

of Canada

Transportation Bureau de la sécurité Safety Board des transports du Canada

Canada

TSB Recommendation A23-01

Screening tools for pilot medical exams

The Transportation Safety Board of Canada recommends that the Department of Transport establish a framework for routine review and improvement to the Handbook for Civil Aviation *Medical Examiners* to ensure it contains the most effective screening tools for assessing medical conditions such as cardiovascular health issues.

Air transportation safety investigation report	<u>A21W0089</u>
Date the recommendation was issued	14 March 2023
Date of the latest response	June 2023
Date of the latest assessment	August 2023
Rating of the latest response	Satisfactory Intent
<u>File status</u>	Active

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Summary of the occurrence

On 09 October 2021, the privately registered, amateur-built Cavalier SA102.5 aircraft (registration C-FBWF, serial number 6958) was conducting a local recreational flight from Lacombe Aerodrome, Alberta, with 1 pilot and 1 passenger on board. When the aircraft was 14 nautical miles east of the aerodrome, it entered an aerodynamic stall, resulting in a left-hand spin and collision with terrain. The pilot, who was seated in the left seat, was fatally injured; the passenger received serious injuries. The aircraft was substantially damaged; there was no postimpact fire.

The Board concluded its investigation and released report A21W0089 on 14 March 2023.

Rationale for the recommendation

The Office of the Chief Medical Examiner in Alberta reported that the cause of death was attributed to blunt force trauma with cardiovascular disease as a significant contributing factor. The report also noted that the pilot had evidence of a heart attack, although it was not possible to determine the exact time of this event.

The pilot's Category 1 medical certificate, which was valid until 01 February 2022, did not list any limitations.

The occurrence pilot, who was older than 40, regularly attended a Transport Canada (TC) medical examination every 12 months as required for his airline transport pilot licence. For each visit, a medical examination report was completed as required. However, for his most recent medical certificate, issued in 2021, the pilot did not undergo a medical examination. Instead, he completed and signed an attestation that he did not have any limitations or restrictions or other conditions that could impair his ability to exercise the privileges of the licence. This attestation was allowed in accordance with an exemption issued by TC¹ due to the global COVID-19 pandemic.

There was no cardiovascular risk profiling performed as part of any of the pilot's medical examinations. However, using data from the Civil Aviation Medical Examiner (CAME) medical examinations, the blood lipids from the family physician's records, and various risk-profiling methods, including the Framingham risk scoring tool, an independent cardiology review performed for this investigation confirmed that the pilot's calculated annual risk for a cardiovascular event was approximately 1% per year. This is considered a low-to-average risk for his age, and acceptable for commercial pilot operations. Even if the CAME had performed risk profiling, these results would not have triggered secondary screening testing for underlying coronary disease.

The independent cardiology review highlighted that, although most cardiovascular disease is indicative via blood lipids, some 10–20% of heart attack victims do not present with these traditional risk factors. Therefore, cardiologists advise that other mechanisms may also be required to screen for coronary atherosclerosis. For example, elevated lipoprotein Lp(a) has been identified as a significant additional hereditary risk factor in some individuals. Lipoprotein Lp(a) measurement has been incorporated into the recommended periodic screening for cardiovascular risk.²

An independent cardiology review performed for another TSB investigation³ highlighted that, based on the consensus of a multinational consortium of aviation cardiologists published in 2019,⁴ cardiovascular risk screening should be required for all pilots over the age of 40, and for those pilots identified to be at an increased risk (based on risk calculation). Such screening should always include an assessment of blood lipids and, in some cases, other methods might be needed for the 10–20% of heart attack victims that do not present with traditional risk factors.

¹ Transport Canada, Exemption NCR-062-2020: Exemption from paragraphs 404.03(2)(a) and (b) and 404.04(1)(b) of the *Canadian Aviation Regulations* (03 June 2020).

² G. J. Pearson, G. Thanassoulis, T.J. Anderson, et al., "2021 Canadian Cardiovascular Society Guidelines for the Management of Dyslipidemia and the Prevention of Cardiovascular Disease in Adults," in *Canadian Journal of Cardiology*, Vol. 37, Issue 8 (August 2021), available at onlinecjc.ca/article/S0828-282X(21)00165-3/fulltext (last accessed on 08 August 2022).

³ TSB Air Transportation Safety Investigation A19P0142.

⁴ British Cardiovascular Society, *Heart*, Vol. 105, Supplement 1: Aviation Cardiology (January 2019).

Current TC CAME guidelines, which were published in 2012, only recommend—they do not mandate—enhanced screening using laboratory data, such as screening for blood lipids. Given that it is not policy to screen using laboratory data, CAMEs are not required to use such screening for periodic certification examinations, even for those applicants over the age of 40.

