Transport Canada Transports Canada

Staff Instruction

Subject: **Fatigue Risk Management Systems – Review Procedures**

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1.0 Introduction

1.1 Purpose

(1) This staff instruction (SI) describes the review procedures to be used by Transport Canada Civil Aviation (TCCA) personnel. who are involved with air operators seeking to operate flights under an exemption pursuant to the Division V FRMS regulations, to ensure they effectively comply with their regulatory requirements.

1.2 Applicability

(1) This document applies to Transport Canada Civil Aviation (TCCA) Headquarters and regional personnel.

1.3 Description of changes

(1) Not applicable.

2.0 References and requirements

2.1 Reference documents

(1) It is intended that the following reference materials be used in conjunction with this document:

- (a) Part VII, Division V of the Canadian Aviation Regulations (CARs) — Exemptions – Fatigue Risk Management Systems
- (b) Advisory Circular (AC) 700-045 — Exemption and Safety Case Process for FRMS
- (c) Advisory Circular (AC) 700-046 — Fatigue Risk Management System Requirements
- (d) Advisory Circular (AC) 700-047 — Flight Crew Fatigue Management - Prescriptive Regulations

2.2 Cancelled documents

(1) Not applicable.

(2) By default, it is understood that the publication of a new issue of a document automatically renders any earlier issues of the same document null and void.

2.3 Definitions and abbreviations

(1) The following **abbreviations** are used in this document:

- (a) **AC**: Advisory circular
- (b) **FCM**: Flight crew member
- (c) **FDT**: Flight and duty times
- (d) **FRMS**: Fatigue risk management system
- (e) **LOC**: Letter of confirmation
- (f) **POI**: Principal operations inspector
- (g) **SI**: Staff instruction

(h) **SME**: Subject matter expert

(i) **VEA**: Variance effect analysis

(2) The following definitions are used in this document:

(a) **Scientific studies**: Original systematic research relating to fatigue and human performance that has been tested for validity through scientific method and has been published in a reputable, peer-reviewed scientific journal or by an accredited body.

3.0 Background

(1) New regulations for managing flight crew fatigue were published on December 2018 in the *Canada Gazette*, Part II with a delayed coming into force date. The amended regulations include two approaches to fatigue management: prescriptive and performance-based.

(2) Performance-based requirements allow an air operator to vary from specific prescriptive provisions to conduct a flight using a Fatigue Risk Management System (FRMS), in order to ensure that the variance will not adversely affect the levels of flight crew member (FCM) fatigue and alertness.

(3) FRMS implementation is mandatory only when an air operator wishes to use an exemption from specific prescriptive provisions to conduct a flight.

4.0 General

(1) The authority for an air operator and a flight crew member to vary from prescriptive regulations is per a 5.9(1) Exemption by Governor in Council. With this type of exemption all of the conditions are provided in regulation, which obliges compliance with all of the Division V regulations, 700.200 to 700.259.

(2) Any review conducted related to this exemption shall be an objective review for compliance, as detailed in the review worksheets.

(3) The following items are subject to a TCCA compliance review, and the operator will be notified by letter of the result:

(a) Notice of Intent

(b) Variance effect analysis

(c) Safety case

(d) Letter of confirmation.

(4) The safety case is the only item that requires TCCA approval, in accordance with CAR 700.233.

(5) FRMS documentation that the operator has developed in support of their FRMS, such as manuals that describe the system and procedures, is not required to be approved. This documentation is not required to be placed in the Company Operations Manual, though the operator may choose to do so.

(6) If a non-compliance is detected, any enforcement action that may be taken will be with reference to the designated provision in the prescriptive regulations from which the variance has been established, and not against the FRMS regulations.

5.0 Assistance to operators

(1) Prior to submitting a Notice of Intent, TCCA may be asked by operators to review their proposed or draft FRMS documentation. This assistance should be provided to operators who are participating in an FRMS Pilot Project, and may be provided to others as time and resources permit.

(2) Resources should be made available to accommodate requests for review of draft Notices of Intent (NOI) for any operator who is approaching their in-force date or other anticipated start date. As considerable time and effort will have been spent in implementing their FRMS, it is reasonable for the operator to want assurance in advance that their proposed NOI is compliant, to ensure a smooth transition on the planned start day and avoid interruption to their operation.

6.0 Subject Matter Experts

(1) The review teams in the sections that follow should include SMEs from both Commercial Flight Standards (CFS) group and the FRMS group. To arrange SME participation for the review team, please contact the:

(a) Chief, Commercial Flight Standards, for an FDT SME, and

(b) National Coordinator Flight Crew Fatigue Management, for an FRMS SME at

(i) TC.FCFM-GFEC.TC@tc.gc.ca

7.0 Notice of Intent

7.1 General

(1) Prior to operating any flights under a variance, the operator must first submit a compliant Notice of intent (NOI) to the Minister in accordance CAR 700.201(1)(a) or (2)(a), that contains all of the information required by CAR 700.206.

