Assume that second pilot will always take control effectively during non-critical flight periods
5) Likelihood of event occurrence during a 1-hour flight is about 10^{-6}	Assume uniform distribution of pilot incapacitations and there are 10,000 hours in a year
6) Probability flight in critical period when incapacitation event occurs about 10% (10^{-1})	Assume 10% of flight time is in critical period (i.e., below 1500 ft AGL)
7) Probability second pilot fails to assume effective control in response to incapacitation event during a critical period is about 10^{-2}	A single study of airline simulator training that incorporated pilot incapacitation event during approach to landing
8) Probability of (a), (b) and (c) = 10^{-2} x 10^{-6} x 10^{-1} = 10^{-9}, therefore acceptable	The individual probabilities can be multiplied yielding the probability 10^{-9}, which is an acceptable level of risk

Evaluation of 1% rule statements

Rule statements	Assessment	Revisions
2) This is about 10^{-6} incapacitation events/hour	Inaccurate	1.14×10^{-6}
3) Flight duration is about 1 hour	Inaccurate	2 hours
4) Assume fatal accident only if (a) incapacitation event occurs, (b) critical phase of flight, and (c) ineffective assumption of control by second pilot	Implicit assumption, accept as valid	---
5) Likelihood of event occurrence during a 1-hour flight is about 10^{-6}	Inaccurate	1.17×10^{-6}
6) Probability flight in critical period when incapacitation event occurs about 10% (10^{-1})	Inaccurate	3.00×10^{-2}
7) Probability second pilot fails to assume effective control in response to incapacitation event during a critical period is about 10^{-2}	Debatable	0.0025, 0.0050, 0.0100
8) Probability of (a), (b) and (c) = $10^{-2} \times 10^{-6} \times 10^{-1} = 10^{-9}$, therefore acceptable	Valid but inapplicable	Use FAA Order 8040.4C

Weakest assumptions

- Fatal accident only if (a) incapacitation event occurs, (b) critical phase of flight, and (c) ineffective assumption of control by second pilot
  - Concurrent, independent medical incapacitation events statistically unlikely
  - Assumes negligible risk of single pilot completing non-critical flight period
- Probability second pilot fails to assume effective control in response to incapacitation event during a critical phase of flight is about 10^{-2}
  - Actual rate in simulator study (1984) was 1 failure in 400 incapacitations (0.0025)
  - Failure rate adjusted to 0.0100 to account for simulation artifact (event expectation)
  - Debate about impact of interval technological and CRM advancements on likely failure rate
  - 2004 paper suggested using a failure rate of 0.0050 (doubling the simulator study failure rate)

Risk analysis

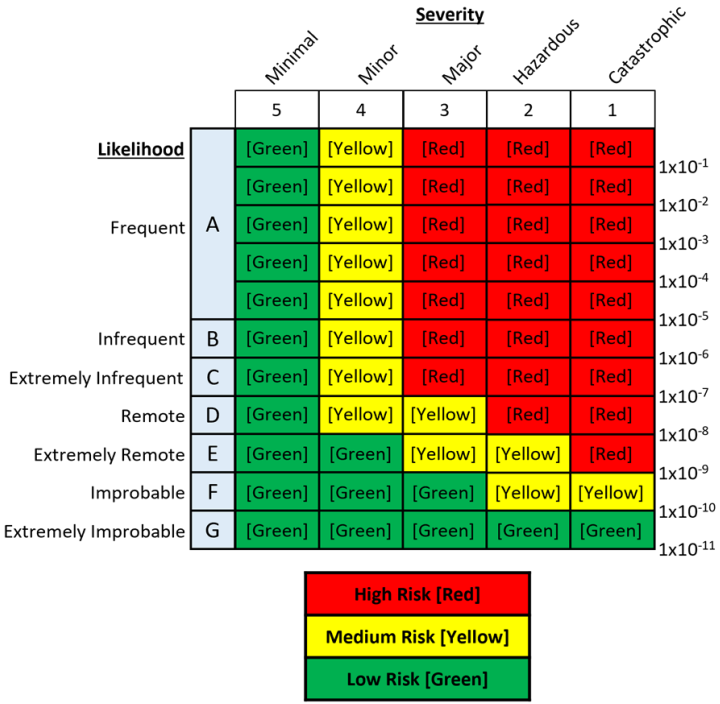
$$AF = (N \times AC) \times P + (N \times AN) \times (1 - P)$$

AF	Accidents per flight hour
N	Number of incapacitation events per hour
AC	Number of accidents per incapacitation event during critical period
AN	Number of accidents per incapacitation event during noncritical period
P	Proportion of flight that is the critical period

Legacy 1% rule	
N	10^{-6}
AC	10^{-2}
AN	0
P	10^{-1}
AF = (*N* x *AC*) x *P* + 0 = 10^{-6} x 10^{-2} x 10^{-1} = 10^{-9}	

Update % rule	
N	1.17 x10^{-6}
AC	10^{-2}
AN	0
P	3 x 10^{-2}
AF = (*N* x *AC*) x *P* + 0 = (1.17 x10^{-6}) x 10^{-2} x (3 x 10^{-2}) = 3.1 x 10^{-10}	

Risk assessment (FAA Order 8040.4C)



Annual incapacitation risk (ALOS)	Number of accidents per incapacitation event during critical period	Accidents per flight hour	Risk Level
1%	0.0100	3.51×10^{-10}	Medium
2%	0.0100	7.02×10^{-10}	Medium
5%	0.0100	1.76×10^{-09}	High
1%	0.0050	1.76×10^{-10}	Medium
2%	0.0050	3.51×10^{-10}	Medium
5%	0.0050	8.78×10^{-10}	Medium
5.7%	0.0050	1.00×10^{-09}	High
1%	0.0025	8.78×10^{-11}	Low
2%	0.0025	1.76×10^{-10}	Medium
5%	0.0025	4.39×10^{-10}	Medium
11.4%	0.0025	1.00×10^{-09}	High

- High risk requires mitigation, tracking, and monitoring and can only be accepted by AVS-1
- Medium risk is acceptable without mitigation but requires tracking and monitoring
- Low risk is acceptable without active management

Next steps

- **AAM accountable executive:**
  - Determine acceptability of this method for setting an aeromedical ALOS
  - If acceptable:
    - Select value for number of accidents per incapacitation event during critical period (risk appetite)
    - Establish corresponding aeromedical ALOS in safety policy
- **Coordinate with AFX:**
  - Consider joint sponsorship for cooperative research project with industry to repeat the simulation study
  - Evaluate/improve the rigor of the 2-pilot risk control as implemented by airlines
    - Pilot incapacitation recognition
    - Contingency single pilot operations

Questions

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