The cardiology reviews conducted for both this occurrence and for TSB Air Transportation Safety Investigation A19P0142 indicate that the TC Civil Aviation Medicine Cardiovascular Guidelines from 2012 have not been updated to include the significant advances in the recommended approach to screening for coronary atherosclerosis. The cardiology review for this occurrence also stated that options for screening could include blood lipids and potentially enhanced laboratory testing for Lp(a), as well as CT (computed tomography) cardiac imaging where possible.

In this occurrence, the cardiologist concluded that if such screening methods were followed, risk factors contributing to the pilot's heart attack may have been identified.

Following a loss of control and collision with terrain that took place in Miramichi, New Brunswick, on 23 April 2010 (<u>investigation report A10A0041</u>), the Board issued a safety concern indicating that medical practitioners may not always be aware of the need or importance of transmitting reportable medical conditions and, further, that deficiencies exist in the guidelines designed to screen for cardiovascular risks.

In 2012, the TC Civil Aviation Medicine Cardiovascular Guidelines were updated.

As of October 2022, there were 32 900 pilots in Canada with Category 1 medical certificates. Of these, 16 607 (approximately 50%) were over the age of 40. Since 2000, there have been 8 accidents, including this one, involving commercial pilots in which cardiovascular disease was identified as a finding as to risk⁵ or finding as to cause.⁶

If TC guidance material and the civil aviation medical examination report do not include up-todate cardiovascular screening methods to perform a global cardiovascular assessment when appropriate, there is an increased risk that cardiovascular disease will remain unidentified and pilots may become incapacitated while operating an aircraft.

Therefore, the Board recommended that

the Department of Transport establish a framework for routine review and improvement to the *Handbook for Civil Aviation Medical Examiners* to ensure it contains the most effective screening tools for assessing medical conditions such as cardiovascular health issues.

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⁵ TSB air transportation safety investigations A19P0142, A14O0077, A07P0357, A07O0165, A03P0265, A02Q0054 and A01P0100.

⁶ TSB Aviation Investigation Report A10A0041.

Previous responses and assessments

N/A

Latest response and assessment

June 2023: response from Transport Canada

Through this investigation, the Transportation Safety Board of Canada (TSB) revealed two safety issues related to ensuring that medical issues that could impact flight safety are identified and addressed.

First, on January 11, 2023, the TSB issued an Aviation Safety Advisory Letter⁷ to Transport Canada Civil Aviation (TCCA) indicating that the investigation found that not all physicians are aware of the requirement to inform TC about medical conditions and/or prescribed medications that could affect the safe operation of an aircraft.

The Department responded⁸ on January 19, 2023, stating that Transport Canada Civil Aviation Medicine (TC CAM) coordinated with the Canadian Medical Association (CMA) to increase awareness of the mandatory reporting obligation outlined by the *Aeronautics Act.*⁹ Specifically, CAM updated the Aviation Medicine section of the CMA Driver's Guide featuring an up-front "alert box"¹⁰ that prominently reminds physicians of their mandatory reporting obligations under the *Aeronautics Act.* In addition, it is clearly indicated for a general practitioner, who is not otherwise a CAME, how to report a potential condition to TC CAM. Given the broad distribution of the CMA Driver's Guide, this will be a high-impact and influential means of communicating the mandatory reporting obligation to Canadian physicians.

Second, as part of the final investigation report, the TSB issued the subject recommendation to address a related safety deficiency about the process for carrying out regular update of guidance for assessing medical conditions such as cardiovascular issues and suggested that TC establish a framework to review and update the Handbook for Civil Aviation Medical Examiners¹¹ (CAMEs).

⁷ Transportation Safety Board of Canada (2023). Air Transportation Safety Advisory Letter A21W0089-D2-A1 – *Physicians' requirement to report to Transport Canada*. [Available at: https://www.tsb.gc.ca/eng/securitesafety/aviation/2023/a21w0089/a21w0089-d2-a1.html]

⁸ Transport Canada (2023). Transport Canada Response to Air Transportation Safety Advisory A21W0089-D2-A1.

⁹ Government of Canada (2023). *Aeronautics Act* (R.S.C., 1985, c. A-2) subsection 6.5(1) – Minister to be provided with information. Available at: https://laws-lois.justice.gc.ca/eng/acts/a-2/page-6.html

¹⁰ Canadian Medical Association (2019). CMA Driver's Guide – 9.1 edition, p. 120. Available at: https://joulecma.ca/publications/drivers-guide

¹¹ Transport Canada (2019). Transport Canada Publication (TP) No. 13312 - Handbook for Civil Aviation Medical Examiners. Available at: https://tc.canada.ca/en/aviation/publications/handbook-civil-aviation-medicalexaminers-tp-13312

TC agrees with the recommendation and the strategy to mitigate this safety deficiency is two-fold.