(2) TCCA will review the NOI and advise the operator whether or not it is in compliance with CAR 700.206.

Note: Guidance to air operators regarding the notice of intent is found in AC 700-045, section 6.2. Their template to submit an NOI is found in both Appendix A of AC 700-045, and also as a stand-alone form per Appendix A of this AC.

7.2 Review

(1) The review team consists of:

(a) Team Lead – Technical Team Lead, Flight Operations

(b) Principal Operations Inspector

(c) Team member – if / as required (e.g. regional SME)

(d) FRMS SME – HQ Standards

(e) FDT SME – HQ Standards

(f) Observer - optional

(2) On receipt of the submitted NOI, the Team Lead:

(a) ensures each team member receives a copy, and

(b) convenes and leads the review meeting to assess the NOI for compliance.

(3) The review is conducted using the form “Notice of Intent – Review Worksheet - FRMS”. The Team Lead is responsible to create, complete, and finalize the master copy of this form, which is found in Appendix A of this SI.

(a) Team Lead fills in the known information in Sections 1, 2, and 3, and saves the form in RDIMS.

(b) As a team, answer all of the questions in Section 6 – Worksheet.

(i) As this is an objective review of whether or not the operator meets the requirements, the choice for response is either Yes or No. The information required must be present, complete, and comprehensible.

(c) Once the review is complete, record the date and select a recommended outcome in Section 4.

(d) Team Lead provides the submitted NOI and the worksheet to the person who will make a decision on the recommendation:

(i) Chief, National Flight Operations, or

(ii) the appropriate Associate Director, Operations

(4) The decision-maker reviews the documents, indicates agreement or not with the recommended action by completing the Record of Decision in Section 5 and returns the completed form to the Team Lead.

(5) NOI’s cannot be officially accepted or rejected until the day the regulations come into force applicable to the operator. Draft NOIs can be reviewed prior to the anticipated start date using the worksheet for the purpose of providing feedback to the operator and as a record of the review. In this case, indicate “Draft” on the form. The actions in Section 5.3 of this SI are only to be taken for a finalized NOI that is sent to the Minister in accordance with CAR 700.206.

7.3 Next Steps

(1) Depending on the outcome, the POI shall take the following actions:

(2) If the NOI is compliant:

(a) Use the template letter to notify the air operator that their NOI is compliant. Ensure that the form for the operators quarterly report of the variance effect analysis is attached.

(b) No further action is required until the 700.200(1)(c) / (2)(c) notification is due from the air operator, or until surveillance activities / safety intelligence identify non-compliance.

(3) If the NOI is not compliant:

(a) Use the template letter to notify the air operator that their NOI is not compliant.

(b) Conduct an unannounced follow-up activity, e.g. a compliance inspection, within the next two weeks to verify that the operator has remained in full compliance with the CAR provisions which they had identified in the NOI.

(c) If that compliance inspection determines that the operator has not been in full compliance with the CAR provisions identified in the NOI, after consultation with Regional or HQ Aviation Enforcement submit a detection notice for investigation.

8.0 Variance Effect Analysis

8.1 General

(1) Operators are required to analyze the effect of the variance on the levels of fatigue and alertness of the FCMs conducting the flight subject to exemption. Throughout the period the initial exemption is in effect, the operator must notify the POI in writing, at least every ninety days, that the analysis is available to the Minister for review, in accordance with CAR 700.200(1)(c) or (2)(c).

(2) TCCA will review the results of the ongoing analysis and inspect as necessary to verify progress in developing the safety case, per CAR 700.207.

Note: Guidance to air operators regarding the VEA is found in AC 700-045, section 6.3.6. Their template to submit the VEA is found both in the template letter for NOI acceptance and as a stand-alone, per Appendix A of this SI..

8.2 Review

(1) The review team consists of:

- (a) Team Lead – Technical Team Lead, Flight Operations
- (b) Principal Operations Inspector
- (c) Team member – if / as required (e.g. regional SME)
- (d) FRMS SME – HQ Standards
- (e) FDT SME – HQ Standards
- (f) Observer - optional

(2) On receipt of the submitted VEA, the Team Lead:

- (a) ensures each team member receives a copy, and
- (b) convenes and leads the review meeting to assess for progress in development of the safety case.

(3) The review is conducted using the form “Variance Effect Analysis – Review Worksheet - FRMS”. The Team Lead is responsible to create, complete and finalize the master copy of this form, which is found in Appendix A of this SI.