In the first part of this response, the Department will outline how the Civil Aviation Documentation Framework¹² allows routine reviews and improvement to the CAMEs Handbook to ensure that it contains the most effective screening tools for assessing medical conditions. In the second part, TC will outline the measures in place and plans to assess cardiovascular health risks and issues which could have an impact on the safe operation of an aircraft.

1. Document Framework and Handbook Update

TC CAM has been actively updating the content of the Handbook for CAMEs (TP13312) since 2019. The process of updating the Handbook for CAMEs involves repealing and replacing sections of the Handbook with the corresponding Staff Instructions (SI), as they go into force. Eventually, the Handbook will be replaced in its entirety by SI documents.

The SI format¹³ is a standardized TC departmental document format chosen to facilitate use of and future regular updating of aeromedical policy topics. SIs provide TCCA employees with specific information and procedures to standardize the delivery of the Civil Aviation Program. They are consistent with departmental principles, policies, and regulatory requirements and are normally national in scope. Also, the SI format supports a modular (i.e., single topic) approach to treating aeromedical subjects, which is generally how medical references manage topics. This format also makes drafting, publication, and updating faster and easier. The TP format (on which the actual Handbook is built) tends to result in a monolithic "textbook" that is not currently the standard for online medical resources and makes resources longer to produce.

SIs are also available through the Civil Aviation Reference Centre.¹⁴ However, TC CAM is working with Digital services and Web services to provide both a CAME and public facing library for ease of reference. TC CAM also circulate SIs by email to CAMEs and to any member of the public requesting them, in the meantime.

The first aeromedical SI¹⁵ was effective as of March 12, 2019 and established the foundational principles of aeromedical decision-making for TC CAM and CAMEs.

TCCA also recently issued other aeromedical SIs that either add-to or update Handbook content:

¹² Transport Canada (2019). Civil Aviation Directive (CAD) No. QUA-002 – *Civil Aviation Documentation Framework*.

¹³ Transport Canada (2019). Staff Instruction (SI) No. QUA-003 – *Civil Aviation Document Development Procedures*.

¹⁴ Transport Canada (2023). *Civil Aviation Reference Centre*. Available at : https://tc.canada.ca/en/aviation/reference-centre

¹⁵ Transport Canada (2019). Staff Instruction (SI) No. 404-001 – *Aeromedical Risk Assessment and Risk Management*.

- SI 424-001 Aviation Medical Review Board Terms of Reference¹⁶ effective 12 March 2019.
- SI 404-002 *Civil Aviation Medicine Cannabis Policy*¹⁷ effective 03 June 2019.
- SI 404-003 *Civil Aviation Medicine Credentialing Requirements*¹⁸ effective 01 January 2020.
- SI 424-002 *Civil Aviation Medicine Directive Substance Use Disorder*¹⁹ effective 01 March 2020 with second update effective 03 June 2022.

TCCA have other SIs currently in the final stages of approval that will add or update the Handbook:

- "Depression and Anti-Depressant Medications"
- "Attention Deficit / Hyperactivity Disorder"
- "Medications and Aviation Medical Certification"

Ultimately, this collection of SIs will provide CAMEs with all the necessary and relevant information regarding TC CAM's policies based on the most recent screening tools used to assess various medical conditions that could have an impact on the safe operation of an aircraft.

2. Cardiovascular Health Issues Assessment

As noted above, the first foundational aeromedical staff instruction SI 404-001²⁰ was published in 2019. It describes the framework for aeromedical risk assessment (RA) and risk management (RM) for use in the medical certification process including cardiovascular risk assessment. The process is based on one developed for astronauts aboard the International Space Station developed, in part, by a pre-eminent Canadian aeromedical cardiovascular expert.

SI 404-001 reminds that all flight crew (i.e., pilot and flight engineer) and ATC licenses and permits must be validated by a current Medical Certificate (MC) that indicates that the holder meets the medical requirements and standards established by TC CAM. For applicants who do not meet the required standards, CARs 424.05 allows for the application of flexibility that permits the issuance of a MC where it is in the public interest and not likely to affect aviation safety. The SI outlines how the principles of aeromedical RA/RM are to be applied in the application of flexibility.

¹⁶ Transport Canada (2019). Staff Instruction (SI) No. 424-001 – Aviation Medical Review Board Terms of Reference.

¹⁷ Transport Canada (2019). Staff Instruction (SI) No. 404-002 – *Civil Aviation Medicine Cannabis Policy*.

¹⁸ Transport Canada (2019). Staff Instruction (SI) No. 404-003 – *Civil Aviation Medicine Credentialing Requirements*.

¹⁹ Transport Canada (2019). Staff Instruction (SI) No. 424-002 – *Civil Aviation Medicine Directive* – *Substance Use Disorder*.

²⁰ Transport Canada (2019). Staff Instruction (SI) No. 404-001 Issue 01 - Aeromedical Risk Assessment and Risk Management.

To keep up to date with medical advances in screening procedures, TC CAM intends to update the cardiovascular guidance currently in the Handbook (TP13312), along with the rest of the Handbook content. This update will reflect the latest guidance from a variety of sources, including the Canadian Cardiovascular Society, but also other aeromedical assessment best practices.

It should be noted that written guidance in medicine tends to lag best practices, especially with the exponential growth being seen in medical knowledge. This is a phenomenon that medicine in general is working hard to manage, given the unprecedented growth of medical knowledge and rapid evolution of best practices. The SI format was selected to replace the single handbook for CAMEs to provide a more flexible means to update guidance on specific topics as the need arises.

It is important to emphasize that cardiovascular risk in aviation is the original and one of the most well-characterized and quantifiable risks in aviation medicine. Indeed, the International Civil Aviation organization (ICAO)²¹ recognizes an acceptable upper threshold of risk for medical events of up to 2% per year; it is therefore impossible to achieve a zero-risk environment.

In the meantime, TC CAMEs – appointed by the Minister of Transport to conduct aviation medical examinations – are physicians licensed in their respective provinces and territories. They are expected both by TC and their Provincial and Territorial medical regulators to apply the most current medical guidelines, including those published by the Canadian Cardiovascular Society²² for cardiovascular health assessment. Finally, TC CAM has a consultant Cardiologist on the Aviation Medical Review Board²³ (AMRB), and any files involving cardiovascular issues are reviewed by a cardiovascular specialist on an individual basis, with the most current cardiovascular guidelines being applied.

August 2023: TSB assessment of the response (Satisfactory Intent)

In its response, Transport Canada (TC) indicated that it agrees with the safety deficiency identified in Recommendation A23-01 and that its strategy to mitigate the safety deficiency would be two-fold.

²¹ International Civil Aviation Organization (2012). *Manual of Civil Aviation Medicine (Doc 8984)*, p. 35. Available at: https://www.icao.int/publications/documents/8984_cons_en.pdf

²² Canadian Cardiovascular Society (2023). Canadian Cardiovascular Society Guidelines. Available at: https://ccs.ca/guidelines/

²³ The AMRB contributes to the CAM aeromedical decision-making process with information and recommendations that assist CAM physicians in reaching an "accredited medical conclusion," in accordance with ICAO. The ICAO Manual of Civil Aviation Medicine section 1.2.4.9 defines an "accredited medical conclusion" as "[t]he conclusion reached by one or more medical experts acceptable to the Licensing Authority for the purposes of the case concerned, in consultation with flight operations or other experts as necessary." (Source: Transport Canada (2019). Staff Instruction (SI) No. 424-001 - Aviation Medical Review Board Terms of Reference.)

First, TC is in the process of replacing the *Handbook for Civil Aviation Medical Examiners* with several Staff Instructions (SIs) that each deal with one topic. This format provides a more flexible way of updating guidance on specific topics as the need arises. From 2019 to 2022, TC issued 5 aeromedical SIs.

Additionally, TC provided an update on 06 July 2023 and confirmed that the following SIs were published on 01 June 2023 and have been added to the Handbook:

- Attention Deficit/Hyperactivity Disorder (SI 404-006)
- Medications and Aviation Medical Certification (SI 404-005)
- Depression and Antidepressant Medications (SI 404-004)

Furthermore, on 31 July 2023, TC informed the TSB that the following SIs were not currently available on its online Civil Aviation Reference Centre:

- Aeromedical Risk Assessment and Risk Management (SI 404-001 Issue 01)
- Civil Aviation Medicine Credentialing Requirements (SI 404-003)
- Aviation Medical Review Board Terms of Reference (SI 424-001)
- Civil Aviation Medicine Directive Substance Use Disorder (SI 424-002)

According to TC, these SIs are undergoing revisions, and updated versions will be published soon, although no specific dates were provided.Next, TC intends to update the cardiovascular guidance currently in the Handbook to reflect the latest guidance from a variety of sources, including the Canadian Cardiovascular Society and other aeromedical assessment best practices.

The Board is encouraged by the plan to replace the *Handbook for Civil Aviation Medical Examiners* with SIs. However, TC's response does not mention any kind of schedule for when the SIs will replace the Handbook or any procedure to regularly review their content. Having a schedule in place would be effective in reducing the risks associated with guidance that does not reflect the most current practices.

These actions, when fully implemented, have the potential to substantially reduce or eliminate the risks associated with the safety deficiency identified in Recommendation A23-01.

Therefore, the Board considers the response to Recommendation A23-01 to show **Satisfactory Intent**.

File status

The TSB will continue to monitor the progress of TC's planned actions to mitigate the risks associated with the safety deficiency identified in Recommendation A23-01, and it will reassess the deficiency on an annual basis or when otherwise warranted.

This deficiency file is **Active**.