- (a) Team Lead fills in the known information in Section 1, 2 and 3 and saves the form in RDIMS.
- (b) As a team, answer all of the questions in Section 6 – Worksheet.
  - (i) The reason for each answer should be documented in the Why column, regardless of whether it’s a Yes or a No.
- (c) Once the review is complete, record the date in Section 3.
- (d) Record the review outcome in Section 4, which is signed by the Team Lead.

8.3 Next Steps

(1) If the outcome is that the variance effect analysis shows progress in developing the safety case, no further action is required until:

- (a) The next 700.200(1)(c) / (2)(c) notification is due from the air operator; or

(b) Surveillance activities / safety intelligence identify non-compliance

(2) If the outcome is that the variance effect analysis does not show progress in developing the safety case, the POI shall take the following actions:

(a) Use the template letter to notify the air operator that in accordance with CAR 700.207, the initial exemption ceases to apply upon receipt of the letter, and the air operator must comply with the CAR provisions from which they had been exempted.

(b) Conduct an unannounced follow-up activity, e.g. a compliance inspection, within the next 2 weeks to verify that the operator has reverted to full compliance with the CAR provisions from which they had been exempted.

(c) If that unannounced inspection determines that the operator has not reverted to full compliance with the CAR provisions from which they had been exempted, after consultation with Regional or HQ Aviation Enforcement submit a detection notice for investigation.

9.0 Safety Case

9.1 General

(1) Air operators who have used an exemption from specific prescriptive provisions are obligated to validate a safety case to demonstrate that the variance will not adversely affect FCM levels of fatigue and alertness, and to submit the validated safety case to the Minister for approval in accordance with CAR 700.232.

(2) The validation period for collection of data is a minimum of one year, and may not exceed two years.

Note: Guidance to air operators regarding the safety case is found in AC 700-045, section 6.3. Their template to submit the validated safety case is found in both AC 700-045, Appendix B and as a stand-alone, per Appendix A of this SI.

(3) TCCA will review the safety case to verify compliance with CARs 700.225, 700.232 and 700.233 and will advise the operator if any requirements are not met.

9.2 Review

(1) The review team consists of:

(a) Team Lead – Technical Team Lead, Flight Operations

(b) Principal Operations Inspector

(c) Team member – if / as required (e.g. regional SME)

(d) FRMS SME – HQ Standard

(e) FDT SME – HQ Standards

(f) Observer - optional

(2) On receipt of the submitted safety case, the Team Lead:

(a) ensures each team member receives a copy, and

(b) convenes and leads the review meeting to assess the validated safety case.

(3) The review is conducted using the form "Safety Case – Review Worksheet - FRMS". The Team Lead is responsible to create, complete and finalize the master copy of this form, which is found in Appendix A of this SI.

(a) Team Lead fills in the known information in Sections 1, 2 and 4, and saves the form in RDIMS.

(b) As a team, answer all of the questions in Section 6 – Worksheet.

(c) Once the review is complete, record the date and select a recommended outcome in Section 3.

(d) Team Lead provides the submitted safety case and the worksheet to the person who will make a decision on the recommendation:

(i) Chief, National Operations, or

(ii) Associate Director, Operations

(e) The decision-maker reviews the documents, indicates agreement or not with the recommended action by completing the Record of Decision in Section 6 and returns the completed form to the Team Lead.

9.3 Next Steps

(1) Depending on the outcome, the following actions shall be taken:

(2) If the safety case is approved, the POI will:

(a) Use the template letter to notify the operator that their safety case is approved in accordance with CAR 700.233 and that the continuing exemption is in effect. The approval letter will be signed by the Director, Standards. Coordinate for this signature with the director's office, and send the letter to the operator.

(b) For each six-month period during which flights are conducted under the continuing exemption, the POI will monitor the operator's activities related to the ongoing collection and analysis of fatigue and alertness data.

Note: Guidance to air operators regarding safety case monitoring is found in AC 700-045, section 6.7.

(3) If the safety case is not approved, the POI will:

(a) Use the template letter to notify the operator that the safety case is not approved and therefore the continuing exemption is not in effect.

(b) Notify the operator that the initial exemption ceases to apply, if they do not re-submit a compliant safety case before their three-year period ends (which starts on the day a compliant NOI was sent to the Minister)

(c) If the operator does not re-submit a compliant safety case in this timeframe:

(i) Conduct an unannounced follow-up activity, e.g. a compliance inspection, within the next 2 weeks to verify that the operator has reverted to full compliance with the CAR provisions from which they had been exempted.

(ii) If that unannounced inspection determines that the operator has not reverted to full compliance with the CAR provisions from which they had been exempted, after consultation with Regional or HQ Aviation Enforcement, submit a detection notice for investigation.

10.0 Letter of Confirmation

10.1 General

(1) Once a safety case is approved, it can be used as a basis to conduct another flight under the same continuing exemption, if that other flight meets established criteria, and the operator provides the Minister a letter of confirmation in accordance with CAR 700.240.

(2) TCCA will review the letter of confirmation for compliance with CAR 700.240 and will advise the operator if any requirements are not met.

Note: Guidance to air operators regarding the letter of confirmation is found in AC 700-045, section 8.0, and their template letter is found in Appendix C..

10.2 Review

(1) The review team consists of:

- (a) Team Lead – Technical Team Lead, Flight Operations
- (b) Principal Operations Inspector
- (c) Team member – if / as required (e.g. regional SME)
- (d) FRMS SME – HQ Standard
- (e) FDT SME – HQ Standards
- (f) Observer – optional

(2) On receipt of the letter of confirmation, the Team Lead:

- (a) ensures each team member receives a copy, and
- (b) convenes and leads the review meeting to assess the letter.

(3) The review is conducted using the form “Letter of Confirmation – Review Worksheet - FRMS”. The Team Lead is responsible to create, complete and finalize the master copy of this form, which is found in Appendix A of this SI.

11.0 Scientific studies

(1) As part of the NOI submission the operator must include a list of the safety data and scientific studies that are used to demonstrate that the variance is not likely to have an adverse effect on FCM’s levels of fatigue and alertness. As with all items on the “Notice of Intent – Review Worksheet - FRMS”, compliance is determined collectively by the review team.

(2) All scientific studies in a (credible) scientific journal are peer-reviewed. That said, disreputable publishers will say they do peer review but then not actually do it. One way to try to assess this is by comparing the submitted and accepted dates on the published article. If submission and acceptance happen within a few days of each other, peer review did not happen. If the articles do not include submitted and accepted dates, that is a red flag as any reputable publisher will include these dates because they establish precedence should multiple authors publish similar studies and/or results.

(3) Here are a few sources that either provide criteria for assessing whether a journal is reputable / credible or vet journals:

- (a) Think.Check.Submit (https://thinkchecksubmit.org/) has a checklist for authors to use when assessing the trustworthiness of journals.

(b) The Directory of Open Access Journals (https://doaj.org/) is an organization that vets open access journals (and most predatory or unethical journals are open access). It has a rigorous vetting process so if a journal is listed on the directory you can assume that it is reputable. If you look at their application form (https://doaj.org/application/new), you can see all the criteria they use to vet journals.

(c) There is an unofficial blacklist (https://beallslist.net/) that identifies suspicious journals and publishers. It was started by a librarian at a US university and the list is based on his assessment of the journals.

(4) The TC Centre of Fatigue Expertise may also be utilized to vet scientific studies cited by operators.

12.0 Information management

(1) The team shall save all records from their review activities in RDIMS in the applicable company files according to regional or divisional policies.

(2) At the conclusion of review and surveillance activities, inspectors shall update all applicable TCCA databases, e.g. NACIS.

(a) Under the Remarks tab, select “New”

(b) Under Subject Area drop-down, select “FRMS”

(c) In the Subject field, enter the applicable activity, e.g. initial exemption, continuing exemption, safety case approval, etc.

(d) In the Details filed, enter relevant RDIMS numbers.

(3) All information management practices shall respect applicable privacy issues where appropriate.

13.0 Document history

(1) Not applicable

14.0 Contact us

For more information, please contact:

Director, Standards (AART)
E-mail: AARTinfodoc@tc.gc.ca

We invite suggestions for amendment to this document. Submit your comments to:
Civil Aviation Communications Centre
Telephone: 1-800-305-2059
E-mail: services@tc.gc.ca

Original signed by

Félix Meunier
Director, Standards branch
Civil Aviation

Appendix A — Document Index

Notice of Intent	Variance Effect Analysis	Safety Case	Letter of Confirmation
Template - Operator NOI Submission AC 700-045, App A & RDIMS-#16664484	**Template - Operator VEA Notification** RDIMS-#16594082 & RDIMS-#16664664	**Template - Operator Safety Case Submission** AC 700-045, App B	**Template – operator LOC submission** AC 700-045, App C
Form – NOI Review Worksheet RDIMS-#16659028	**Form – VEA Review Worksheet** RDIMS-#16601717	**Form – Safety Case Review Worksheet** RDIMS-#16634215	**Form – LOC Review Worksheet** **RDIMS--#TBA**
Template Letter - NOI Compliant RDIMS-#16664664	-	**Template Letter - Safety Case Approval** RDIMS-#16832621	
Template Letter - NOI Not Compliant RDIMS-#16664692	**Template Letter - VEA Shows No Progress** RDIMS-#16594082	**Template Letter - Safety Case Rejection** RDIMS-#16832921	

Other
FRMS Documentation Guide RDIMS-#17008334